

# Envoy Medical, Inc.

## Initiating Coverage with BUY and \$8.50 Target

Large market opportunities for its Acclaim CI to treat hearing loss. We believe expected positive clinical milestones in 2024 to be strong catalysts for stock.

**Initiating with BUY:** We are initiating coverage of Envoy Medical with a BUY rating and a 12-month price target of \$8.50. Envoy Medical is a hearing health company focused on providing innovative medical technologies for hearing loss.

**Focus on hearing loss:** The company's medical devices are designed to bring both providers and patients hearing devices with improved technology, ease of use, access, usability, independence, and quality of life.

**Acclaim CI:** Envoy has developed the Acclaim CI, a fully implanted cochlear implant. The Acclaim CI does not have the need for any external component to be worn on the ear. The Acclaim CI is designed to address severe to profound sensorineural hearing loss that is not adequately addressed by hearing aids.

**Large market potential:** According to the National Center for Health Statistics, hearing loss impacts about 15% of the adult population in the U.S. 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.

**Acclaim CI market potential:** The company believes there is a significant population of adults in the U.S. who are cochlear implant candidates but choose not to get the therapy because of the external component required for daily hearing. The company believes there will be ~25,000 - 30,000 adults implanted with a cochlear implant in the U.S. every year by 2026, representing an annual market opportunity that exceeds \$750 million. ~50% of the hearing device market is international, so that offers significant opportunity for expansion.

**Late 2024 IDE:** The Acclaim CI is currently in process (expected 2H 2024) to file an IDE application with the FDA to begin clinical testing. The Acclaim currently has three EFS (early feasibility study) participants (enrolled and device implanted at the Mayo Clinic in Rochester, MN in Q4 2022).

**Potential 2026 FDA approval:** The company believes its pivotal clinical trial will require ~50 to 60 patients and take about a year. If the IDE is approved in 2H 2024, clinical trials will start shortly after, and the company anticipates the potential to obtaining FDA approval in 2026.

**Esteem:** The company's first commercial 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 was approved for sale in 2010 by the U.S. FDA (Food and Drug Administration).

**However, challenges exist:** Envoy Medical operates in a highly competitive environment and competes against a wide range of other medical devices, therapeutics, and treatments. There is the chance that competing devices and therapeutic treatments for hearing loss may be developed and launched before the company's devices are launched.

**Positive high risks versus high rewards:** Overall, concerns outweighed by growth prospects and valuation. Envoy Medical's 2 devices still have long development and commercialization roads left and the high risks of clinical trials or commercial failures, but we believe the ~billion dollars market potential presents high rewards for the risks.

**Current valuation attractive:** We calculate a 12-month price target for shares of Envoy Medical to be \$8.50 based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with its high growth prospects and large upside opportunities.

### Company Description

Based in White Bear Lake, MN, Envoy Medical is a hearing health company focused on providing innovative medical technologies for hearing loss.

## COVERAGE INITIATION

### Rating: BUY

Ticker: COCH

Price: \$2.29

Target: \$8.50

### Stock Data

Exchange:	NasdaqCM
52-week Range:	0.75 – 11.72
Shares Outstanding (million):	20
Market cap (\$million):	\$46
EV (\$million):	\$46
Debt (\$million):	\$5
Cash (\$million):	\$5
Avg. Daily Trading Vol. (\$million):	\$0.3
Float (million shares):	7
Short Interest (million shares):	~0
Dividend, annual (yield):	\$0 (NA%)

### Revenues (US\$ million)

	<u>2023A</u>	<u>2024E</u>	<u>2025E</u>
	(Cur.)	(Cur.)	(Cur.)
Q1 Mar	0.1A	0.1A	0.1E
Q2 Jun	0.1A	0.1E	0.1E
Q3 Sep	0.1A	0.1E	0.1E
Q4 Dec	<u>0.1A</u>	<u>0.1E</u>	<u>0.1E</u>
Total	<b>0.3A</b>	<b>0.3E</b>	<b>0.3E</b>
EV/Revs	N/A	N/A	N/A

### Earnings per Share (pro forma)

	<u>2023A</u>	<u>2024E</u>	<u>2025E</u>
	(Cur.)	(Cur.)	(Cur.)
Q1 Mar	(1.36)A	(0.32)A	(0.26)E
Q2 Jun	(1.36)A	(0.26)E	(0.26)E
Q3 Sep	0.14A	(0.26)E	(0.25)E
Q4 Dec	<u>(0.20)A</u>	<u>(0.25)E</u>	<u>(0.24)E</u>
Total	<b>(2.38)A</b>	<b>(1.09)E</b>	<b>(1.01)E</b>
P/E	N/A	N/A	N/A

### Important Disclosures

Ascendant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

**For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 35.**

## Exhibit 1: Envoy Medical, Inc. Stock Price (4-years since IPO)

SPAC (Anzu Special Acquisition Corp I) IPO - 3/4/21

SPAC Merger Announcement (with Envoy Medical Corporation) - 4/17/23

SPAC Merger Completion (to form Envoy Medical, Inc.) - 9/29/23



Source: <https://bigcharts.marketwatch.com/>

## INVESTMENT THESIS

**We are initiating coverage of Envoy Medical with a BUY rating and a 12-month price target of \$8.50.**

Based in White Bear Lake, MN, Envoy Medical is a hearing health company focused on providing innovative medical technologies for hearing loss. The company's technologies and medical devices are designed to shift the paradigm within the hearing industry and bring both providers and patients hearing devices with improved technology, ease of use, access, usability, independence, and quality of life.

Envoy Medical's fully implanted technology includes a sensor designed to leverage the natural anatomy of the ear instead of a microphone to capture sound. The company's first commercial 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 was approved for sale in 2010 by the U.S. FDA (Food and Drug Administration).

The Esteem suffered from a lack of reimbursement due to its categorization by Medicare as a hearing aid and not eligible for coverage. Recently, a new Congressional 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 change is successful, then it is likely the Esteem commercialization will accelerate.

In late 2015, Envoy made the decision to shift its focus from the Esteem to a new product that would leverage the proven sensor technology and incorporate it into a cochlear implant. As a result, it has developed the Acclaim CI — a fully implanted cochlear implant.

The company’s second planned commercial product, the fully implanted Acclaim Cochlear Implant (“Acclaim CI”), is a first-of-its-kind cochlear implant. The Acclaim CI is designed to address severe to profound sensorineural hearing loss that is not adequately addressed by hearing aids. The Acclaim CI is currently in process (expected 2H 2024) to file an IDE application with the FDA to begin clinical testing.

## Exhibit 2: Envoy Medical, Inc. Corporate Overview



### Who We Are

## COMPANY OVERVIEW

Envoy Medical (NASDAQ: COCH) is:

- an innovative hearing health company based in the United States (MN) focused on hearing implants,
- leading the way in “fully” or “totally” implanted hearing devices,
- the only company in the world that has successfully gotten a fully implanted hearing device approved by the FDA,
- planning to disrupt a complacent cochlear implant industry,
- dedicated to improving patient access, usability, compliance, and ultimately quality of life.

**We are different because our devices:**

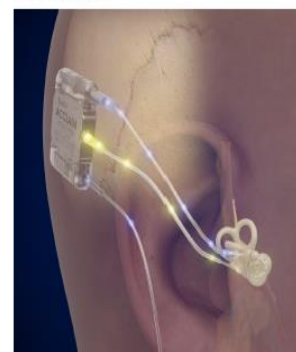
- leverage the natural ear to pick up sound.
- do not rely on artificial microphones.
- allow the outer ear to be used by the patient.

### Esteem®



The only FDA-approved, fully-implanted active middle ear implant. FDA approval in 2010. Implanted in approx. 1,000 patients.

### Acclaim®



A fully implanted cochlear implant (“FICI” or “TICI”) that represents a paradigm shift in cochlear implants. It is currently in clinical trials and investigational.

Source: Company reports.

According to the National Center for Health Statistics, hearing loss impacts about 15% of the adult population in the U.S. 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. 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. The WHO estimates economic impact of untreated or undertreated hearing loss is approximately \$750 billion each year.

There are several different types of hearing devices to address hearing loss. It is common for hearing loss to progress – continue to get worse – over the course of an individual’s life, so a patient may have one or more hearing devices during the course of their lives.

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. Envoy Medical believes the fully implanted 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).

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, multichannel 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.

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### Exhibit 3: Envoy Medical’s Acclaim CI Opportunity

## FULLY IMPLANTED COCHLEAR IMPLANT: AN OBVIOUS OPPORTUNITY

- We believe that if a given an opportunity to choose between a fully-implanted cochlear implant with no externals and a partially-implanted cochlear implant with externals, a significant portion of patients would choose the fully implanted cochlear implant.
- Externals associated with traditional cochlear implants are obvious and can get in the way of a person’s life.
- Envoy Medical intends to be the catalyst for change the market wants and, frankly, needs.
- Envoy Medical has developed *an important missing piece in the solution* – our sensor technology.
- Envoy Medical’s sensor is an elegant solution for a fully implanted device.
  - Leverages the natural outer and middle ear.
  - Low power needs.
  - Not an artificial microphone.
  - Not a sub-dermal microphone (lowers chances of body noise issues).

Source: Company report.

#### Exhibit 4: Hearing Loss Global Market Opportunity

## HEARING LOSS: THE OVERALL GLOBAL MARKET

### Key Facts from the World Health Organization<sup>1</sup>:

- More than 1.5 billion people may have some form of hearing loss during their lifetime.
- Approximately 430 million of those individuals have “disabling hearing loss” that requires intervention.
- It is estimated that nearly \$1 trillion (USD) may be lost every year globally due to a failure to address hearing loss properly.
- By 2050, these numbers are expected to jump significantly:
  - 2.5 billion people are projected to have some degree of hearing loss,
  - 700 million may have “disabling hearing loss” that requires hearing rehabilitation.
- Hearing loss is significantly more common with increased age. Approximately 1 in 4 (25%) of people over the age of 60 are impacted by “disabling hearing loss.”

Sources:

(1) World report on hearing, Geneva: World Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO.

(2) “Disabling hearing” refers to a level of hearing loss that is 35 decibels (dB) or more in the better hearing ear.

Source: Company report.

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 fully implanted 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.

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.

The Acclaim CI is designed to address severe to profound sensorineural hearing loss that is not adequately addressed by hearing aids. The company believes there is a significant population of adults in the U.S. who are cochlear implant candidates but choose not to get the therapy because of the external component required for daily hearing. The company believes this is one of the main reasons why there is an estimated only 5-8% penetration rate for cochlear implants in the adult population.

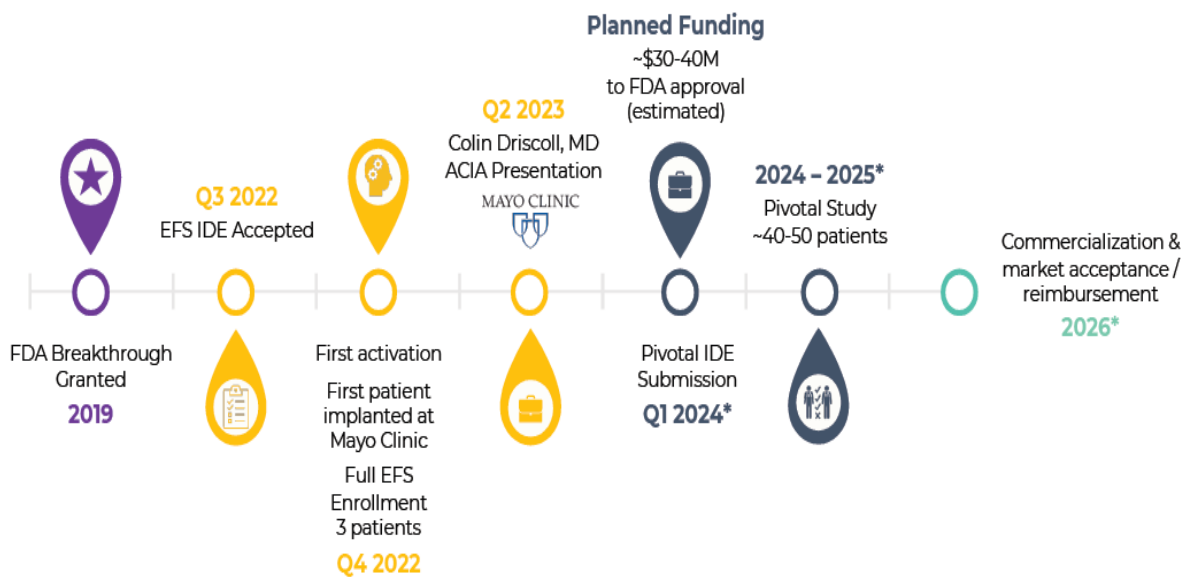
Based on industry sources (prior to candidacy expansion for cochlear implant candidates), including the American Journal of Public Health, the company believes there are approximately 6.6 million Americans age 12 or older with severe to profound hearing loss in at least one ear. Incorporating estimates for clinical indications (including limited benefit from hearing aids), the company believes there are approximately 2.8 million adults in the U.S. who could qualify for a cochlear implant.

The company believes there will be roughly 25,000 - 30,000 adults implanted with a cochlear implant in the U.S. every year by 2026. Based on an assumed selling price of \$30,000, that is an annual market opportunity that exceeds \$750 million.

The company believe that the Acclaim CI will be in a unique position to capture existing market share quickly and to also capture a large portion of the unserved market – based on its advantages particularly those who do not want a cochlear implant because of the external components.

**Exhibit 5: Envoy Medical Acclaim CI Timeline**

*Clinical Strategy*  
**ILLUSTRATIVE TRACK TO COMMERCIALIZATION**



Source: Company reports.

Envoy Medical share price has been weak and volatile since the completion of its SPAC merger on September 29, 2023. Envoy Medical’s share price was \$7.02 on 9/29/23, but closed at \$4.80 on 10/02/23 and \$1.81 on 12/29/23. However, so far in 2024, the stock has been strong at +27% (to the current share price of \$2.29 as of 6/21/24). Since 9/29/23, the stock has traded between \$0.75 (on 11/17/23) and \$11.46 (on 3/7/24).

We believe this stock price volatility is likely due to the high general stock price volatility with small/microcap technology stocks particularly after a SPAC merger event. We believe that there are near term catalysts that can drive the stock (particularly for key clinical milestones (IDE approval and start of clinical trials) in late 2024). As the company is likely to make significant progress in its businesses (including potential FDA PMA approval for Acclaim CI) over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price.

Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.



The company's near term plans over the next year is to advance (Acclaim CI) in its clinical trials towards a FDA approval for the treatment of hearing loss. We believe expected positive milestones and clinical data (particularly its expected late 2024 filing and approval of its IDE application for the Acclaim CI to the FDA) over the next year to be strong catalysts for stock.

Our investment thesis factors in an uncertain medical device development process and very competitive industry which is offset by the very large potential upside opportunities created from a successful device. We believe that the current valuation for Envoy Medical has already factored in many of its risks (principally device approval and successful commercialization) but is under valuing its overall growth prospects and product portfolio, resulting in a positive risk versus reward scenario for an investment in Envoy Medical.

**We believe the current valuation is attractive.**

Based on our expectations and assumptions and our NPV analysis, we calculate a 12-month price target for shares of Envoy Medical to be \$8.50, representing significant upside from current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities. We acknowledge that Envoy Medical is still at a very early stage in its medical device development and product commercialization, but we believe key milestones over the next year should be positive catalysts for the stock.

## **INVESTMENT RISKS**

### **Long and Uncertain Medical Device Development Cycles**

Envoy Medical is highly dependent upon securing medical device approvals for its products in order to sell them (produce revenue). The drug and device development cycle can be long (average of 12 years), expensive (average of \$350 million), complicated, and uncertain. On average only about 10% of drugs and devices entering clinical trials ever make it to final approval. Because Envoy Medical's main device (Acclaim CI) is still in pre-clinical development (pre-Investigational Device Exemption ("IDE")), there are still significant risks and a long time horizon to receive FDA approval. We estimate that it likely at least two years before the Acclaim CI can receive FDA approval. With a high likelihood of binary outcomes (either success or failure), the risks are high but the potential rewards can also be very high as well.

### **Product Commercialization Risks**

Even after obtaining device approvals, there is still a chance that commercial success will not be achieved (due to competition, changes in the market, better or newer device or technologies, lack of reasonable reimbursements, or lack of market acceptance). While there are currently no good therapeutics to prevent or treat hearing loss and existing hearing aids and cochlear implants have major limitations, there is the chance that other potential devices or therapeutic treatments and options may be developed and launched before the company's devices are launched. In addition, Envoy Medical will need to replace existing and competing devices and treatments currently being used as standards of care. Like most health care devices and drugs, the company will also need to get suitable insurance and government reimbursements for its products. The company's Esteem FI-AMEI product was FDA approved in 2010, but failed to gain commercial traction, primarily due to a lack of reimbursement or insurance coverage.

### **High Level of Competition**

Envoy Medical operates in a highly competitive environment and competes against a wide range of other biopharmaceutical and medical device companies that are attempting to replicate or already have comparable products as the company's devices. Some of these competitors are much larger or have greater resources, and proprietary technology; which could result in lower projected sales for its devices and higher costs, reduced margins, and lowered profitability for the company. Even if Envoy Medical were to be successful with its device development, its products will have to compete with existing or new standards of care.

**Concentrated Product Pipeline**

The company is currently developing one cochlear implant device (Acclaim CI), and has an existing FDA approved fully implanted hearing device (Esteem FI-AMEI). If Envoy Medical were to experience difficulties with development or commercialization of its devices, then it may have a material negative impact on its business and financials as there are no meaningful products which can offset.

**Concentrated Ownership**

Glen Taylor, a member of the Board, holds ~53% of the common stock and ~22% of the Series A Preferred Stock. As a result, Mr. Taylor is able to exert significant influence over the company. Mr. Taylor is a billionaire and the founder and chairman of Taylor Corporation, a global printing and communications company and one of the nation's largest privately held companies. Mr. Taylor's support of the company has been instrumental to the company including a recent (March 2024) \$10 million, five-year lending facility he has provided. If there is any change in his support or ownership of the company, this would likely have a negative effect on the company.

**Coronavirus and Economic Uncertainties**

While healthcare costs tends to be less correlated with economic activity and income levels due to their nondiscretionary nature, major deterioration in economic conditions tends to result in an overall decline in consumer spending. This was demonstrated during the 2008 and 2009 Great Recession and global economic slowdown. While consumer spending levels and economic conditions have rebounded since and have been strong most of the 2010s, the global macroeconomic environment can change significantly quickly as was shown with the start of the COVID-19 pandemic in March 2020. Since then, due to huge government stimulus the U.S. economy has been very strong the past 4 years. However, the pandemic has still negatively impacted many businesses and has been a huge disruption to the U.S. (and global) economy. This includes biotechs as many have seen FDA drug development reviews, feedback, and approvals delayed along with disruptions in clinical trials. We note most of the economy is currently back to normal, but potential economic weakness or volatility may result in depressed government, enterprise, and consumer spending levels; this may have a negative impact on Envoy Medical, its business partners, government, and consumers.

**Capital Markets Risks**

We believe Envoy Medical has enough cash to fund its operations into late 2024 (Q4 (December) 2024), so we estimate that it will need to raise capital by Q4 2024 (December 2024). We believe that it will be at least several years before the company can be cash flow self-sufficient from operations. Many biopharmaceutical and medical device companies fund their operations from the sale of equity or debt capital until their products reach commercial success or until they sell off the commercial rights to other companies. Biopharmaceuticals ("biotechs") valuations tend to fluctuate widely, and though they are reasonably strong now (due to a strong M&A market for biotechs and large government funding for healthcare), there is always the chance that market interests and valuations for companies in this industry decline significantly. Share price weakness and volatility for small/micro cap and biotech stocks may make capital raising much more difficult and expensive.



## VALUATION

We are initiating coverage of Envoy Medical with a BUY rating and a 12-month price target of \$8.50, which is based on a NPV analysis. As the company is primarily a clinical stage medical device development company, it currently generates minimal revenue and significant losses so traditional valuation metrics are not useful. We believe a more accurate valuation should take into consideration the potential value of its medical device product pipeline. We do acknowledge that this valuation is complex and requires a large number of forward assumptions that we have to estimate that may be imprecise and may vary significantly from actual results. This is particularly so for a company like Envoy Medical which is still in preclinical (pre-Investigational Device Exemption (“IDE”)) work with its main device (Acclaim CI).

However, we believe our assumptions are fair and provide a reasonable basis for our valuation analysis. Our analysis considers future estimated revenue from each of its major device product pipelines (based on estimated future sales, a probability rate of success, and discounted this back to a current value), mainly focused on its 2 hearing medical devices (Acclaim CI (cochlear implant) and Esteem FI-AMEI (fully implanted active middle ear implant)). We apply a high discount rate and a low probability of success to capture the high uncertainties associated generally with devices in development. We then added up the values, made an assumption about future investments required and allocated the value based on current share count. Based on our NPV analysis, we arrived at our 12-month price target of \$8.50, which we believe appropriately balances out the company’s risks with its high growth prospects.

Envoy Medical share price has been weak and volatile since the completion of its SPAC merger on September 29, 2023. Envoy Medical’s share price was \$7.02 on 9/29/23, but closed at \$4.80 on 10/02/23 and \$1.81 on 12/29/23. However, so far in 2024, the stock has been strong at +27% (to the current share price of \$2.29 as of 6/21/24). Since 9/29/23, the stock has traded between \$0.75 (on 11/17/23) and \$11.46 (on 3/7/24). This is in contrast with general stock price weakness and volatility with small/microcap tech stocks in 2022 and then a sharp rebound in 2023 (Russell 2000 Index of small-cap U.S. stocks was -20% in 2022 and +19% in 2023). While the Russell 2000 Index has been relatively flat in 2024 (+1% YTD and compares to the S&P500 +15% and NASDAQ +18%), it and small and micro-cap companies have remained volatile even as the overall stock market has been strong and positive.

We believe this stock price volatility is likely due to the high general stock price volatility with small/microcap technology stocks particularly after a SPAC merger event. We believe that there are near term catalysts that can drive the stock (particularly for key clinical milestones (IDE approval and start of clinical trials) in late 2024). As the company is likely to make significant progress in its businesses (including potential FDA PMA approval for Acclaim CI) over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price.

Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.

We expect valuations for Envoy Medical to improve as visibility into cash flow generation becomes clearer (though we acknowledge that product commercialization for the Acclaim CI is likely at least 2 years away), resulting in significant upside to the current share price. We also want to note that investor’s interest in medical hearing device companies are high with many companies in this area attributed high valuations due to the large market opportunities and the high hearing loss incidence rate. We note that its main direct Cochlear Implant competitors have large market valuations.

**Exhibit 6: Company Valuation (DCF) (in \$ millions)**

**Valuation of Business Segments (in millions)**

Device Products	Estimated NPV	% of Success	Calculated NPV	Discount Rate	Estimated Annual Sales	% of Market Share	Market Potential per year
Acclaim Cochlear Implant	\$ 185	33%	\$ 556	30%	\$ 167	33%	\$ 500
Esteem Fully Implanted Active Middle Ear Implant	\$ 25	100%	\$ 25	20%	\$ 5	5%	\$ 100
<b>Total</b>	<b>\$ 210</b>						
Net cash	\$ -						
Estimated additional investments (& debt) required	\$ 40						
Current Value for existing shareholders	\$ 170						
Shares Outstanding (mils)	20						
<b>Estimated Value per share</b>	<b>\$ 8.50</b>						

Source: Ascendant Capital Markets estimates.

**Exhibit 7: Envoy Medical Stock Price (since merger on September 29, 2023)**



Source: <https://bigcharts.marketwatch.com/>

**Exhibit 8: Cochlear Implant Competition**

*Cochlear Implant Market Opportunity*  
**COMPLACENT EXISTING PLAYERS**



Source: Cochlear Ltd.



**Cochlear®**  
 Market Share: ≈65%  
 (ASX: COH)  
 \$1.2B Revenue  
 ~\$9.9B Market Cap<sup>1</sup>



Source: Med-EL



**MED-EL**  
 Market Share: ≈15%  
 Privately Held



Source: Advanced Bionics



**sonova** ADVANCED BIONICS  
 HEAR THE WORLD  
 Market Share: ≈10%  
 (SWX: SOON)  
 \$3.9B Revenue  
 ~\$15.8B Market Cap



Source: Oticon Medical






**Demant oticon**  
 MEDICAL  
 Market share: < 5%  
 (CSE: DEMANT)  
 \$2.9B Revenue  
 ~\$6.5B Market Cap<sup>7</sup>

Source: Company report.

**Exhibit 9: Cochlear Implant Competitors Financial Metrics**

**MULTI-\$B MARKET CAP INCUMBENTS WITH ATTRACTIVE GROSS MARGINS**

Companies	Description	Revenue (USD) <sup>1</sup>	Gross Margin (%) <sup>7</sup>	Market Cap (USD) <sup>1</sup>
 (SWX: SOON)	Sonova is one of the world's largest manufacturers and distributors of hearing aids. The company is based in Switzerland and distributes its products in more than 100 countries through its internal sales team and independent retailers. It also sells cochlear implants through its advanced bionics subsidiary.	~\$3.9B <small>TTM Total As of 31 March 2023</small>	71%	~ \$15.8B
 (ASX: COH)	<b>Cochlear is the leading cochlear implant device manufacturer with around 60% global market share.</b> Developed markets contribute 80% of group revenue where cochlear implants are the standard of care for children with severe to profound hearing loss. The company also actively targets the growing cohort of seniors in developed markets. Main products include cochlear implants, bone-anchored hearing aids, and associated sound processors.	~\$1.2B <small>TTM Total As of 30-June-2022</small>	75%	~ \$9.9B
 (CSE: DEMANT)	Demant is a Denmark-based manufacturer and distributor of hearing solutions, such as hearing aid devices and audio diagnostic equipment. More than 80% of the company's sales come from North America and Europe.	~\$2.9B <small>TTM Total As of 30-June-2022</small>	75%	~ \$6.5B

**ENVOY** MEDICAL

Current Market Cap of Envoy Medical (COCH) is less than 1% of the existing players.

Our belief is that difference will not continue to be as great over time.

Source: Company report.

## COMPANY

Based in White Bear Lake, MN, Envoy Medical is a hearing health company focused on providing innovative medical technologies for hearing loss. The company's technologies and medical devices are designed to shift the paradigm within the hearing industry and bring both providers and patients hearing devices with improved technology, ease of use, access, usability, independence, and quality of life.

Envoy Medical's fully implanted technology includes a sensor designed to leverage the natural anatomy of the ear instead of a microphone to capture sound. The company's first commercial 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 was approved for sale in 2010 by the U.S. FDA (Food and Drug Administration).

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Anzu Special Acquisition Corp I (Anzu) was a blank check company (SPAC - special purpose acquisition company) incorporated in December 2020 as a Delaware corporation and formed for the purpose of acquiring businesses. Anzu completed its IPO in March 2021.

In April 2023, Anzu announced that it has entered into a definitive business combination agreement to acquire privately-held Envoy Medical Corporation (Legacy Envoy). On September 29, 2023, the business combination was completed. Legacy Envoy became the primary operations of the combined company and the name of the company was changed to Envoy Medical, Inc. from Anzu Special Acquisition Corp I.

Legacy Envoy was founded in 1995 to create a fully implanted hearing device that leveraged the natural ear — not an artificial microphone — to pick up sound. Its first product, the Esteem FI-AMEI was created and received CE mark in 2006 and FDA approval in 2010. In late 2015, Envoy made the decision to shift its focus from the Esteem to a new product that would leverage the proven sensor technology and incorporate it into a cochlear implant. As a result, it has developed the Acclaim CI — a fully implanted cochlear implant.

As of December 2023, Envoy Medical had ~34 employees.

### **Management Team**

Brent Lucas (age 42) Chief Executive Officer - Mr. Lucas has served as CEO and a member of the Board since the closing of the Business Combination in September 2023. At that time, Mr. Lucas was the CEO (since 2015) of Envoy Medical Corporation. Mr. Lucas brings over 15 years of experience in active implantables in the hearing health industry. He has served in various roles with Envoy Medical and gained a tremendous amount of specialized experience, working his way up from an intern to CEO. Mr. Lucas received his bachelor's degree from the University of St. Thomas and Juris Doctor degree from the Mitchell Hamline School of Law.

David Wells (age 61) Chief Financial Officer - Mr. Wells has served as CFO since the closing of the Business Combination in September 2023. Mr. Wells has over 30 years of experience in finance, operations and administrative positions. From June 2021 to September 2022, Mr. Wells served as CFO of GHS Investments, LLC, a privately held "super value" fund focused on investing in small-to-mid cap companies. From June 2014 to June 2021, he served as the CFO of ENDRA Life Sciences, a publicly traded clinical diagnostics technology company. Also, in June 2021 Mr. Wells founded Atlas Bookkeeping, LLC, a technology-based financial services firm that provides bookkeeping and reporting services for emerging growth and small cap public and privately held companies. Mr. Wells holds an MBA from Pepperdine University and a BS in Finance and Entrepreneurship from Seattle Pacific University.

**Exhibit 10: Envoy Medical Management Team and Board**

# Executive Summary

## KEY LEADERS – MANAGEMENT TEAM



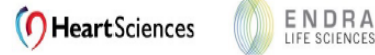
**Brent Lucas, CEO**

Mr. Lucas has been the Chief Executive Officer of Envoy Medical Corporation for the last seven years and brings over 15 years of experience in the active implantables in the hearing health industry. He has served in various roles and gained a tremendous amount of specialized experience, working his way up from an intern to CEO. Mr. Lucas received his Bachelor's Degree from the University of St. Thomas and JD from the Mitchell Hamline School of Law.



**David R. Wells, CFO**

Mr. Wells has 20 years of experience in the small-cap public company arena. Mr. Wells joined Envoy Medical, Inc. as its Chief Financial Officer in August, 2023. From 2014 to 2021 he was the CFO of ENDRA Life Sciences Inc. (NASDAQ: NDRA), a publicly traded clinical diagnostics technology company, where he directed ENDRA's initial public offering (IPO) and subsequently raised an additional \$55 million across multiple transactions. In December 2022, David joined the Board of Directors of HeartSciences (NASDAQ: HSCS), which is developing a cardiac device which seeks to bridge today's "diagnostic gap" in cardiac care by providing effective front-line solutions that assist in the detection of heart disease in at-risk patients.



**Tom Hoegh, VP of R&D**

Mr. Hoegh has over 30 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 Nuvector, 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.



## Key Leaders

# ENVOY MEDICAL, INC. BOARD OF DIRECTORS



**Chuck Brynelsen**  
Independent Director,  
Nominee for Board  
Chair

- Most recently serving as Senior VP 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
- Served on private companies boards of directors, including Aletra Technologies since 2010 and Neuspera Medical from 2022 to 2023
- Served as SVP 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 CEO of IntraPace from 2005 to 2012
- MBA from Kellogg School of Management at Northwestern University and his BA from Bradley University



**Susan Kantor**  
Independent Director,  
Nominee for Audit  
Committee Chair

- An Advisory Partner for PwC from 2011 to 2016, a Partner and CFO & Treasurer of PRIM Management Consultants from 1997 to 2011
- Previously a CFO at corporate strategy and operations consulting firms Monitor Group and BCG, as well as Parexel International, a CRO
- Board member and Audit Committee chair of Anzu, Teknor Apex Company, a \$12 billion dollar privately-held material science company, Guest Services Inc., a privately-held hospitality company, and the International Council on Clean Transportation.
- Six-board director and the Audit Committee Chair for Lionbridge Technologies Inc. when it was a \$550 million publicly-held company. Sold to private equity in 2016
- Bachelor's degree from Grove City College in Accounting and Business Administration and her CPA in MA



**Janis Smith-Gomez**  
Independent Director, Nominee for  
NomGov Committee  
Chair

- Over 30 years of executive experience at Johnson & Johnson, Mars, Kraft, and PepsiCo
- Most recent role with J&J, Janis led the brand identity efforts to evolve the \$2.7B medical devices business into a leading patient-centered, customer-focused, digitally powered MedTech Innovator
- Previously accountable P&L owner of businesses as large as \$3B, managing budgets from \$10M to \$215M
- On non-profit boards of New York Academy of Medicine and Black Public Media
- Graduate of University of Chicago with an MBA in Marketing & Business Policy and a Bachelor's degree in Business



**Whitney Haring-Smith**  
CEO of Anzu SPAC,  
Nominee for  
Compensation  
Committee Chair

- Co-founding managing partner at Anzu Partners since March 2015
- Serves on the board of multiple private technology companies, including Sofregen (medical device company), and previously on the board of MultiMechanics (acquired by Siemens) and Assun Technologies (acquired by Excelitas)
- Formerly a BCG consultant from January 2011 to March 2015 in San Francisco, Hong Kong, Nigeria and United Kingdom
- BS and MS from Yale University in Political Science and his PhD from Oxford University as a Rhodes Scholar



**Mona Patel**  
Independent  
Director

- Over 30 years of experience in medical devices in marketing, market development, clinical education and mergers and acquisitions
- Former VP of Marketing and Clinical Education at Boston Scientific in their neuromodulation division where she helped build the start-up into a market leader with ~\$1B in sales
- Introduced the first rechargeable spinal cord stimulator into a market and helped convert the market from non-rechargeables to rechargeables
- Launched the first rechargeable in Deep Brain Stimulation for Parkinson's
- BSE in Mechanical Engineering from the University of Michigan and an M.B.A. from the Wharton School of Business



**Brent Lucas,**  
CEO of Envoy  
Medical

- Served as CEO of Envoy for the past seven years and brings over 15 years of experience in the active implantables in the hearing health industry
- Served in various roles with Envoy and gained a tremendous amount of specialized experience, working his way up from an intern to CEO
- Received his bachelor's degree from the University of St. Thomas and Juris Doctor degree from the Mitchell Hamline School of Law



**Glen Taylor**  
Chairman Emeritus

- Founder and chairman of Taylor Corporation, a global printing and communications company and one of the nation's largest privately held companies
- A member (and former chair) of the Board of Governors of the National Basketball Association
- Served in the Minnesota State Senate from 1980 to 1990 and as Minority Leader from 1985 to 1988
- President of the YMCA, director of the Mankato Chamber of Commerce, director of the Greater Minnesota Corporation and the Minnesota Business Partnership, and served on the Minnesota State University Foundation Board of Directors
- Attended Harvard Graduate School of Business and earned his BS at Minnesota State University in Mankato



Source: Company reports.



## DEVICE PIPELINE

Envoy Medical was founded to create a fully implanted hearing device that leveraged the natural ear - not an artificial microphone - to pick up sound. The company's fully implanted technology includes a sensor designed to leverage the natural anatomy of the ear instead of a microphone to capture sound and is a viable alternative and option to external or implanted microphones.

The company's first commercial 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 CE mark in 2006 (approved for sale in the EU) and was approved for sale in the U.S. in 2010 by the FDA (Food and Drug Administration).

The Esteem suffered from a lack of reimbursement due to its categorization by Medicare as a hearing aid and not eligible for coverage. At an average retail price of ~\$25,000, very few individuals were willing or able to pay for the Esteem as a hearing aid (typical external hearing aids are ~\$2,500). The company believes 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 is fully implanted and replaces the function of the middle ear. Although efforts to change that categorization have been unsuccessful, recently, a new bipartisan Congressional bill, titled the Hearing Device Coverage Clarification Act was introduced in February 2024. 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 change is successful, then it is likely the Esteem commercialization will accelerate.

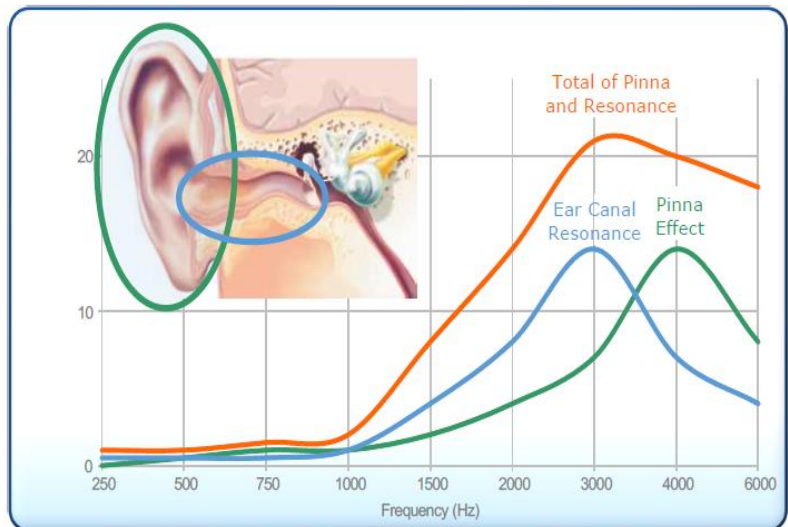
Despite the commercial challenges of the Esteem, ~1,000 devices were implanted globally. Some devices were implanted in the early 2000s during clinical trials, providing the company with nearly two decades of experience with its implantable sensor technology.

### Exhibit 11: The Ear

*Who We Are*

## NATURE'S MICROPHONE – THE EAR

Both of our devices leverage the ear's anatomy. There is nothing in the ear. Sound enters the outer ear and funnels down the ear canal causing your eardrum to vibrate. All as nature designed and intended.

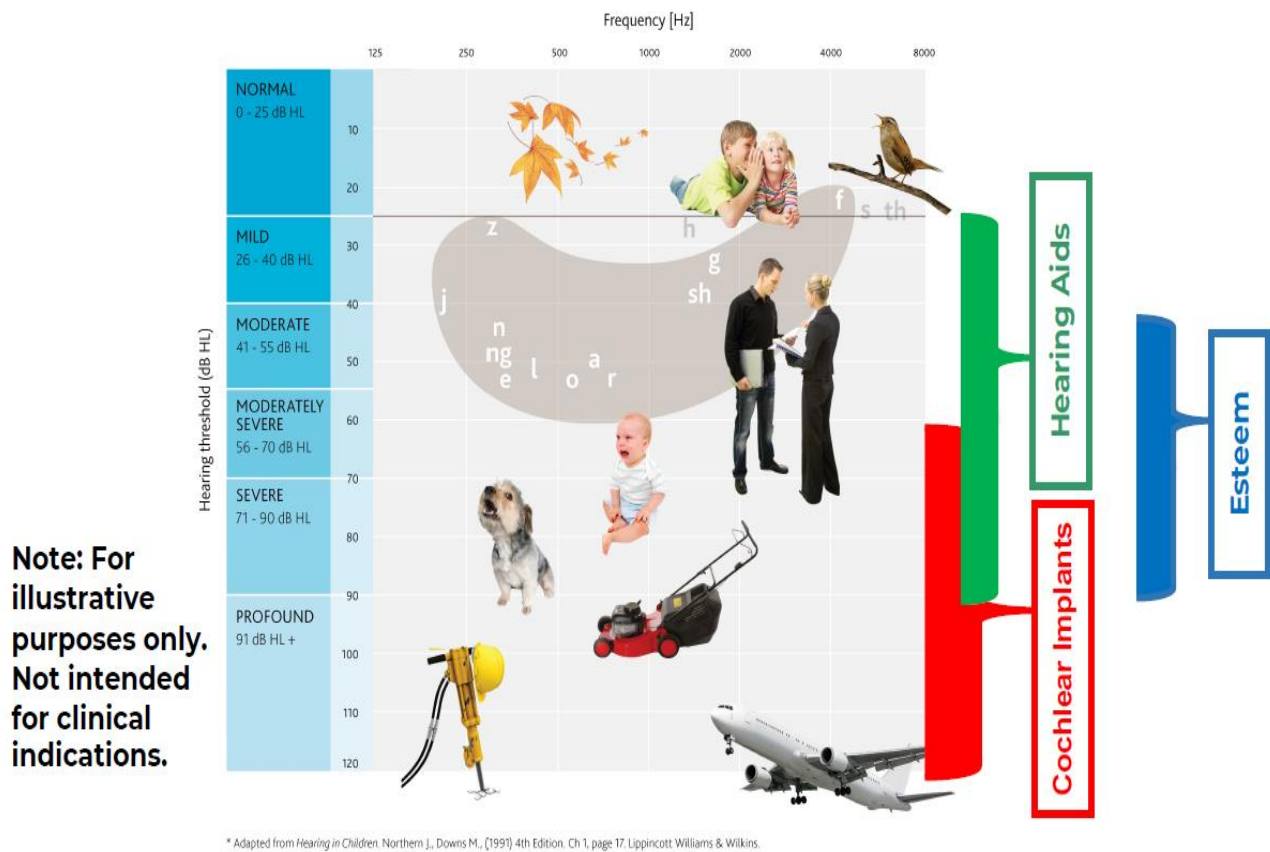


Blatrix, Minary, Leisses, 2004

Source: Company report.



Exhibit 12: Envoy Medical’s Hearing Loss Products Positioning



Source: Company report.

The company’s second planned commercial product, the fully implanted Acclaim Cochlear Implant (“Acclaim CI”), is a first-of-its-kind cochlear implant. The Acclaim CI is designed to address severe to profound sensorineural hearing loss that is not adequately addressed by hearing aids. The Acclaim CI is currently in process (expected 2H 2024) to file an IDE (Investigational Device Exemption) application with the FDA to begin clinical testing.

The company filed an earlier version of an IDE application at the end of Q1 2024, but decided to convert that IDE application to a “pre-submission” (sometimes referred to as a Q-submission). Strategically, this conversion allows for additional data collection on the three EFS (early feasibility study) participants (enrolled and device implanted at the Mayo Clinic in Rochester, MN in Q4 2022), pending testing to be completed, and further interactive discussions with FDA.

In the U.S., before the company can market a new Class III medical device, which the Acclaim CI is, it must first receive FDA approval via the premarket application (“PMA”) approval process. The company currently anticipates obtaining FDA approval in 2026. A large component of its PMA will be a successful pivotal clinical study of approximately 50 to 60 patients. The pivotal clinical study will have several safety and efficacy endpoints. Study design, including the clinical protocol, have not been finalized and are pending discussions with the FDA.

## Overview of Hearing Loss

According to the National Center for Health Statistics, hearing loss impacts about 15% of the adult population in the U.S. 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. 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. The WHO estimates economic impact of untreated or undertreated hearing loss is approximately \$750 billion each year.

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. 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.

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.

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.

Severe 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.

Moderate to profound 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.

## Overview of Hearing Devices

There are several different types of hearing devices to address hearing loss. It is common for hearing loss to progress – continue to get worse – over the course of an individual’s life, so 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 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 U.S.

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. Envoy Medical believes the fully implanted 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 (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.

## Market Trends

The ear itself is an ideal way to capture sound from the environment. 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 cochlea is the part of the inner ear involved in hearing. 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.

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, multichannel 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.

Exhibit 13: U.S. Hearing Loss Market

## HEARING LOSS: THE OVERALL AMERICAN MARKET

- “Hearing loss is the third most common chronic physical condition in the United States and is twice as prevalent as diabetes or cancer.”<sup>1</sup>
- Approximately 48 million Americans have some form of hearing loss. Over the next four decades, that number may increase to approximately 80 million.<sup>2</sup>
- As Americans live longer, more people will experience hearing loss.<sup>2</sup>
  - 68% of people in their 70s experience hearing loss.<sup>3</sup>
  - 90% of people 80 or older experience hearing loss.<sup>3</sup>
- Age-related hearing loss has been estimated to have an economic cost to society of around \$297,000 (USD) per affected person over their lifetime.<sup>4</sup>
- Hearing loss is correlated with risk of cognitive decline, depression, anxiety, and a higher risk of falls.<sup>2</sup>

Source: Company reports.

Exhibit 14: Cochlear Implant U.S. Market Opportunity

## ~2.8M U.S. ADULTS SUFFER MODERATE TO PROFOUND HEARING LOSS AND MAY BE CANDIDATES FOR COCHLEAR IMPLANTS<sup>1</sup>

~5%-8% of the people that could benefit from an implantable hearing solution have received one<sup>2</sup>



We believe one of the primary reasons – whether said or unsaid – adults do not pursue a cochlear implant is the obvious external hardware.

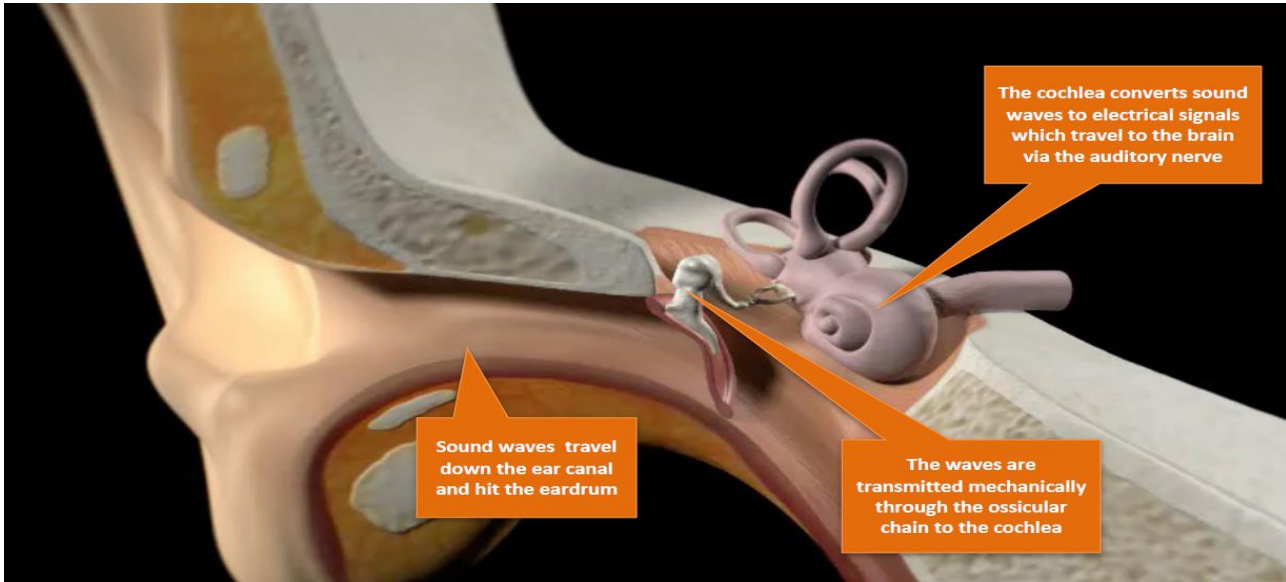
## ~\$84B

and growing untapped potential cochlear implant U.S. market opportunity<sup>3,4</sup>

Source: Company report.



Exhibit 15: How The Ear Works



### How the Ear Works

Your ear is made up of three different sections: the outer ear, the middle ear, and the inner ear. They work together to collect sounds and send them to your brain.

**The Outer Ear**

The outer ear gathers sound waves from your environment. These sound waves are sent down the **ear canal** to the **ear drum**.

**Did you know?** Glands in the ear canal make earwax, which helps to clean out dirt and prevent infections.

**The Middle Ear**

The sound waves make the eardrum vibrate. This in turn makes the three tiny bones (the **hammer**, **anvil** and **stirrup**) vibrate too, which causes the fluid in the **cochlea** to move.

**Did you know?** The collective name for the three bones is the **ossicles**.

**The Inner Ear**

The **cochlea** changes the vibrations into nerve signals. These signals then travel to your brain along the **auditory nerve**.

**Did you know?** The **semicircular canals** are full of fluid and tiny hairs which help you to balance. When you move your head, the fluid in the canals sloshes around, moving the hairs. The hairs send this position information to your brain.

OUTER EAR      MIDDLE EAR      INNER EAR

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www.planbee.com

Source: [www.planbee.com](http://www.planbee.com) and Company report.

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). The company believes that the trend over the next decade will be a continuation of the focus on usability, comfort, connectivity, lifestyle, appearance, personalization, and miniaturization.

Another major trend within the industry is a 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, the company estimates 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.

### **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. has agreed in principle to purchase 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.

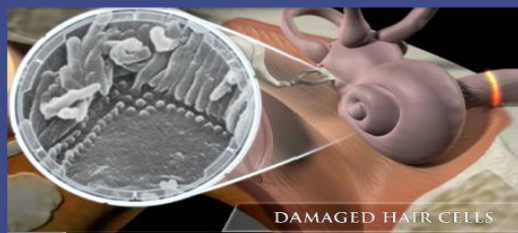
Cochlear Ltd. (ASX: COH) is the leading cochlear implant device manufacturer with approximately 60% of global market share and a market capitalization of ~\$13 billion (US Dollars) as of December 31, 2023.

In comparison to Envoy Medical, the three 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. At the same time, the much larger financial valuations of these companies also demonstrates the significant financial rewards for companies that are successful in this hearing products area.



**Exhibit 16: The Cochlea**

**Source of Most Hearing loss – The Cochlea**



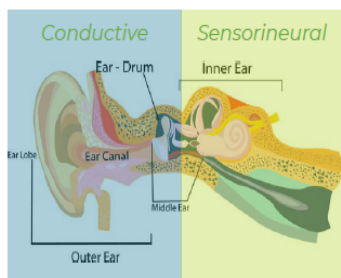
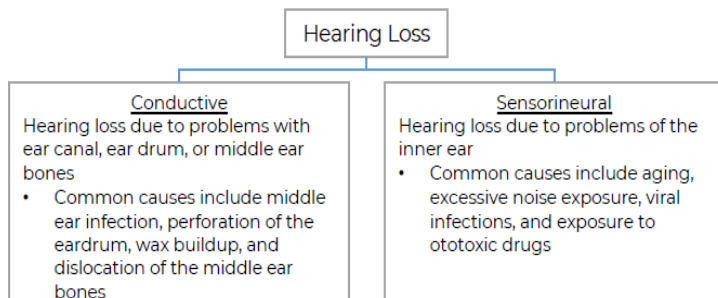
- Filled with liquid that moves in response to vibrations coming from the middle ear.
- Thousands of tiny hair cells move in response to this motion.
- Hair cells convert motion to electrical signals that are transmitted via the hearing nerve to the brain.
- Damaged hair cells within the cochlea are the primary reason for hearing loss.
- As hair cells are damaged, the hearing organ is not as effective and needs help getting information to the brain.
- At a certain point, the electrical stimulation is needed. thus less effective.

Source: Company reports.

**Exhibit 17: Hearing Loss: Types and Severity Overview**

**Hearing Loss: Types and Severity Overview**

Hearing loss can be due to damage of the outer/middle (conductive) or inner (sensorineural) ear and can range from mild to profound.



**Severity of Hearing Loss**

Category	dB Loss	example
Normal	0-20dB	n/a
Mild	20-40dB	Difficulty hearing soft spoken people
Moderate	40-70dB	Often can hear speech but not understand
Severe	70-90dB	Cannot hear speech
Profound	90+dB	Unable to hear loud sounds like fire alarms

Source: Company reports.

### **Acclaim CI's Market Opportunity**

The Acclaim CI is designed to address severe to profound sensorineural hearing loss that is not adequately addressed by hearing aids. The company believes there is a significant population of adults in the U.S. who are cochlear implant candidates but choose not to get the therapy because of the external component required for daily hearing. The company believes this is one of the main reasons why there is an estimated only 5-8% penetration rate for cochlear implants in the adult population.

Based on industry sources (prior to candidacy expansion for cochlear implant candidates), including the American Journal of Public Health, the company believes there are approximately 6.6 million Americans age 12 or older with severe to profound hearing loss in at least one ear. Incorporating estimates for clinical indications (including limited benefit from hearing aids), the company believes there are approximately 2.8 million adults in the U.S. who could qualify for a cochlear implant.

Based on an assumed selling price in the U.S. for a traditional cochlear implant of \$30,000 (a \$5,000 premium over the average sale price of current partially-implanted devices), the company believes the adult cochlear implant market in the U.S. alone represents a potential market opportunity of over \$80 billion.

The company believes there will be roughly 25,000 - 30,000 adults implanted with a cochlear implant in the U.S. every year by 2026. Based on an assumed selling price of \$30,000, that is an annual market opportunity that exceeds \$750 million.

Two major shifts in clinical candidacy have likely increased the market sizes: (a) the Centers for Medicare & Medicaid Services ("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.

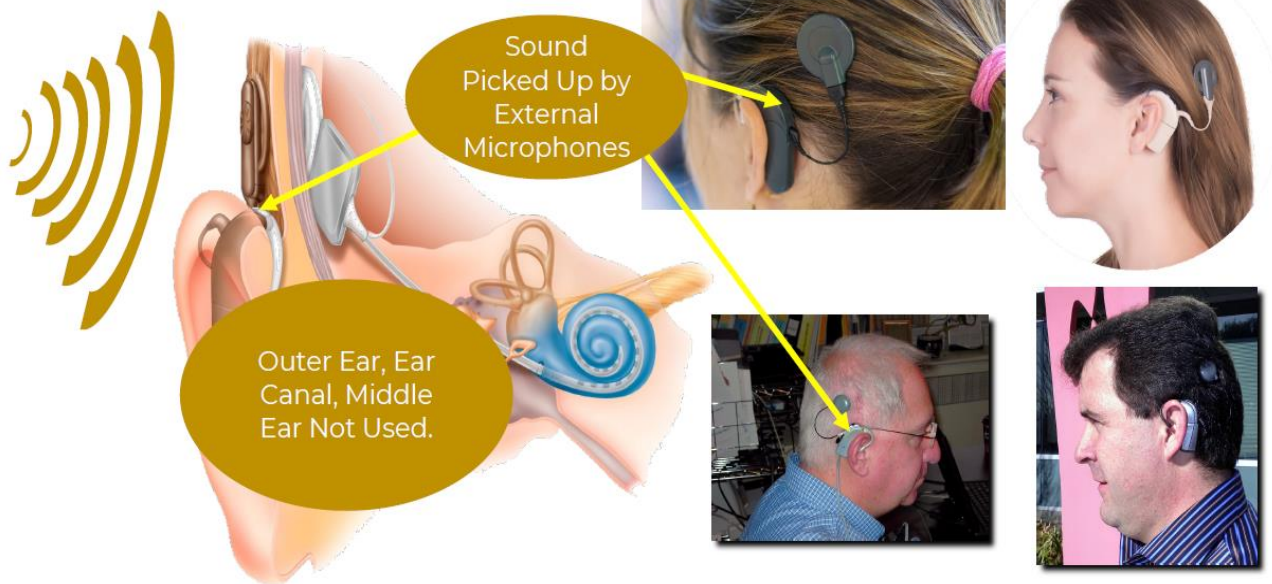
The company believe that the Acclaim CI will be in a unique position to capture existing market share quickly and to also capture a large portion of the unserved market – based on its advantages particularly those who do not want a cochlear implant because of the external components.

The company also believes there are substantial market opportunities outside the U.S. Approximately 50% of the hearing device market is international, so that market offers significant opportunity for expansion.

Exhibit 18: Cochlear Implant Market Opportunity

Acclaim Opportunity

**TRADITIONAL COCHLEAR IMPLANTS**



Acclaim Opportunity

**TRADITIONAL COCHLEAR IMPLANTS**

Cochlear implants replace the function of the inner ear by providing direct electrical stimulation of the auditory nerve.

**Sound processor - External**

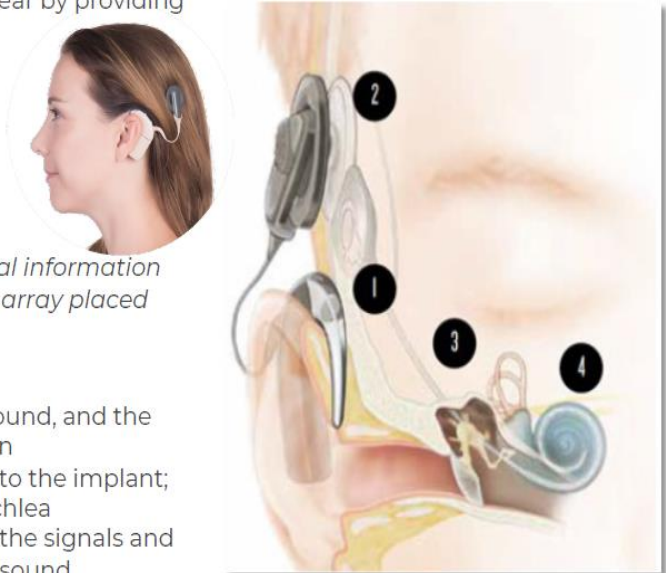
Picks up and processes sound into detailed digital information

**Implant - Internal**

Converts the digital sound information into electrical information that is sent to the auditory nerve from an electrode array placed inside the cochlea

**Illustrative Device Overview:**

- 1) Microphones on the sound processor pick up sound, and the processor converts them into digital information
- 2) This information is transferred through the coil to the implant; the implant sends electrical signals into the cochlea
- 3) The hearing nerve fibers in the cochlea pick up the signals and send them to the brain, giving the sensation of sound



Source: Company reports.

## 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 stimulate the auditory nerve.

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 processor, 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.

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 fully implanted 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.

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.

The Acclaim CI will be able to offer hearing benefit over alternative hearing loss treatments, such as:



- Increased daily usage. The Acclaim CI 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.
- 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.
- 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.
- Lowered battery maintenance. Other cochlear implants require near-daily battery replacement or battery charging. 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.
- 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 Acclaim CI processor is implanted and therefore not susceptible to damage, discomfort or issues associated with moisture, germs, dirt, or other external causes of loss or physical damage due to having an externally worn processor.
- No interference with equipment designed for non-hearing impaired. The externally worn components of currently available cochlear implants can make wearing equipment or accessories difficult for cochlear implant patients.
- Earlier adoption of cochlear implant technology from reduced stigma. The Acclaim CI, with no externally worn components, may help reduce or perhaps even eliminate such stigma.
- Potential to significantly reduce overall costs while improving net healthcare outcomes. A fully implanted cochlear implant should reduce cochlear implant costs over time by eliminating costly external components that are frequently replaced.

The Acclaim CI is implanted by a surgeon through a procedure that will average around two and a half to three hours under general anesthesia. 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).



Exhibit 19: Acclaim CI (Cochlear Implant)

*Novel Technology*  
**ACCLAIM® EXPECTS TO BE FIRST OF-ITS-KIND FULLY IMPLANTED COCHLEAR IMPLANT (FICI) DEVICE**

**FDA**  
*Breakthrough  
 Device  
 Designation*

device not to scale

**DISCREET**

- No need for externally worn components.
- Ear will pick up the sound naturally. No external artificial microphone needed.

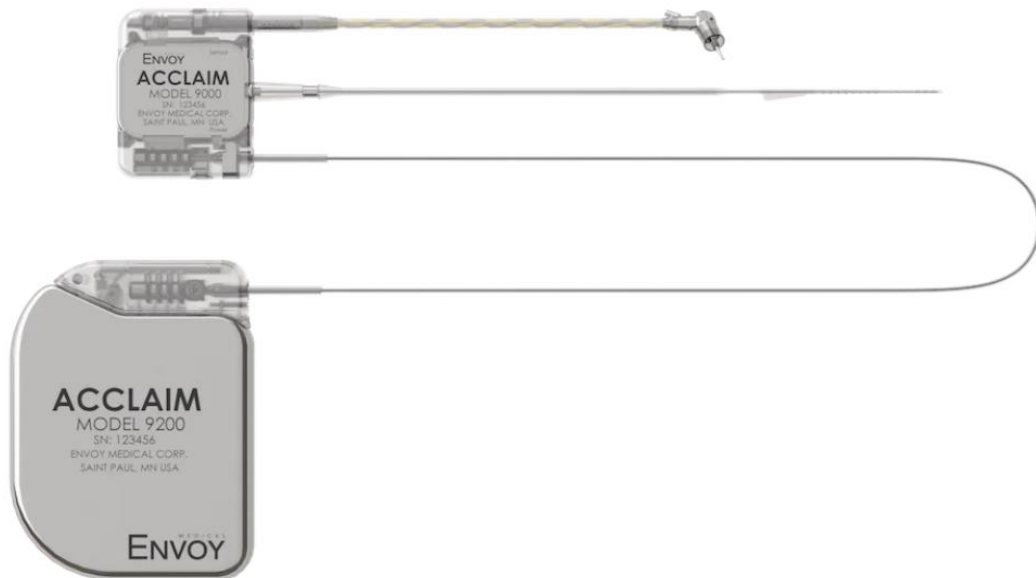
**DEPENDABLE**

- Designed to allow true 24/7 hearing.
- Reliable in many environments and activities.

**EASY**

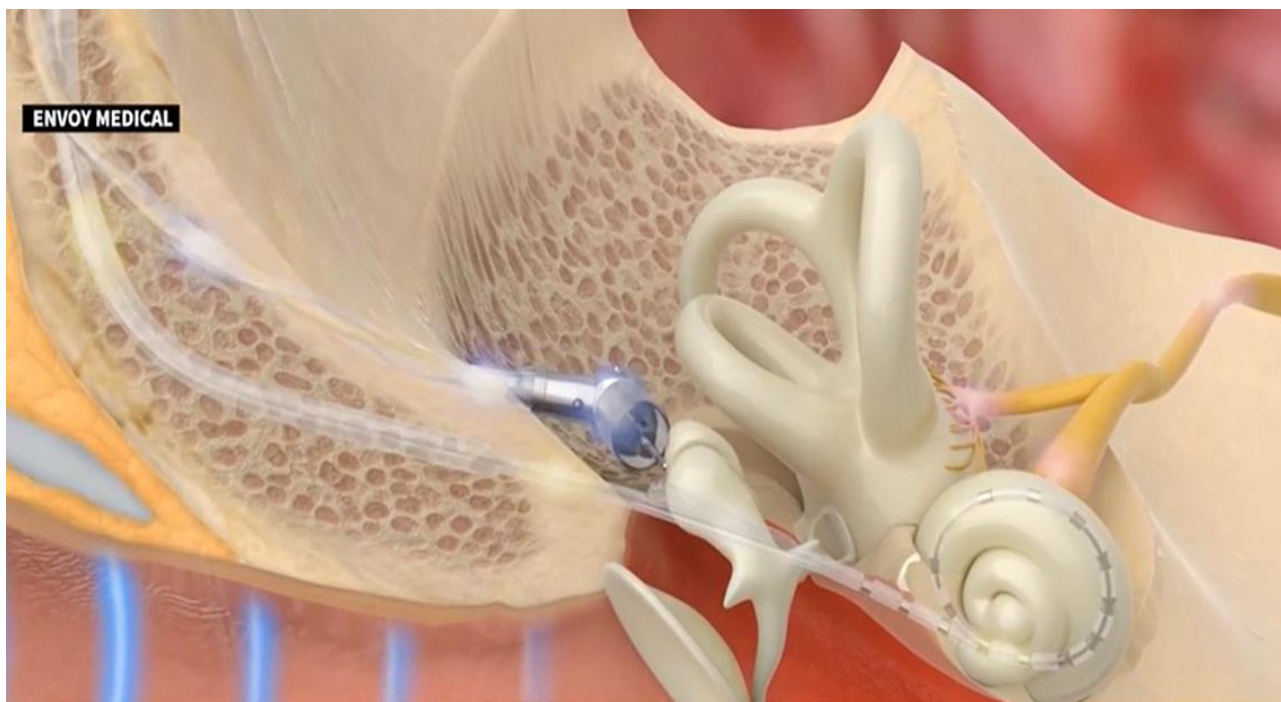
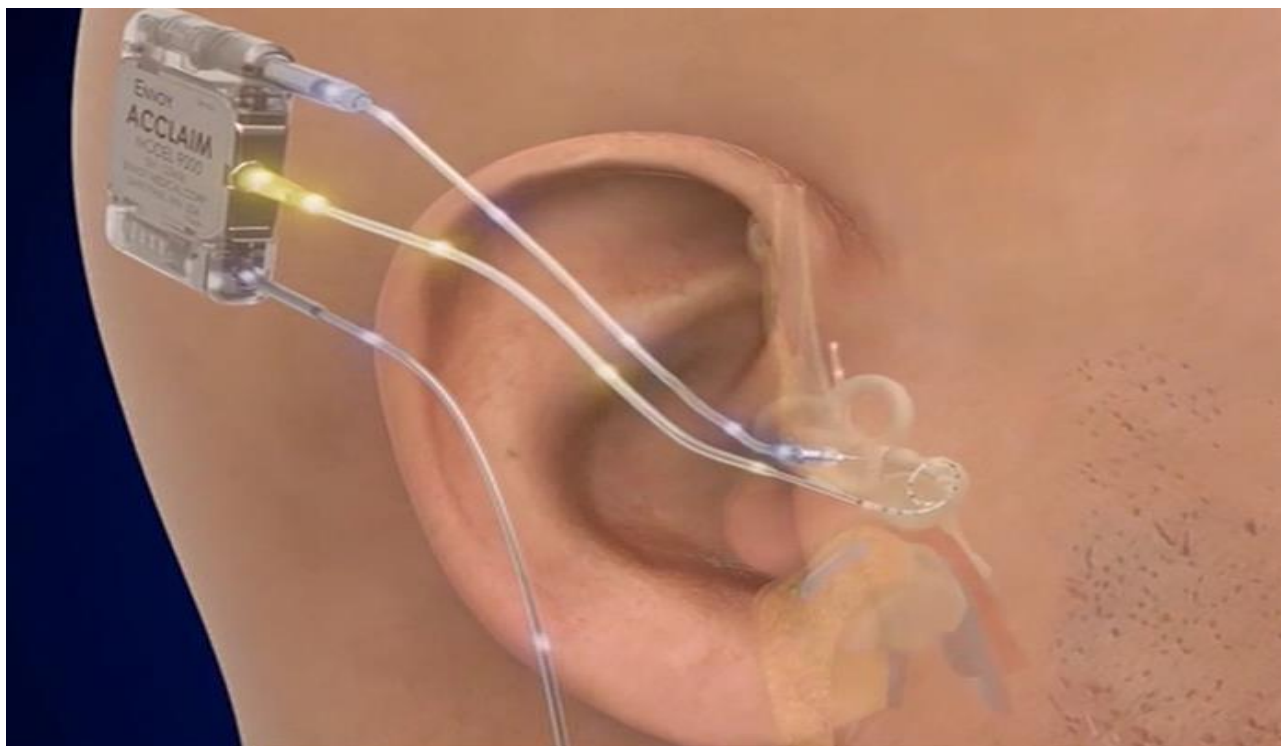
- No expensive external sound processors to replace when lost or damaged.
- No frequent battery changes or charging. Rechargeable battery expected to last several days between charges and designed to last 8-12 years.
- No magnets. Designed to be MRI compatible.\*

\*MRI compatibility not yet determined).



Source: Company reports.

Exhibit 20: Acclaim CI (Cochlear Implant)



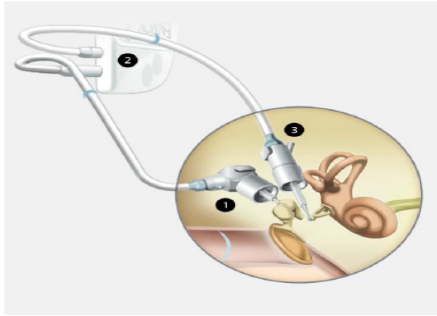
Source: Company reports.



Exhibit 21: Esteem FI-AMEI (Fully Implanted Active Middle Ear Implant)

Executive Summary

**PRODUCT OVERVIEW – ESTEEM®**

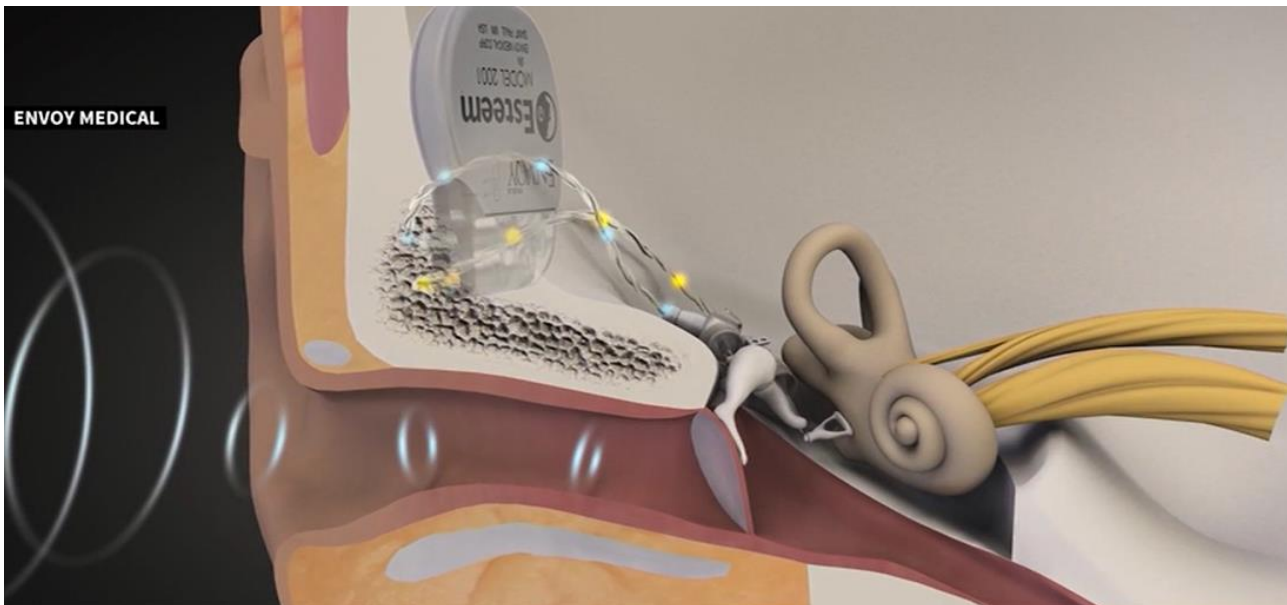


The Esteem® is the first and only FDA-approved, fully-implanted active middle ear implant (AMEI).

- 1) The Envoy Sensor converts the vibrations into electrical signals that are sent to the implanted Esteem Sound Processor
- 2) The Esteem Sound Processor receives, adjusts and intensifies the signals to fit your unique hearing needs
- 3) The Esteem Driver directly transfers these signals to the inner ear where the hair cells are stimulated, causing you to hear

The Esteem® Opportunity

**THREE FULLY IMPLANTED COMPONENTS**



Source: Company reports.

## FINANCIALS

Envoy Medical's fiscal year ends on December 31. We expect its next earnings report (for Q2 2024 ending June 2024) to be in mid-August. Because the company is primarily a clinical stage medical device development company, it currently generates minimal revenue and significant losses as it funds its device development. Currently, the company's revenue consists of its Esteem FI-AMEI product. This product was FDA approved in 2010, but has failed to gain commercial traction, primarily due to a lack of reimbursement or insurance coverage from third-party payors. The company does not anticipate revenue for its Esteem FI-AMEI product to increase significantly until favorable reimbursement policy and coverage changes. Going forward long term, the company's main revenue is expected to be from its Acclaim CI implant product clinical device in development.

On September 29, 2023, Anzu Special Acquisition Corp I (Anzu) completed the acquisition of Envoy Medical Corporation (Legacy Envoy) at a value of \$150 million. The merger was accounted for as a reverse recapitalization ("reverse merger") so Anzu is treated as the acquired company and Legacy Envoy is treated as the acquirer for financial reporting purposes (so historical financials before the merger were restated to reflect Legacy Envoy's financials).

Anzu SPAC IPO was completed in March 2021, raising \$420 million to be held as trust asset until an acquisition is completed. However, prior to the completion of the Anzu / Legacy Envoy merger, almost all of the proceeds from the IPO were redeemed by Anzu shareholders.

We note Anzu's and Envoy's historical financials and many special charges and accounting adjustments made its Q3 and Q4 2023 financial reports complicated and not reflective of its expected ongoing financial operations and reporting.

### **Exhibit 22: Envoy Medical Historical and Projected Financials**

<b>FYE Dec 31</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>
<b>(in millions except EPS)</b>					
<b>Total Revenue</b>	<b>0.3</b>	<b>0.2</b>	<b>0.3</b>	<b>0.3</b>	<b>0.3</b>
Research & development costs	<b>3.9</b>	<b>4.5</b>	<b>9.0</b>	<b>9.9</b>	<b>10.4</b>
<b>Operating income (loss)</b>	<b>(6.9)</b>	<b>(8.7)</b>	<b>(18.4)</b>	<b>(19.8)</b>	<b>(21.1)</b>
<b>Net income (pro forma)</b>	<b>(10.7)</b>	<b>(17.9)</b>	<b>(29.9)</b>	<b>(22.1)</b>	<b>(22.6)</b>
<b>EPS</b>	<b>\$ (1.05)</b>	<b>\$ (1.77)</b>	<b>\$ (2.38)</b>	<b>\$ (1.09)</b>	<b>\$ (1.01)</b>

Source: Company reports and Ascendant Capital Markets estimates.

### **Recent Results (fiscal Q1 2024 ending March 2024)**

Envoy Medical's recent financial performance is reflective of its developmental stage. In its Q1 2024 report (on May 15, 2024), the company reported revenue of \$0.1 million and net loss was \$6.3 million. Operating expenses were \$4.8 million (down from \$6.9 million in Q4 2023), consisting mainly of research and development costs and general and administrative expenses. Q1 EPS was \$(0.32).

We note that in 2H 2024 (Q3 or Q4), the company is expected to re-submit an updated IDE (Investigational Device Exemption) application for its Acclaim CI to the FDA. Clinical trials should start shortly after IDE approval, and be finished by late 2025/early 2026, with potential FDA approval (PMA or Premarket Approval) by the end of 2026.

The company does not provide specific quarterly financial guidance, but we believe that R&D expenses should remain relatively stable until the company expands clinical trial activities. Going forward, we believe operating expenses of \$4 - 5 million is a reasonable near term quarterly cash burn rate. The company expects continued progress on its device development milestones in 2024. We do not expect the company to experience revenue until its Acclaim CI make significant progress towards FDA approval (either from product sales or from the sales of device marketing rights to new partners), which is likely at least two years away. We have modeled relatively steady operating costs over the next year, primarily driven by its expected device clinical trials expenses.

For 2024 (ending December 2024), we expect revenues of \$0.3 million, and a net loss of \$22 million and EPS of \$(1.09). For 2025 (ending December 2025), we expect revenues of \$0.3 million and a net loss of \$23 million and EPS of \$(1.01).

We believe investors should be focused on its progress on its device development, which will likely take at least two years before a potential FDA approval. Within this year (expected late 2024), the company is expected to re-submit an updated IDE (Investigational Device Exemption) application for its Acclaim CI to the FDA.

We believe that the biggest potential variable in our financial model is the ability of the company to get FDA (or equivalent) approval for its Acclaim CI device. It is these approvals that are ultimately how Envoy Medical will be able to finally be able to generate revenue. If the company can make significant progress towards these goals, then revenue and earnings will likely be able to grow significantly. However, if the company has difficulties in making progress towards getting device approvals, then revenue and profitability may not be achieved or will likely grow at a moderate rate or even not at all. Even after device approvals, Envoy Medical faces a big challenge to successfully commercialize its products. However, given the lack of good therapeutics to prevent or treat hearing loss and existing cochlear implants have major limitations, we believe Acclaim CI commercial prospects are very positive if it obtains FDA approval.

The company's balance sheet has \$5 million in cash and \$5 million in debt as of March 2024. We believe Envoy Medical has enough cash to fund its operations into late 2024 (Q4 (December) 2024), so we estimate that it will need to raise capital by Q4 2024 (December 2024). We do note that in March 2024, the company entered into a \$10 million, five-year lending facility with Glen Taylor, its largest shareholder. It drew \$5 million in March (Q1), and another \$2.5 million so far in Q2.

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## Exhibit 23: Q1 2024 Financial Report (as of May 15, 2024)

### Envoy Medical Reports First Quarter 2024 Results

May 15, 2024

*The Company, a current leader in fully implanted hearing devices, continues to steadily march towards its ambition of disrupting the existing cochlear implant industry with its "breakthrough" fully implanted cochlear implant.*

WHITE BEAR LAKE, Minn., May 15, 2024 (GLOBE NEWSWIRE) -- Envoy Medical®, Inc. ("Envoy Medical") (Nasdaq: COCH), a revolutionary hearing health company focused on fully implanted hearing devices, today announces its corporate and financial results for the first quarter ended March 31, 2024.

### Financial and Corporate Highlights from Q1 2024

- All three participants in the ongoing Early Feasibility Study (EFS) at Mayo Clinic (Rochester, MN) have completed their 12-month follow up visits, continue to be enrolled in the study, and report using their devices on a daily basis.
- Company continues to field growing interest from both hearing health professionals and potential candidates about its investigational fully implanted cochlear implant. Company likely will have to turn away several leading cochlear implant institutions that have expressed interest in participating as a site in its next clinical study.
- Company continues to advocate for its commercial Esteem® device, a fully implanted active middle ear implant, to be properly classified as a hearing prosthetic and not improperly as a hearing aid. The bi-partisan Hearing Device Coverage Clarification Act (H.R. 7254) has added co-sponsors and has continued to get attention.
- Envoy Medical plans to file its application for an investigational device exemption (IDE) to begin its fully implanted cochlear implant pivotal clinical trial later in 2024. The Company filed an earlier version of an IDE application at the end of Q1, but decided to convert that IDE application to a "pre-submission" (sometimes referred to as a Q-submission). Strategically, this conversion allows for additional data collection on the three EFS participants, pending testing to be completed, and further interactive discussions with FDA.
- Upon FDA approval, should it be granted, Envoy Medical intends to target a portion of the significantly under-penetrated adult cochlear implant market in the United States.
- In March, the Company entered into a \$10 million, five-year lending facility provided by existing investor and billionaire entrepreneur Glen Taylor. The facility is unsecured and does not provide for conversion into equity. Envoy Medical drew an initial \$5 million on the facility at its origination. It is expected that the financing will support, among other things, the process of applying for an investigational device exemption (IDE) to begin a US-based pivotal clinical trial for its breakthrough fully implanted Acclaim® cochlear implant. The terms ensure the long-term commitment of Envoy Medical's largest investor, instilling confidence in the Company's direction and long-term positioning. Funds will be available as needed and bear interest at 8% over the term of the loan.

"Envoy Medical continues to make steady progress towards our goal of becoming a household name in the hearing loss market," commented Brent T. Lucas, Envoy Medical's Chief Executive Officer. "We strongly believe that Envoy Medical has a bright future ahead of it. We look forward to the prospect of disrupting the hearing industry with new competition and significant innovation."

Source: Company reports.

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**Exhibit 24: Envoy Medical Financial Metrics**

Recent Share Price (6/21/24)	\$ 2.29
52-Weeks Share Price (Low - High)	\$0.75 - 11.72
Shares Outstanding	20 million
Market Capitalization	\$46 million
Enterprise Value	\$46 million
Cash (3/31/24)	\$5 million
Debt (3/31/24)	\$5 million
2023A Revenue	\$0.3 million
2023A Net loss	\$30 million
2023A EPS	\$ (2.38)
2024E Revenue	\$0.3 million
2024E Net loss	\$22 million
2024E EPS	\$ (1.09)
2025E Revenue	\$0.3 million
2025E Net loss	\$23 million
2025E EPS	\$ (1.01)

Source: Company reports and Ascendant Capital Markets estimates.

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## FINANCIAL MODEL

### Envoy Medical, Inc.

Income Statement (\$ mils)	2021	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025
Fiscal Year End: December 31	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2E	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
<b>Total Revenue</b>	<b>0.310</b>	<b>0.101</b>	<b>0.059</b>	<b>0.057</b>	<b>0.020</b>	<b>0.237</b>	<b>0.078</b>	<b>0.063</b>	<b>0.080</b>	<b>0.095</b>	<b>0.316</b>	<b>0.059</b>	<b>0.075</b>	<b>0.075</b>	<b>0.075</b>	<b>0.284</b>	<b>0.075</b>	<b>0.075</b>	<b>0.075</b>	<b>0.075</b>	<b>0.300</b>
Cost of Revenues	0.769	0.213	0.218	0.106	0.420	0.957	0.294	0.333	0.189	(0.027)	0.789	0.153	0.150	0.150	0.150	0.603	0.150	0.150	0.150	0.150	0.600
Gross Profit	(0.459)	(0.112)	(0.159)	(0.049)	(0.400)	(0.720)	(0.216)	(0.270)	(0.109)	0.122	(0.473)	(0.094)	(0.075)	(0.075)	(0.075)	(0.319)	(0.075)	(0.075)	(0.075)	(0.075)	(0.300)
Research & development	3.939	1.046	1.361	0.935	1.174	4.516	1.809	1.981	1.850	3.316	8.956	2.360	2.500	2.500	2.500	9.860	2.600	2.600	2.600	2.600	10.400
Sales and marketing						0.000				1.666	1.666	0.325	0.400	0.400	0.400	1.525	0.400	0.400	0.400	0.400	1.600
General & administrative	2.473	0.652	0.674	0.812	1.332	3.470	1.746	2.229	1.426	1.875	7.276	2.119	2.000	2.000	2.000	8.119	2.200	2.200	2.200	2.200	8.800
Restructuring and other						0.000					0.000					0.000					0.000
Total operating expenses	6.412	1.698	2.035	1.747	2.506	7.986	3.555	4.210	3.276	6.857	17.898	4.804	4.900	4.900	4.900	19.504	5.200	5.200	5.200	5.200	20.800
<b>Operating income (loss)</b>	<b>(6.871)</b>	<b>(1.810)</b>	<b>(2.194)</b>	<b>(1.796)</b>	<b>(2.906)</b>	<b>(8.706)</b>	<b>(3.771)</b>	<b>(4.480)</b>	<b>(3.385)</b>	<b>(6.735)</b>	<b>(18.371)</b>	<b>(4.898)</b>	<b>(4.975)</b>	<b>(4.975)</b>	<b>(4.975)</b>	<b>(19.823)</b>	<b>(5.275)</b>	<b>(5.275)</b>	<b>(5.275)</b>	<b>(5.275)</b>	<b>(21.100)</b>
Interest income (expense)						0.000					0.000	(0.036)	(0.181)	(0.375)	(0.375)	(0.967)	(0.375)	(0.375)	(0.375)	(0.375)	(1.500)
Other income (expense)	(3.804)	(0.561)	0.458	0.457	(9.571)	(9.217)	(9.982)	(9.266)	4.948	2.763	(11.537)	(1.336)	0.000	0.000	0.000	(1.336)	0.000	0.000	0.000	0.000	0.000
Income before income taxes	(10.675)	(2.371)	(1.736)	(1.339)	(12.477)	(17.923)	(13.753)	(13.746)	1.563	(3.972)	(29.908)	(6.270)	(5.156)	(5.350)	(5.350)	(22.126)	(5.650)	(5.650)	(5.650)	(5.650)	(22.600)
Income taxes	0.000					0.000					0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Net income (loss)	(10.675)	(2.371)	(1.736)	(1.339)	(12.477)	(17.923)	(13.753)	(13.746)	1.563	(3.972)	(29.908)	(6.270)	(5.156)	(5.350)	(5.350)	(22.126)	(5.650)	(5.650)	(5.650)	(5.650)	(22.600)
Nonrecurring/noncash adjustme	0.000					0.000					0.000					0.000					0.000
<b>Net income (pro forma)</b>	<b>(10.675)</b>	<b>(2.371)</b>	<b>(1.736)</b>	<b>(1.339)</b>	<b>(12.477)</b>	<b>(17.923)</b>	<b>(13.753)</b>	<b>(13.746)</b>	<b>1.563</b>	<b>(3.972)</b>	<b>(29.908)</b>	<b>(6.270)</b>	<b>(5.156)</b>	<b>(5.350)</b>	<b>(5.350)</b>	<b>(22.126)</b>	<b>(5.650)</b>	<b>(5.650)</b>	<b>(5.650)</b>	<b>(5.650)</b>	<b>(22.600)</b>
EBITDA																					
Shares, Basic	10.123	10.123	10.123	10.123	10.123	10.123	10.123	10.123	10.214	19.600	12.553	19.600	20.100	20.600	21.100	20.350	21.600	22.100	22.600	23.100	22.350
Shares, Diluted	10.123	10.123	10.123	10.123	10.123	10.123	10.123	10.123	11.215	19.600	12.553	19.600	20.100	20.600	21.100	20.350	21.600	22.100	22.600	23.100	22.350
EPS Basic (pro forma)	(\$1.05)	(\$0.23)	(\$0.17)	(\$0.13)	(\$1.23)	(\$1.77)	(\$1.36)	(\$1.36)	\$0.15	(\$0.20)	(\$2.38)	(\$0.32)	(\$0.26)	(\$0.26)	(\$0.25)	(\$1.09)	(\$0.26)	(\$0.26)	(\$0.25)	(\$0.24)	(\$1.01)
EPS Diluted (pro forma)	(\$1.05)	(\$0.23)	(\$0.17)	(\$0.13)	(\$1.23)	(\$1.77)	(\$1.36)	(\$1.36)	\$0.14	(\$0.20)	(\$2.38)	(\$0.32)	(\$0.26)	(\$0.26)	(\$0.25)	(\$1.09)	(\$0.26)	(\$0.26)	(\$0.25)	(\$0.24)	(\$1.01)
<b>Margins</b>																					
Gross margin	-148%	-111%	-269%	-86%	-2000%	-304%	-277%	-429%	-136%	128%	-150%	-159%	-100%	-100%	-100%	-112%	-100%	-100%	-100%	-100%	-100%
Research & development	1271%	1036%	2307%	1640%	5870%	1905%	2319%	3144%	2313%	3491%	2834%	4000%	3333%	3333%	3333%	3472%	3467%	3467%	3467%	3467%	3467%
General & administrative	798%	646%	1142%	1425%	6660%	1464%	2238%	3538%	1783%	1974%	2303%	3592%	2667%	2667%	2667%	2859%	2933%	2933%	2933%	2933%	2933%
Operating margin	-2216%	-1792%	-3719%	-3151%	-14530%	-3673%	-4835%	-7111%	-4231%	-7089%	-5814%	-8302%	-6633%	-6633%	-6633%	-6980%	-7033%	-7033%	-7033%	-7033%	-7033%
Tax rate, GAAP	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net margin	-3444%	-2348%	-2942%	-2349%	-62385%	-7562%	-17632%	-21819%	1954%	-4181%	-9465%	-10627%	-6874%	-7133%	-7133%	-7791%	-7533%	-7533%	-7533%	-7533%	-7533%
<b>Y/Y % change</b>																					
Total Revenue						-24%	-23%	7%	40%	375%	33%	-24%	19%	-6%	-21%	-10%	27%	0%	0%	0%	6%
Gross margin						57%	93%	70%	122%	-131%	-34%	-56%	-72%	-31%	-161%	-33%	-20%	0%	0%	0%	-6%
Research & development						15%	73%	46%	98%	182%	98%	30%	26%	35%	-25%	10%	10%	4%	4%	4%	5%
General & administrative						40%	168%	231%	76%	41%	110%	21%	-10%	40%	7%	12%	4%	10%	10%	10%	8%
Operating income (loss)						27%	108%	104%	88%	132%	111%	30%	11%	47%	-26%	8%	8%	6%	6%	6%	6%
Net income (loss)						68%	480%	692%	-217%	-68%	67%	-54%	-62%	-442%	35%	-26%	-10%	10%	6%	6%	2%
EPS Diluted (pro forma)						68%	480%	692%	-205%	-84%	35%	-76%	-81%	-286%	25%	-54%	-18%	0%	-4%	-4%	-7%

Source: Company reports and Ascendant Capital Markets estimates.



**Envoy Medical, Inc.**

Balance Sheet (\$ mils)	Dec-21	Dec-22	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
Fiscal Year End: December 31	Q4A	Q4A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
<b>Assets</b>													
Cash and cash equivalents	1.121	0.183	0.068	7.440	4.218	4.945	4.943	(0.255)	(5.453)	(10.951)	(16.449)	(21.947)	(27.445)
Short term investments				9.400			0.000	0.000	0.000	0.000	0.000	0.000	0.000
Restricted cash							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Accounts receivable, net	0.088	0.041	0.055	0.109	0.070	0.189	0.063	0.063	0.063	0.063	0.063	0.063	0.063
Inventory	1.060	1.295	1.306	1.397	1.404	1.455	0.750	0.750	0.750	0.750	0.750	0.750	0.750
Deferred income taxes							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Prepaid expenses and other	0.167	0.129	0.294	1.997	1.133	1.141	0.075	0.075	0.075	0.075	0.075	0.075	0.075
Total current assets	2.436	1.648	1.723	20.343	6.825	7.730	5.830	0.632	(4.566)	(10.064)	(15.562)	(21.060)	(26.558)
Property and equipment, net	0.188	0.331	0.345	0.378	0.351	0.317	0.329	0.300	0.271	0.242	0.213	0.184	0.155
Leases		0.577	0.525	0.494	0.464	0.433	0.433	0.433	0.433	0.433	0.433	0.433	0.433
Intangibles, net							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred income tax							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other							0.000	0.000	0.000	0.000	0.000	0.000	0.000
<b>Total assets</b>	<b>2.624</b>	<b>2.556</b>	<b>2.593</b>	<b>21.215</b>	<b>7.640</b>	<b>8.480</b>	<b>6.592</b>	<b>1.365</b>	<b>(3.862)</b>	<b>(9.389)</b>	<b>(14.916)</b>	<b>(20.443)</b>	<b>(25.970)</b>
<b>Liabilities and stockholders' equity</b>													
Accounts payable	0.661	1.003	2.360	3.381	1.554	0.913	2.250	2.250	2.250	2.250	2.250	2.250	2.250
Accrued expenses	0.475	0.608	0.747	4.052	4.613	5.621	2.250	2.250	2.250	2.250	2.250	2.250	2.250
Payable to related party				4.000			0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred revenue							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred income tax							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Leases		0.125	0.148	0.149	0.158	0.157	0.157	0.157	0.157	0.157	0.157	0.157	0.157
Product warranty liability		0.335	0.256	0.228	0.311	0.305	0.305	0.305	0.305	0.305	0.305	0.305	0.305
Warrant liabilities	0.248			0.846			0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other				0.034			0.000	0.000	0.000	0.000	0.000	0.000	0.000
Short term debt		0.448	0.676				0.000	0.000	0.000	0.000	0.000	0.000	0.000
<b>Total current liabilities</b>	<b>1.384</b>	<b>2.519</b>	<b>4.187</b>	<b>12.690</b>	<b>6.636</b>	<b>6.996</b>	<b>4.962</b>	<b>4.962</b>	<b>4.962</b>	<b>4.962</b>	<b>4.962</b>	<b>4.962</b>	<b>4.962</b>
Deferred income taxes							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Product warranty liability	2.750	2.143	2.090	2.025	1.923	1.923	1.923	1.923	1.923	1.923	1.923	1.923	1.923
Leases		0.565	0.467	0.440	0.404	0.378	0.378	0.378	0.378	0.378	0.378	0.378	0.378
Deferred revenue							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities		0.127	0.231	1.274	0.439	1.775	1.775	1.775	1.775	1.775	1.775	1.775	1.775
Other long term liabilities							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Long term debt	23.477	33.397	55.324			4.821	10.000	10.000	10.000	10.000	10.000	10.000	10.000
<b>Total other liabilities</b>	<b>26.227</b>	<b>36.232</b>	<b>58.112</b>	<b>3.739</b>	<b>2.766</b>	<b>8.897</b>	<b>14.076</b>	<b>14.076</b>	<b>14.076</b>	<b>14.076</b>	<b>14.076</b>	<b>14.076</b>	<b>14.076</b>
Preferred stock	19.973		19.973				0.000	0.000	0.000	0.000	0.000	0.000	0.000
Common stock	1.392	0.001	1.392	0.002	0.002	0.002	0.125	0.248	0.371	0.494	0.617	0.740	0.863
Additional paid-in capital	163.818	189.904	171.528	255.912	255.596	257.581	257.581	257.581	257.581	257.581	257.581	257.581	257.581
Retained earnings	(210.062)	(225.985)	(252.484)	(251.012)	(257.242)	(264.877)	(270.033)	(275.383)	(280.733)	(286.383)	(292.033)	(297.683)	(303.333)
Other							0.000	0.000	0.000	0.000	0.000	0.000	0.000
Accumulated other comprehensive in	(0.108)	(0.115)	(0.115)	(0.116)	(0.118)	(0.119)	(0.119)	(0.119)	(0.119)	(0.119)	(0.119)	(0.119)	(0.119)
<b>Total stockholders' equity</b>	<b>(24.987)</b>	<b>(36.195)</b>	<b>(59.706)</b>	<b>4.786</b>	<b>(1.762)</b>	<b>(7.413)</b>	<b>(12.446)</b>	<b>(17.673)</b>	<b>(22.900)</b>	<b>(28.427)</b>	<b>(33.954)</b>	<b>(39.481)</b>	<b>(45.008)</b>
<b>Total stockholders' equity and liabili</b>	<b>2.624</b>	<b>2.556</b>	<b>2.593</b>	<b>21.215</b>	<b>7.640</b>	<b>8.480</b>	<b>6.592</b>	<b>1.365</b>	<b>(3.862)</b>	<b>(9.389)</b>	<b>(14.916)</b>	<b>(20.443)</b>	<b>(25.970)</b>

**Balance Sheet Drivers**

	Dec-21	Dec-22	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
	Q4A	Q4A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Prepaid as % of total rev	54%	645%	467%	2496%	1193%	1934%	100%	100%	100%	100%	100%	100%	100%
Inventory as % of total rev	342%	6475%	2073%	1746%	1478%	2466%	1000%	1000%	1000%	1000%	1000%	1000%	1000%
A/P as % of total rev	213%	5015%	3746%	4226%	1636%	1547%	3000%	3000%	3000%	3000%	3000%	3000%	3000%
Accrued exp related as % of total rev	153%	3040%	1186%	5065%	4856%	9527%	3000%	3000%	3000%	3000%	3000%	3000%	3000%
<b>Activity Ratios</b>													
A/R Days Sales Outstanding	0	185	79	123	66	288	75	75	75	75	75	75	75
<b>Book &amp; Cash Value (per share)</b>													
Book Value per Share (diluted)	-\$2.47	-\$3.58	-\$5.90	\$0.43	-\$0.09	-\$0.38	-\$0.62	-\$0.86	-\$1.09	-\$1.32	-\$1.54	-\$1.75	-\$1.95
Cash per Share (diluted)	\$0.11	\$0.02	\$0.01	\$0.66	\$0.22	\$0.25	\$0.25	-\$0.01	-\$0.26	-\$0.51	-\$0.74	-\$0.97	-\$1.19
Net cash per Share (diluted)	-\$2.21	-\$3.33	-\$5.53	\$0.66	\$0.22	\$0.01	-\$0.25	-\$0.50	-\$0.73	-\$0.97	-\$1.20	-\$1.41	-\$1.62

Source: Company reports and Ascendant Capital Markets estimates

**Envoy Medical, Inc.**

Cash Flow Statement (\$ mils)	2021	Jun-22	Sep-22	Dec-22	2022	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025	
Fiscal Year End: December 31	FY-A	Q1&2A	Q3A	Q4A	FY-A	Q1&2A	Q3A	Q4A	FY-A	Q1A	Q2E	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E	
<b>Cash flow from operating activities</b>																				
Net income	(8,675)	(3,107)	(1,339)	(11,477)	(15,923)	(26,499)	1,472	(4,881)	(29,908)	(6,270)	(5,156)	(5,350)	(5,350)	(22,126)	(5,650)	(5,650)	(5,650)	(5,650)	(22,600)	
Depreciation	0.071	0.027	0.022	0.026	0.075	0.056	0.029	0.048	0.133	0.034	0.050	0.050	0.050	0.184	0.050	0.050	0.050	0.050	0.200	
Amortization					0.000				0.000					0.000					0.000	
Non-cash lease expense					0.000				0.000					0.000					0.000	
Debt related amortization expense					0.000				0.000					0.000					0.000	
Stock comp					0.000			1,575	1,575	0.123	0.123	0.123	0.123	0.492	0.123	0.123	0.123	0.123	0.492	
Deferred income taxes					0.000				0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Change in fair value of warrant	1,748	(0,899)	(0,551)	8,575	7,125	18,247	(5,042)	(1,602)	11,603	1,336				1,336					0.000	
Lease		0.052	0.030	0.037	0.119	0.052	0.031	(0,211)	(0,128)	0.031				0.031					0.000	
Inventory reserve	0.001	(0,011)	0.000	(0,030)	(0,041)	(0,017)	(0,105)	0.023	(0,099)	0.089				0.089					0.000	
Accrued interest					0.000				0.000					0.000					0.000	
Writedowns and impairments					0.000				0.000					0.000					0.000	
Other gains/losses	0.001				0.000				0.000					0.000					0.000	
Other					0.000		4,000	(4,000)	0.000					0.000					0.000	
Changes in operating assets and liabilities:																				
Accounts receivable	(0,019)	(0,009)	0.000	0.056	0.047	(0,014)	(0,054)	(0,137)	(0,205)	(0,119)	0.127	0.000	0.000	0.008	0.000	0.000	0.000	0.000	0.000	
Inventory	0.055	(0,076)	(0,150)	0.032	(0,194)	0.006	0.014	(0,030)	(0,010)	(0,140)	0.705	0.000	0.000	0.565	0.000	0.000	0.000	0.000	0.000	
Prepaid expenses & other current assets	(0,023)	0.078	(0,115)	0.075	0.038	(0,165)	(0,703)	0.040	(0,828)	0.101	1,066	0.000	0.000	1,167	0.000	0.000	0.000	0.000	0.000	
Income tax					0.000				0.000					0.000					0.000	
Other assets					0.000				0.000	(0,027)	0.000	0.000	0.000	(0,027)	0.000	0.000	0.000	0.000	0.000	
Accounts payable	0.227	0.092	(0,333)	0.583	0.342	1,357	1,021	(1,827)	0.551	(0,641)	1,337	0.000	0.000	0.696	0.000	0.000	0.000	0.000	0.000	
Accrued expenses	(0,153)	(0,042)	(0,034)	0.203	0.127	0.064	0.529	(0,687)	(0,094)	(0,357)	(3,371)	0.000	0.000	(3,728)	0.000	0.000	0.000	0.000	0.000	
Deferred revenue					0.000				0.000					0.000					0.000	
Other liabilities	(0,169)	(0,053)	(0,008)	(0,459)	(0,520)	(0,132)	(0,093)	(0,019)	(0,244)	(0,006)	0.000	0.000	0.000	(0,006)	0.000	0.000	0.000	0.000	0.000	
<b>Net cash (used in) provided by</b>	<b>(6,936)</b>	<b>(3,948)</b>	<b>(2,478)</b>	<b>(2,379)</b>	<b>(8,805)</b>	<b>(7,045)</b>	<b>1,099</b>	<b>(11,708)</b>	<b>(17,654)</b>	<b>(5,846)</b>	<b>(5,119)</b>	<b>(5,177)</b>	<b>(5,177)</b>	<b>(21,319)</b>	<b>(5,477)</b>	<b>(5,477)</b>	<b>(5,477)</b>	<b>(5,477)</b>	<b>(21,908)</b>	
<b>Cash flow from investing activities</b>																				
Purchases of property and equipment	(0,125)	(0,101)	(0,076)	(0,041)	(0,218)	(0,070)	(0,062)	(0,021)	(0,153)	(0,109)	(0,062)	(0,021)	(0,021)	(0,213)	(0,021)	(0,021)	(0,021)	(0,021)	(0,084)	
Purchases of short-term investments					0.000				0.000					0.000					0.000	
Acquisitions					0.000				0.000					0.000					0.000	
Other					0.000				0.000					0.000					0.000	
<b>Net cash used in investing activities</b>	<b>(0,125)</b>	<b>(0,101)</b>	<b>(0,076)</b>	<b>(0,041)</b>	<b>(0,218)</b>	<b>(0,070)</b>	<b>(0,062)</b>	<b>(0,021)</b>	<b>(0,153)</b>	<b>(0,109)</b>	<b>(0,062)</b>	<b>(0,021)</b>	<b>(0,021)</b>	<b>(0,213)</b>	<b>(0,021)</b>	<b>(0,021)</b>	<b>(0,021)</b>	<b>(0,021)</b>	<b>(0,084)</b>	
<b>Cash flow from financing activities</b>																				
Issuance of debt	8,000	3,000	3,000	2,000	8,000	7,000	3,000		10,000	5,000	5,179	0.000	0.000	10,179	0.000	0.000	0.000	0.000	0.000	
Repayment of debt					0.000				0.000					0.000					0.000	
Issuance of stock					0.000		12,736	(0,891)	11,845	1,683	0.000	0.000	0.000	1,683	0.000	0.000	0.000	0.000	0.000	
Proceeds from stock option exercise	0.058		0.092	0.000	0.092				0.000					0.000					0.000	
Other					0.000				0.000					0.000					0.000	
Dividends and distributions					0.000				0.000					0.000					0.000	
<b>Cash provided by (used in) financing activities</b>	<b>8,058</b>	<b>3,000</b>	<b>3,092</b>	<b>2,000</b>	<b>8,092</b>	<b>7,000</b>	<b>15,736</b>	<b>(0,891)</b>	<b>21,845</b>	<b>6,683</b>	<b>5,179</b>	<b>0.000</b>	<b>0.000</b>	<b>11,862</b>	<b>0.000</b>	<b>0.000</b>	<b>0.000</b>	<b>0.000</b>	<b>0.000</b>	
Effect of exchange rate on cash	(0,010)		(0,001)	(0,006)	(0,007)		(0,001)	(0,002)	(0,003)	(0,001)				(0,001)					0.000	
<b>Net increase (decrease) in cash</b>	<b>0,987</b>	<b>(1,049)</b>	<b>0,537</b>	<b>(0,426)</b>	<b>(0,938)</b>	<b>(0,115)</b>	<b>16,772</b>	<b>(12,622)</b>	<b>4,035</b>	<b>0,727</b>	<b>(0,002)</b>	<b>(5,198)</b>	<b>(5,198)</b>	<b>(9,671)</b>	<b>(5,498)</b>	<b>(5,498)</b>	<b>(5,498)</b>	<b>(5,498)</b>	<b>(21,992)</b>	
Beginning cash and equivalents	0,134	1,121	0,072	0,609	1,121	0,183	0,068	16,840	0,183	4,218	4,945	4,943	(0,255)	4,218	(5,453)	(10,951)	(16,449)	(21,947)	(5,453)	
Ending cash and equivalents	1,121	0,072	0,609	0,183	0,183	0,068	16,840	4,218	4,218	4,945	4,943	(0,255)	(5,453)	(5,453)	(10,951)	(16,449)	(21,947)	(27,445)	(27,445)	

Source: Company reports and Ascendant Capital Markets estimates

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## **Envoy Medical, Inc.**

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Total return is defined as price appreciation plus dividend yield.

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Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
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Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	56	100%	18	32%

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