UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-42756

CARLSMED, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1081863**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1800 Aston Ave, Suite 100 Carlsbad, California	**92008**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (760) 766-1923

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	CARL	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

As of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public market for the Registrant's common stock. Therefore, the aggregate market value of its common stock held by non-affiliates as of such date cannot be calculated. The Registrant's common stock began trading on the Nasdaq Global Select Market on July 23, 2025.

The number of shares of Registrant's Common Stock outstanding as of February 23, 2026 was 26,731,992.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report"), including the sections titled "*Risk Factors*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," and "*Business*," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our ability to advance the aprevo Technology Platform, which consists of artificial intelligence ("AI")-enabled software solutions, and interbody implants that we custom design for each patient's unique pathology and vertebral bone topography, and single-use surgical instruments (the "aprevo Technology Platform"), and any potential future products through applicable regulatory approval processes;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our ability to maintain or improve our third-party payor reimbursement strategy;
- our ability to attract and retain customers and surgeon users;
- our expectations concerning orders for our products and utilization by existing customers and surgeon users;
- our expectations regarding the potential market size for the aprevo Technology Platform;
- our ability to maintain our competitive technological advantages;
- our intentions to pursue adjacent and international markets;
- our ability to continue improving our products and technology;
- our commercialization and marketing capabilities and strategies;
- our ability to maintain or reduce our manufacturing times of our contract management organizations ("CMOs");
- our reliance on a limited number of CMOs;
- the implementation of our business model and strategic plans for our business and products and technology;
- our relationships with, and the capabilities of, our suppliers;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products;
- our ability to effectively manage our growth;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act");
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing, and our ability to obtain additional capital; and
- our future financial performance.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "*Risk Factors*" and elsewhere in this Annual Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report, and the documents that we reference in this Annual Report, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

This Annual Report also contains estimates, projections, and other information concerning our industry, our business, and the markets for our products. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research, as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report, their estimates, in particular as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "*Risk Factors*" and elsewhere in this Annual Report.

We own certain trademarks used in this Annual Report that are important to our business, including, among others, Carlsmed®, aprevo® and myaprevo®. We also intend to apply for various trademarks that we use in connection with the operation of our business. This Annual Report may also contain trademarks, service marks, and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship by, us. Solely for convenience, the trademarks, service marks, and trade names referred to in this Annual Report may appear without the "™," "®," or "SM" symbol, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks, and trade names.

PART I

Item 1. Business.

Overview

We are a commercial-stage medical technology company pioneering AI-enabled personalized spine surgery solutions with a focus on becoming the standard of care for spine fusion surgery. Our mission is to improve outcomes and decrease the cost of healthcare for spine surgery and beyond. The aprevo Technology Platform was designed to address the limitations of traditional lumbar and cervical spine fusion surgery, aiming to optimize patient outcomes and reduce the need for revision surgeries.

Our technology is powered by AI-enabled, outcome-based algorithms that provide personalized surgical plans for spine fusion. The aprevo surgical kit delivered to customers includes interbody implants for a custom vertebral fit for each patient's unique pathology and bone topography, and single-use surgical instruments. The aprevo Technology Platform supports surgeons in achieving proper spinal alignment for patients with degenerative disc disease ("DDD"), which can improve clinical outcomes and reduce the likelihood of revision surgeries. We currently market the aprevo Technology Platform for lumbar and cervical spine fusion surgeries.

DDD is the progressive breakdown of spinal discs that are interposed between vertebrae to provide mobility and shock absorption. The disease occurs naturally with age and can be accelerated by factors such as injury, repetitive loading, obesity, or genetic predisposition. Adult spinal deformity ("ASD") is a more severe form of DDD and is a condition where the spine has systematic structural abnormalities and/or abnormal curvature often affecting multiple levels of the spine. These conditions often cause a loss of disc height and spine function, and lead to chronic pain, disability, and other chronic spinal pathologies, significantly impacting patients' lives. As the conditions progress and patients experience debilitating pain or disabilities, surgical intervention may become necessary. One study estimated that the overall prevalence of diagnosed DDD was 27.3% for individuals over the age of 65, and increased with age.

Non-surgical interventions are typically the first line of treatment for DDD and are aimed at managing symptoms and slowing disease progression without invasive procedures. When non-surgical treatments fail to alleviate debilitating symptoms or disabilities, surgical interventions may become necessary. The most common surgical intervention and current standard of care is traditional spine fusion, which we define as a spine fusion procedure with stock implants that are fixed in size and shape. Based on projections contained in the 2024 Spinal Fusion - US Market Report (the "SmartTRAK Report") by BioMedGPS we estimate that approximately 445,200 lumbar fusion surgeries and approximately 372,600 cervical fusion surgeries were performed in the United States in 2025, which assumes a compound annual growth rate ("CAGR") of approximately 1.5% in the spinal fusion market.

Despite its wide adoption, we believe traditional spine fusion surgery has several limitations and can lead to poor clinical outcomes. First, traditional spine fusion often lacks robust pre-operative planning, relying on two dimensional ("2D") imaging without advanced tools, such as three-dimensional ("3D") modeling. This limits the surgeon's ability to plan for optimal correction. Second, the stock implants that are used during surgery are largely symmetric in shape and only come in pre-defined dimensions, which often fail to match the unique anatomy of each patient and can lead to unpredictable alignment. Third, during the surgery, the surgeon must visually choose the correct stock implant from dozens of options, which involves a prolonged trialing process, which we believe elevates the risk of secondary complications. Finally, post-operatively, there is no integrated means for reconciling achieved outcomes against surgical objectives and utilizing these insights systematically to improve future surgical plans. As a result of these limitations, traditional spine fusion surgery can fail to achieve proper alignment, leading to post-operative complications and increasing the likelihood of revision surgery.

Recent publications on traditional spine fusion report rates of revision surgery for mechanical complications between 14% and 32% over a mean postoperative period of one to two years in ASD patients. We believe that these limitations and poor clinical outcomes not only impair patients' health and quality of life but also impose a significant economic burden on the healthcare system, with the direct and indirect costs of a single revision surgery frequently exceeding $100,000.

The aprevo Technology Platform represents an end-to-end, integrated digital technology platform designed to deliver better surgical results, reduce the need for revision surgery, and improve long-term outcomes. The aprevo Technology Platform is the first available solution to provide personalized digital surgical plans and the accompanying aprevo interbody implants that are tailored to each patient's unique pathology and vertebral bone topography.

Our pre-operative planning software utilizes standard-of-care diagnostic imaging in combination with our AI-enabled algorithms to develop personalized digital surgical plans, allowing us to design aprevo interbody implants for each patient's unique pathology and anatomy. Additionally, the aprevo Technology Platform supports the collection of post-operative data to inform our digital surgical planning process. The U.S. Food and Drug Administration ("FDA") cleared the aprevo lumbar interbody implants through its 510(k) regulatory pathway for the correction of adult spinal deformity in December 2020 and several degenerative conditions of the lumbar spine in August 2022. In October 2021, we commenced our U.S. commercial launch of aprevo for lumbar interbody fusion surgeries. Lumbar procedures using our aprevo interbody implants are covered by Medicare, Medicare Advantage, and commercial payors; these are generally mapped to Medicare Severity-Diagnosis Related Groups ("MS-DRGs") codes that provide for premium reimbursement relative to those that use stock implants. We believe this also helps drive surgeon adoption while also supporting patient access to our patient-centric technology.

We have also developed our aprevo Technology Platform for use in cervical spine fusion surgeries. In November 2024, we received FDA 510(k) clearance for our aprevo interbody implants for cervical interbody fusion surgeries after previously receiving FDA Breakthrough Device Designation for this technology, and in July 2025, we successfully completed the first in-human personalized cervical procedure in the United States using our aprevo Technology Platform. In August 2025, in the CMS Final Rule, the Centers for Medicare and Medicaid Services ("CMS") finalized X-codes for the use of custom-made anatomically designed interbody fusion devices for cervical spine fusion surgeries and established a New Technology Add-on Payment ("NTAP") of up to $21,125 additional reimbursement to hospitals for qualifying inpatient cervical spine fusion procedures. The new X-codes and NTAP went into effect on October 1, 2025. In December 2025, we received FDA 510(k) clearance for our cervical plating system. We have generated limited early sales of aprevo interbody implants for use in cervical spine fusion surgery following a commercial launch in December 2025 and expect to more broadly commercialize the aprevo cervical platform, including the anticipated commercial launch of our corra Cervical Plating System, in 2026.

Our current commercial focus is on the U.S. market. We estimate that there is a total addressable market of approximately $13.4 billion for aprevo lumbar devices in the United States. This figure is based on our current average revenue per lumbar fusion procedure and our estimate (informed by projections contained in the SmarkTRAK Report) that approximately 445,200 lumbar fusion surgeries were performed in the United States in 2025. We estimate that the total addressable market for aprevo cervical devices in the United States. is approximately $6 billion, based on our current average revenue per cervical fusion procedure and our estimate (informed by projections contained in the SmartTRAK Report) that approximately 372,600 cervical fusion surgeries were performed in the United States in 2025. This total addressable market is calculated based on the overall revenue opportunity that we believe is possible if we achieve 100% U.S. market share for aprevo in lumbar and cervical fusion surgeries.

We estimate there are approximately 4,000 surgeons across the United States whose patients could benefit from using the aprevo Technology Platform. As of December 31, 2025, 253 surgeon users had completed one or more procedures using the aprevo Technology Platform, compared to 152 surgeon users as of December 31, 2024. We believe this suggests ample opportunity to grow our surgeon user base and further penetrate the market by engaging more surgeons across the United States.

*As of December 31, 2025.

We market the aprevo Technology Platform to support our personalized solutions and sell personalized implant devices to hospitals and ambulatory surgical centers through a combination of our direct sales team and independent sales agents. Our direct sales team consists of Area Vice Presidents, Sales Directors, Account Managers, and Strategic and National Account leadership, who are primarily responsible for promoting the aprevo Technology Platform to surgeons and working with customers to secure product approval. They are also responsible for recruiting independent sales agents who cover each surgery, generate leads, and train clinics. We plan to grow our commercial infrastructure, including both our direct sales team and our number of independent sales agents, and expand various market access initiatives, including utilizing medical education programs and surgeon training at top academic institutions.

- A large body of evidence supports the clinical benefits of the aprevo Technology Platform for spine fusion, including eight peer-reviewed clinical data publications and 20 peer-reviewed clinical data abstracts. Across the various studies and publications, the aprevo Technology Platform has shown favorable results in two of the most critical success measures in spine fusion surgery: (1) achieving proper post-operative alignment and (2) significantly reducing the need for revision surgery due to implant related complications. We continue to develop our growing base of clinical and patient reported outcomes to serve as evidence of the aprevo Technology Platform's value to all key stakeholders, including patients, clinicians, customers, and payors. For example, we are currently conducting a 338-patient study, our COMPASS Registry, to track clinical outcomes from lumbar procedures using the aprevo Technology Platform in both DDD and ASD patients. Based on interim data from the first 67 ASD patients in our COMPASS Registry, these patients demonstrated improved alignment and reduced mechanical complications post-operatively, with a revision rate of 1.5% at one-year follow-up that were mechanical complication–related reoperations unrelated to the aprevo interbody implant. In addition, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of distal lumbar lordosis ("DLL") with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up. Other studies have shown patients with unrestored DLL have experienced a 25.9% revision rate for adjacent segment degeneration at minimum two-years follow-up. Separate studies have shown that approximately 40%-80% of short fusion patients present with a low DLL preoperatively.

We have established a significant competitive advantage through multiple strategic initiatives, including creating a robust intellectual property portfolio and a comprehensive data set. As of December 31, 2025, our patent portfolio contains 45 total issued patents and approximately 120 pending patent applications along with various trademarks and trade secrets. The portfolio covers our aprevo interbody implants, associated manufacturing processes, design process, software user interface for surgeons, and AI-enabled algorithms and software for anatomical spine segmentation and for generating and delivering personalized digital surgical plans.

Our competitive position is further strengthened by our significant base of patient and imaging data. As of December 31, 2025, we estimate that we have used approximately four million de-identified radiographic images to train our AI models, analyzed more than one million radiographic images of patients who have undertaken a procedure using our aprevo Technology Platform, and created more than 40,000 3D patient specific models ("PSMs") of patients' anatomies. We use clinical and post-operative data to refine personalized surgical planning, implant design, and physician workflow, and our expanding data assets support our research and development efforts, intellectual property portfolio, and product pipeline.

We have experienced sequential quarterly and annual revenue growth, driven primarily by growth in our surgeon user base and increased utilization by our existing surgeon users. For the years ended December 31, 2025 and 2024, we recognized revenue of $50.5 million and $27.2 million, respectively, representing year-over-year growth of 85.9%. For the three months ended December 31, 2025 and 2024, we recognized revenue of $15.2 million and $9.4 million, respectively, representing period-over-period growth of 61.2%. For the year ended December 31, 2025, we recognized a gross margin of 75.3% and a net loss of $29.6 million, compared to a gross margin of 73.8% and a net loss of $24.3 million for the year ended December 31, 2024. For the three months ended December 31, 2025, we recognized a gross margin of 76.5% and a net loss of $8.6 million, compared to a gross margin of 74.7% and a net loss of $4.7 million for the three months ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $100.8 million.

Our Success Factors

We believe that the continued growth of our company will be driven by the following success factors:

- ***Paradigm-shifting, patient-centric platform aiming to set the new standard of care for spine surgery.*** The aprevo Technology Platform represents an end-to-end, integrated digital technology platform designed to deliver better surgical results, reduce the need for revision surgery, and improve long-term outcomes. The aprevo Technology Platform is the first available solution in the United States to provide personalized digital surgical plans and the accompanying aprevo interbody implants that are tailored to each patient's pathology and vertebral bone topography. Our platform begins by analyzing each patient's pathology and spinal anatomy, relying on standard diagnostic imaging to create a 3D model that is then used to identify, in collaboration with the health care provider, the corrections necessary to bring the spine within alignment. Our surgical planning software then designs a personalized interbody implant and surgical plan to achieve that goal. Additionally, the aprevo Technology Platform uses post-operative data to continuously improve the personalized digital surgical planning process and drive improved patient outcomes. We believe that the unique and differentiated benefits of the aprevo Technology Platform have helped drive strong adoption since our commercial launch.

- ***Large and established addressable market opportunity with a significant unmet clinical need.*** According to the Mayo Clinic News Network, approximately 20% of U.S. adults experience some amount of disc degeneration by the age of 65. We estimate, based on projections contained in the SmartTRAK Report, that approximately 445,200 lumbar fusion surgeries and approximately 372,600 cervical fusion surgeries were performed in the United States in 2025. This represents an existing, annual addressable U.S. market of $13.4 billion for our lumbar fusion implants and approximately $6 billion for our cervical fusion implants, based on our average revenue per procedure. Despite its wide adoption, we believe traditional spine fusion is hindered by several shortcomings that may contribute to high rates of malalignment and resulting, frequent complications and increased likelihood of revision surgery. For example, one analysis has shown that, following surgery for ASD, 62% of patients remain sagittally malaligned and 25% of patients remain coronally malaligned. This results in serious complications and may require one or more revision surgeries. One study reported that 10% of ASD patients included in the study underwent revision surgery at one year due to implant-related complications, while another observed revision rates for implant-related complications up to 50% by year four. Malalignment is equally problematic for patients receiving surgery for DDD. For example, a study of 578 patients and a study of 335 patients observed malalignment present in 30% and 85%, respectively, of DDD patients preoperatively (typically impacting the levels being treated with fusion), and that 70% and 90% of these patients remained malaligned, respectively, following surgery. Revision surgery represents a burdensome cost to the healthcare system. Based on published data, the direct and indirect costs of a single revision surgery frequently exceeds $100,000. We designed the aprevo Technology Platform to address the limitations of traditional spine surgery by providing surgeons with personalized digital surgical plans and patient-specific aprevo interbody implants to achieve the desired surgical correction. Our total addressable market is the total overall revenue opportunity that we believe is available for the aprevo Technology Platform in the United States if we achieve 100% market share for lumbar fusion and cervical fusion surgeries, and it is not a representation that we will achieve such market share.

- ***Compelling benefits for patients and providers supported by a robust body of clinical studies and real-world evidence.*** A large body of evidence supports the clinical benefits of the aprevo Technology Platform for spine fusion, including eight peer-reviewed clinical data publications and 20 peer-reviewed clinical data abstracts. Across the various studies and publications, the aprevo Technology Platform has shown favorable results in two of the most critical success measures in spine fusion surgery: (1) achieving proper post-operative alignment and (2) significantly reducing the need for revision surgery due to implant-related complications. We continue to develop our growing base of clinical and patient reported outcomes to serve as evidence of the aprevo Technology Platform's value to all key stakeholders, including patients, clinicians, hospitals, and payors. For example, we are currently conducting a 338-patient study, our COMPASS Registry, to track clinical outcomes from lumbar procedures using the aprevo Technology Platform in both DDD and ASD patients. Based on interim data from the first 67 ASD patients in our COMPASS Registry, these patients demonstrated improved alignment and reduced mechanical complications post-operatively, with a revision rate of 1.5% at one-year follow-up that were attributable to mechanical complication–related reoperations unrelated to the aprevo interbody implant. A December 2025 publication in the Global Spine Journal reported two-year follow-up data on a retrospective cohort of ASD patients treated with aprevo interbody implants, comparing the rate of mechanical complication-related reoperations at two years among such patients to the reoperation rate among patients who had been treated using stock implants. The study demonstrated a significantly reduced rate of mechanical complication–related reoperations in the aprevo cohort as compared to the patients who had been treated using stock implants. Patients treated with aprevo had a reoperation rate at two years of 4.3% (n=115) as compared to a two-year reoperation rate of 16.6% (n=997) for patients who had been treated using stock devices ($p<0.001$), representing a 74% relative reduction. The study authors noted that the reoperation rate in the selected comparator was relatively low, as these patients were treated by highly experienced and renowned surgeons. When factoring in three other published studies that were noted in the paper, the average two-year revision rate due to mechanical complications was 24.9%, making the comparative reoperation rate associated with aprevo even more meaningful. In addition, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of DLL with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up. Other studies have shown patients with unrestored DLL have experienced a 25.9% revision rate for adjacent segment degeneration at minimum 2-years follow-up. Separate studies have shown that approximately 40%-80% of short fusion patients present with a low DLL preoperatively.
- ***Established and distinct reimbursement with favorable payment levels.*** In October 2024, CMS established new MS-DRG codes that included "custom-made anatomically designed" devices. These new MS-DRG codes provide premium reimbursement for most lumbar spine fusion surgeries that utilize aprevo interbody implants relative to those that use stock implants. Additionally, in August 2025, CMS finalized X-codes for the use of custom-made anatomically designed interbody fusion devices for cervical spine fusion surgeries and established an NTAP of up to $21,125 additional reimbursement to hospitals for qualifying inpatient cervical spine fusion procedures. The new X-codes and NTAP went into effect on October 1, 2025. We believe that this reimbursement helps drive surgeon adoption while also supporting patient access to our patient-centric technology. Procedures using our aprevo interbody implants are covered by Medicare, Medicare Advantage, and commercial payors.

- ***Scalable, inventory-light business model with attractive gross margins.*** We have purposefully designed the aprevo Technology Platform, our supply chain, and our commercial strategy to enable rapid adoption and efficiently scale our operations. We leverage our AI-enabled algorithms and software to convert standard-of-care diagnostic patient imaging into a personalized digital surgical plan with limited human interaction and labor costs. Our made-on-demand aprevo interbody implants and our single-use surgical instruments allow us to operate an asset-light business model. Unlike traditional orthopedic device manufacturers who must build significant inventory in order to provide surgeons a range of devices for potential use in each procedure, our aprevo interbody implants are manufactured on demand by our CMOs and personalized for each patient. As a result, at any given time, our inventory consists primarily of devices used in personalized patient procedures, including patient-specific and standard components manufactured for a specific patient's procedure. Importantly, as of February 2026, our streamlined Digital Production System ("DPS") allows us to typically deliver our patient-specific aprevo interbody implants to our customers within six business days of surgical plan approval. We utilize independent sales agents for case coverage, allowing our team of direct sales professionals to focus on widening and deepening the adoption of the aprevo Technology Platform. We expect these highly attractive business model attributes to drive revenue and enable our path to profitability.
- ***Strong competitive position supported by robust intellectual property and comprehensive data moat.*** As of December 31, 2025, our patent portfolio contained 48 total issued patents and approximately 120 pending patent applications along with various trademarks and trade secrets. The portfolio covers our (i) implants, (ii) associated manufacturing processes, (iii) design processes, (iv) software user interface for surgeons, and (v) AI-enabled algorithms and software that is used for generating personalized digital surgical plans. Our competitive position is further strengthened by our significant base of patient and imaging data. As of December 31, 2025, we estimate that we have used approximately four million de-identified radiographic images to train our AI models, analyzed more than one million radiographic images of aprevo patients, and created more than 40,000 3D PSMs of patients' anatomies. We use clinical and post-operative data to refine personalized surgical planning, implant design, and physician workflow, supporting our research and development efforts, intellectual property portfolio, and product pipeline.
- ***Experienced leadership team.*** Our team of industry professionals is dedicated to our mission and embodies our "patient-obsessed" culture. Our senior management team has deep expertise across various disciplines, including technology, spine and orthopedic surgery, research and development, sales and marketing, operations, engineering, data science, manufacturing, and intellectual property.

Our Growth Strategies

We believe that the following strategies will advance our mission and contribute to our future success and growth:

- ***Continue to drive adoption and market share capture for aprevo in lumbar fusion surgeries***. Our focus is to establish the aprevo Technology Platform as the standard of care for lumbar fusion. Since its full commercial launch of the aprevo Technology Platform for spine fusion surgery in October 2021, the aprevo Technology Platform has been used to treat more than 3,200 patients. We estimate that there are approximately 4,000 spine surgeons in the United States. As of December 31, 2025, we had 253 trained surgeons that performed at least one aprevo procedure and believe this represents a large opportunity to further penetrate the market with a wider surgeon base. Over time, we expect to not only expand the number of surgeons actively using the aprevo Technology Platform, but to also increase the annual average number of aprevo procedures performed by surgeons in their practice. To achieve this, we plan to grow our commercial infrastructure and expand various market access initiatives, including utilizing medical education programs, fellowship programs, and surgeon training at top academic institutions. Our medical education and surgeon training initiatives support our commercial operations by increasing awareness of the benefits of the aprevo Technology Platform. Additionally, we are investing in key initiatives to grow patient awareness, including our physician locator web page, which we believe will drive increased patient volume to surgeons who currently utilize the aprevo Technology Platform.

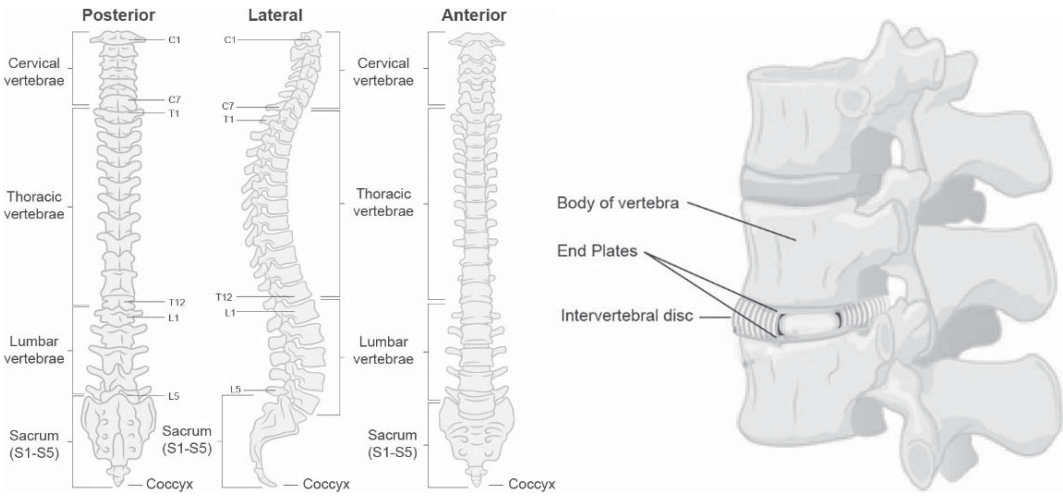
- ***Broadly commercialize our aprevo Technology Platform for cervical spine fusion surgeries***. We believe that cervical spine fusion surgery using stock implants has significant challenges, and this creates an opportunity for the aprevo Technology Platform to significantly improve upon the standard of care in cervical fusion. In November 2024, we received FDA 510(k) clearance for our aprevo interbody implants for cervical spine fusion surgery as part of the FDA-cleared aprevo Technology Platform. In July 2025, we successfully completed the first in-human personalized cervical procedure in the United States and commenced commercialization in December 2025. Also in December 2025, we received FDA 510(k) clearance for our personalized cervical plating solutions as part of the aprevo cervical platform. In February 2026, we completed the first personalized plating procedure using the corra Cervical Plating System at the University of California San Francisco and are planning for its commercial launch later this year. We expect to drive adoption with our existing base of surgeons who are actively using the aprevo Technology Platform for lumbar spine fusion surgeries.
- ***Invest in further growing our base of clinical evidence.*** We are committed to building upon our strong foundation of clinical evidence demonstrating the efficacy of the aprevo Technology Platform. Clinical data publications are important tools for patients and surgeons to educate themselves on what we believe are the clear benefits of the aprevo Technology Platform when compared to traditional spine surgery using stock implants. For example, our COMPASS Registry is generating real-world evidence on the performance and outcomes of the aprevo Technology Platform for use in lumbar spine fusions, and we anticipate that our COMPASS Registry will support a robust cadence of clinical publications. In addition, although the outcomes of our studies cannot be guaranteed, we plan to continue to engage in studies and a registry to further validate the clinical benefits of the aprevo Technology Platform in cervical spine fusion. We believe that our ongoing clinical initiatives will further validate the benefits of the aprevo Technology Platform, drive surgeon adoption, and strengthen our reimbursement profile.
- ***Continue to develop our research and development initiatives***. Our research and development initiatives are focused on introducing enhancements and new capabilities aimed at increasing the value provided by the aprevo Technology Platform to patients, surgeons, and third-party payors. We will continue introducing iterations of our AI-enabled algorithms and software to drive further improvements in our planning. We believe that these improvements will strengthen our ability to leverage the post-operative data we collect to improve our planning process and thus help physicians make better decisions earlier on in treatment. We also believe we can further develop the aprevo Technology Platform to address additional indications and disease states within the spine, such as cervical corpectomy and cervical disc arthroplasty. While spine surgery remains our current focus and we do not currently have a definitive timeline to expand beyond cervical and lumbar at this time, we believe that our platform technology may also benefit other musculoskeletal applications beyond spine.

Market Overview

Spinal Anatomy

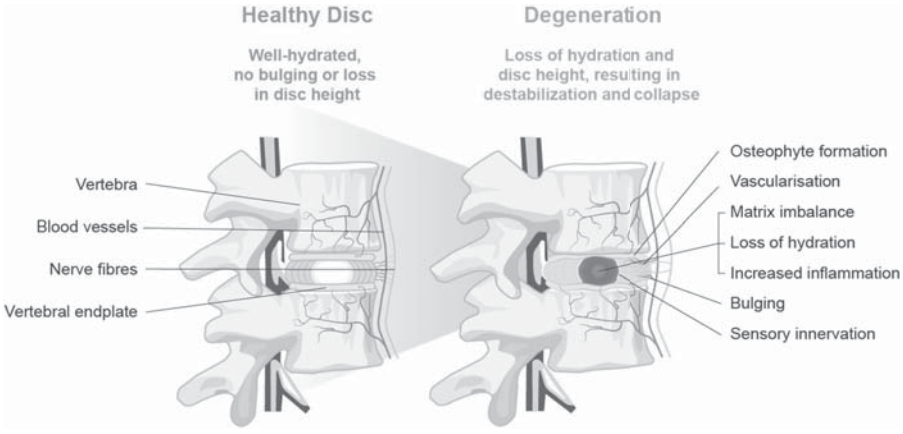
The human spine is a complex and critical structure that provides support, protects the spinal cord, and enables mobility. The spine or spinal column consists of 24 individual bones, or vertebra, and intervertebral discs that are stacked vertically and categorized into distinct regions: cervical (seven vertebrae), thoracic (12 vertebrae), and lumbar (five vertebrae). The vertebral body is the large, cylindrical, weight-bearing portion of a vertebra. The vertebral endplate, which is a thin layer of bone at the upper and lower surfaces of the vertebral body, plays an important role because it facilitates nutrient exchange between the vertebral body and disc. The spinal cord runs the length of the spine and passes through each vertebra; nerves exit the spine through spaces between the vertebra to send and receive signals from the rest of the body.

A fully functional spine is characterized by proper spinal alignment and healthy discs. Proper alignment is essential for stability and effective load distribution, while healthy discs provide mobility and shock absorption. Healthy discs are well-hydrated and have sufficient height to allow for passage of nerves and movement of the spine. Healthy endplates are generally smooth and uniform and may be slightly concave.

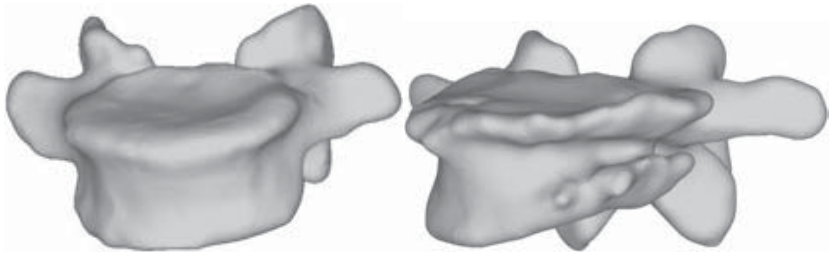


Degenerative Disc Disease

DDD refers to the progressive breakdown of the spinal discs that occurs naturally with age and can be accelerated by factors such as injury, repetitive loading, obesity, or genetic predisposition. DDD can occur in any region of the spine; however, DDD is most prevalent in the lumbar and cervical regions. DDD often causes a loss of disc height and spine function, resulting in compressed nerves and malalignment of the spine. These conditions often lead to chronic pain (nerve impingement, discogenic pain), disability (reduced mobility), and other chronic spinal pathologies, significantly impacting patients' lives. The progression of DDD typically results in worsening symptoms. In its early phase, disc degeneration involves subtle dehydration and minor structural changes, manifesting as discomfort or reduced functionality. These issues can typically be treated with conservative treatment, including physical therapy and pain medication. As the condition progresses, the discs may lose significant height and functionality. Degeneration of the discs may include ruptures, herniation, and may contribute to spinal stenosis (narrowing of the spinal canal). Patients at this phase often experience severe, debilitating pain, and substantial limitations in daily activities. These symptoms may force the patient to consider surgical solutions such as spine fusion to improve stability, restore function, and alleviate symptoms. The image below depicts an example of a healthy disc versus a degenerated disc.



Disc degeneration can lead to mechanical stress and damage to the endplates, making the endplate surfaces uneven and coarse. In turn, endplate defects can impair nutrient supply and accelerate disc degeneration, creating a vicious cycle that further contributes to spinal pathology and pain. One study demonstrated the correlation between disc degeneration and vertebral endplate surface irregularities or defects, with an increasing percentage of endplates, up to 48.9%, with disc degeneration exhibiting surface irregularities or defects from the upper spine to lower spine. The below 3D models depict two vertebral bodies from the same patient. The vertebral body on the left has a smooth surface, and the patient's intervertebral disc at this level is healthy. The vertebral body on the right is from a level in which degeneration has caused endplate irregularities and defects.



If multiple sections and levels of the spine are impacted by DDD, the patient may experience systematic structural abnormalities of the spine, which is broadly referred to as ASD. ASD is often characterized by conditions such as scoliosis (curvature of the spine) or spondylolisthesis (slipping of one vertebra relative to another).

We believe that the prevalence of DDD has significantly increased in recent years due to multiple demographic factors, including an aging population and heightened obesity levels. Low back pain, which is strongly connected to the degenerative process of the intervertebral disc, is the fifth most common cause for doctor visits and affects 7.6% to 37% of patients according to a published literature review. One study estimated that the overall prevalence of patients diagnosed with DDD to be over 27% and increased with age.

Current Treatment Landscape

The treatment landscape for DDD spans a continuum of non-surgical and surgical interventions, each addressing different phases of disease progression and patient needs.

Non-Surgical Intervention

Non-surgical interventions are typically the first line of treatment for DDD, aimed at managing symptoms and slowing disease progression without invasive procedures. These approaches typically include physical therapy, pain medications, lifestyle modifications, and alternative therapies, such as chiropractic care or acupuncture. Despite their use, non-surgical approaches have notable shortcomings. They primarily address symptoms rather than the underlying structural degeneration. As degeneration progresses, the loss of disc height and joint stability may become irreversible, requiring surgical intervention.

Surgical Intervention

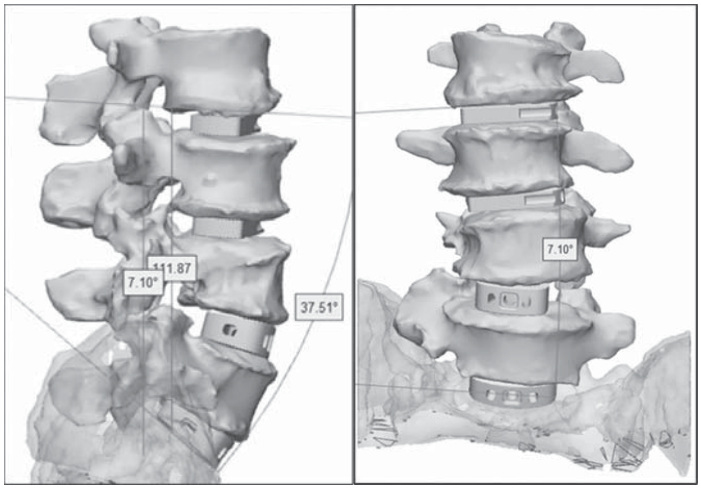
When non-surgical treatments fail to alleviate debilitating symptoms or disabilities, surgical interventions may become necessary.

The most common surgical intervention and current standard of care is traditional spine fusion. The goals of spine fusion surgery are to relieve pain, improve disability, restore function, and provide a durable solution to prevent the need for subsequent surgeries to achieve positive long-term patient outcomes. During the surgery, the degenerated disc is extracted and replaced with an interbody implant made of titanium, polymer, or bone allograft. Prior to placement, the center of the interbody implant is packed with bone graft material. The role of the interbody device is to restore height (allowing the nerves to exit the canal without being impinged), establish spinal alignment (based on the needs of each patient), and stabilize the spinal segment in the desired position while the graft material promotes bone growth between the two vertebral bodies to form a solid fusion. In most instances, the interbody implants are supplemented with additional fixation devices such as rods, screws, and plates to provide added stabilization. Traditional spine fusion is performed using 2D imaging for pre-operative planning and stock implants that are largely fixed in size and shape.

Left to right: images of titanium, polymer, and bone allograft interbody devices.

In lumbar fusion, surgeons may employ various anatomical approaches to access the disc space, including from the front (anterior lumbar interbody fusion (“ALIF”)), from the side (lateral lumbar interbody fusion (“LLIF”)), and from the back (transforaminal interbody fusion), depending on the patient’s pathology and vertebral bone topography. In cervical fusion, the most common anatomical approach is through the front of the neck (anterior cervical discectomy and fusion (“ACDF”)).

The alignment of the spine following surgery is critically important. Proper alignment of the spine must be considered in three dimensions, which involves coronal correction (correcting side-to-side curvature), sagittal correction (correcting front-to-back curvature), and axial correction (height restoration). If the spine is, or becomes, malaligned, as often measured by missing a desired angle by as little as 11 degrees, the patient will likely continue to have symptoms or require additional surgeries. Studies have shown a strong association between spinal malalignment and the degeneration of adjacent spinal segments (adjacent segment disease), and there is a higher risk of undergoing revision surgery if proper sagittal alignment is not achieved during the primary surgery. The achieved alignment at each treated level can have a profound impact on overall alignment and the risk of needing additional surgery.



Limitations of Traditional Spine Fusion

Despite wide adoption, we believe traditional spine fusion is hindered by several shortcomings, which may contribute to poor clinical outcomes post-surgery. These poor outcomes not only meaningfully impair patients' health and quality of life but also impose a significant economic burden on the healthcare system, with the direct and indirect costs of a single revision surgery frequently exceeding $100,000.

We believe that traditional spine fusion is limited in several ways, including:

- ***Lack of Sufficient Pre-Operative Planning***: Traditional spine fusion often lacks robust pre-operative planning, relying on 2D imaging without advanced tools such as 3D modeling. This can limit the surgeons' ability to identify and develop a plan for achieving optimal correction and alignment goals.
- ***Poor Fit of Stock Interbody Implants***: Stock implants are delivered to surgery in a large metal tray containing dozens of interbody implants of different shapes and sizes. Stock implants are largely symmetrical in shape and come in pre-defined dimensions, which can fail to match the unique anatomy of each patient and lead to unpredictable alignment. As a result, stock implants may not deliver proper alignment or correct coronal (side to side) imbalance of the spine. The lack of proper fit and correction often results in uneven loading and unpredictable alignment. The graphic below depicts the poor fit of a stock implant to endplates with damaged and uneven surfaces.

- ***Complicated and Time-Consuming Workflow***: Given the limitations of 2D imaging, during the surgery, surgeons must visually choose the correct stock implant from dozens of options while the patient is anesthetized and with the spine exposed. This approach often requires the surgeon to test the fit of multiple implants in the disc space, which involves multiple passes of instruments into and out of the wound and repeated X-ray imaging. This trial process can prolong surgery time and increase radiation exposure, which elevates the risk of secondary complications.
- ***Lack of Post-Operative Feedback Incorporation into Future Decision Making***: Without a sufficient pre-operative plan, it can be difficult for surgeons to reconcile achieved outcomes against surgical objectives. Reconciling post-operative data can provide valuable insights into whether the optimal alignment of the spine was successfully achieved. However, in traditional spine fusion, there is no integrated means for reconciling the data and communicating these insights back to surgeons. As a result, critical insights cannot be incorporated into future surgical plans that could help to improve surgical outcomes.
- ***Burdensome Inventory Management***: Due to the uniform nature of stock implants, traditional spine fusion requires multiple trays of devices. This can result in an unnecessary, upfront investment from the manufacturers to ensure that there is adequate and properly sterilized inventory on hand for every spine fusion procedure. As a result, we believe that current medical device manufacturers struggle to reach profitability because they must produce stock implants in dozens of sizes and as a result hold large amounts of inventory to address the broad array of patient needs. In addition, stock implants are not delivered sterile to hospitals and ambulatory surgical centers, requiring additional processing and resulting in additional expenses for each.

We believe that these limitations explain why traditional spine fusion procedures can fail to achieve the desired alignment, which often leads to post-operative complications and revision surgery, as discussed below.

- ***High Rates of Malalignment***: Malalignment following spine fusion surgery is a leading cause of poor outcomes, often resulting in complications and revision surgery. Proper spinal alignment is often not achieved following the traditional spine fusion procedure and, according to numerous published studies, post-operative alignment with stock implants is unpredictable. One analysis has shown that 62% of ASD patients remain sagittally malaligned and 25% remain coronally malaligned after traditional spine fusion surgeries. A study of 578 DDD patients that received one- to two-level fusions using stock implants showed that of the 173 patients that were malaligned pre-operatively, only 29% were corrected to normal alignment through surgery. A second study of 335 patients observed that, of 285 patients that were pre-operatively malaligned, only 10% were corrected to normal alignment through spine fusion surgery with stock implants. A third study of 149 DDD patients that received spine fusion surgery using stock implants observed that patients who were malaligned pre-operatively generally had worsened alignment after surgery.
- ***Frequent Complications***: Spine fusion procedures using stock implants can lead to malalignment, which may cause several complications, including penetration of the interbody implant through the vertebral endplate into the vertebral body (subsidence), degeneration of adjacent spinal segments (adjacent segment disease), and mechanical complications, which include implant breakage, pseudoarthrosis (failure of the bone to fuse), and the development of malalignment/kyphosis (abnormal alignment) elsewhere in the spine. A systematic review of 40 articles reporting results on lumbar fusion procedures with stock implants in a mix of both DDD and ASD patients showed that subsidence occurred in 13% to 27% of patients. In a study of 997 ASD patients that received spine fusion surgery using stock implants, implant-related mechanical complications were the most common complications, affecting 28% of patients by two years post-operatively. Another study of 138 ASD patients that underwent spine fusion surgery using stock implants observed a similar rate of implant-related mechanical complications of 30% at two years and increasing to 56% at five years. Other published studies have also identified a strong association between spinal malalignment and the development of adjacent level pathology in DDD patients that receive spine fusion surgery using stock implants.

- ***Increased Likelihood of Revision Surgery***: Post-operative malalignment and the resulting complications significantly increase the likelihood of undergoing revision surgery. Recent publications on traditional spine fusions report rates of revision surgery for mechanical complications between 14% and 32% over a mean postoperative period of one to two years in ASD patients. Other published studies have observed revision rates ranging from 29.5% to 50% in ASD patients receiving spine fusion surgery using stock implants by four-years follow-up. Research has shown that ASD patients requiring revision surgery due to poor alignment suffer from persistent disability and are 93% less likely to achieve meaningful benefit from surgery. One study examined the revision rate in DDD patients in whom abnormal sagittal alignment was not corrected and found that these patients had 19.4% revision rate by 1-year after surgery. Another study of 335 DDD patients showed that 285 (85%) of patients had abnormal sagittal alignment preoperatively and only 28 (10%) were corrected through their surgery. Among the 257 patients having abnormal sagittal alignment after surgery, the revision rate was 20.2% with a mean follow-up of 6.5 years. This revision rate was significantly higher than the 7.7% revision rate among patients in whom abnormal sagittal alignment was corrected, 20.2% vs. 7.7% (p=0.0103). Repeat revision surgeries, each requiring six to 12 months of recovery, can compromise patients' health and quality of life, and represent a burdensome and avoidable cost to the healthcare system.

Our Addressable Market Opportunity

Given the limitations of traditional spine fusion surgery, we believe that DDD presents a significant unmet clinical need and economic burden to the healthcare system. We believe that the aprevo Technology Platform effectively addresses the underlying issues in this large, established market by providing personalized surgical plans, patient-specific spine implants, and holistic post-operative feedback.

Our initial focus has been on the lumbar fusion market for which the aprevo Technology Platform is FDA 510(k) cleared for all lumbar levels. We estimate our total addressable market opportunity for lumbar fusion procedures to be approximately $13.4 billion. This figure is based on our estimate (informed by projections contained in the SmartTRAK Report) that 445,200 lumbar fusion surgeries were performed in the United States in 2025, and the average revenue per lumbar procedure.

We have also developed and recently begun to commercialize our aprevo Technology Platform for use in cervical fusion procedures, after having received FDA 510(k) clearance for our aprevo interbody implants for cervical interbody fusion surgeries in November 2024. We have generated limited early sales of aprevo interbody implants for use in cervical spine fusion surgery in 2025 and expect to more broadly commercialize our cervical platform in 2026. We estimate our total addressable market opportunity for cervical fusion procedures to be approximately $6 billion. This figure is based on our estimate (informed by projections contained in the SmartTRAK Report) that 372,600 cervical fusion surgeries were performed in the United States in 2025, and the average selling price for our cervical fusion implants.

Total addressable market for our aprevo lumbar and cervical devices is calculated based on the total overall revenue opportunity that we believe is available if we achieve 100% market share for lumbar fusion surgeries and cervical fusion surgeries in the United States and is not a representation that we will achieve such market share. The market share we achieve is subject to a number of assumptions, risks and uncertainties, which could fluctuate from time to time. See the risk factor titled "*The size and expected growth of our total addressable market has not been established with precision and may be smaller than we estimate*."

Given the global prevalence of spine fusion procedures, we believe that a significant market opportunity also exists for the aprevo Technology Platform in international markets. We also plan to develop the aprevo Technology Platform to address additional indications and spinal disease states and may target cervical corpectomy and cervical disc arthroplasty solutions. While spine surgery remains our current focus, and we do not currently have a definitive timeline to expand beyond cervical and lumbar at this time, we believe that our platform technology may also benefit other musculoskeletal applications beyond the spine, unlocking greater market potential.

Our Solution

The aprevo Technology Platform represents an end-to-end, integrated digital technology platform designed to deliver better surgical results, reduce the need for revision surgery, and improve long-term outcomes. Our aprevo Technology Platform is the first available solution to provide personalized digital surgical plans and the accompanying aprevo interbody implants that are tailored to each patient's pathology and vertebral bone topography.

Our pre-operative planning software utilizes standard-of-care diagnostic imaging and AI-enabled algorithms to develop personalized digital surgical plans and to design aprevo interbody implants for each patient's pathology and vertebral bone topography. Additionally, the aprevo Technology Platform supports the collection of real-world, post-operative data to inform our digital surgical planning process. The aprevo Technology Platform is commercially available in the United States and is indicated for use in lumbar and cervical interbody fusion procedures.

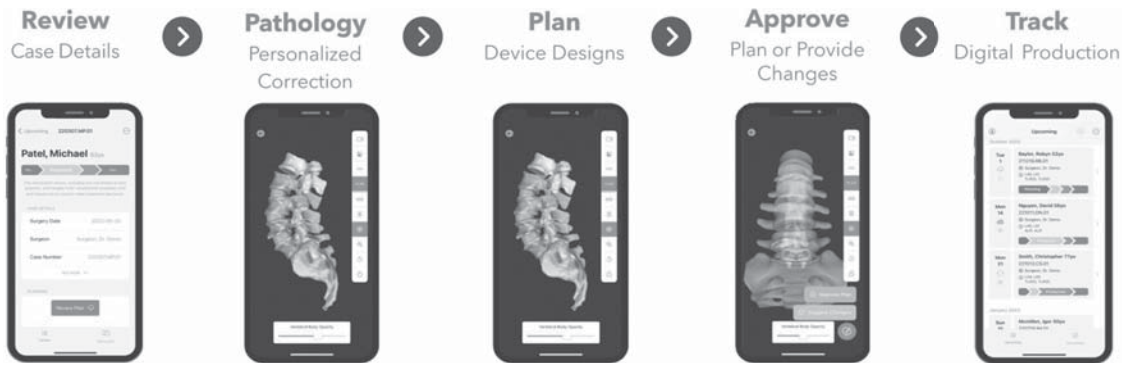
Our Data Asset and Correction AI-Enabled Algorithms

Our aprevo Technology Platform supports our collection of pre- and post-operative data from each patient and utilizes this data to improve our digital surgical planning process. Through our extensive database of radiographic images, we have developed proprietary AI-enabled algorithms to create personalized digital surgical plans for spine surgery. As of December 31, 2025, we estimate that we have used approximately four million de-identified radiographic images to train our AI models, analyzed more than one million radiographic images of aprevo patients, and created more than 40,000 3D PSMs of patients' anatomies. We use clinical and post-operative data to refine personalized surgical planning, implant design, and physician workflow, supporting our research and development efforts, intellectual property portfolio, and product pipeline.

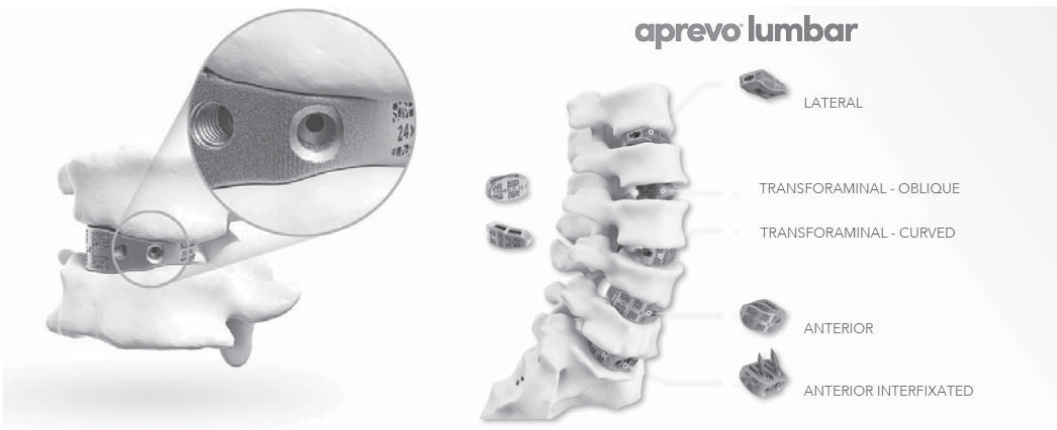
The aprevo Technology Platform and Procedure Surgical Workflow

The aprevo Technology Platform offers solutions for the entire surgical workflow, including pre-operative AI-enabled, surgical planning and post-operative data collection and insights for each surgeon. The following describes this workflow:

- *Pre-Operative*. A procedure using the aprevo Technology Platform begins with designing a personalized digital surgical plan for each patient. Utilizing standard-of-care diagnostic imaging, our proprietary AI-enabled software renders a 3D PSM of the patient's anatomy, including their pathology and vertebral bone topography. The PSM is then virtually manipulated to place the patient's vertebral bodies into the appropriate 3D alignment; this creates a new intervertebral space that we then map to create aprevo interbody implants. This process results in a personalized digital surgical plan and aprevo interbody implants that are designed to match the irregular surfaces of each patient's vertebral bone topography to provide the targeted alignment. We interact with the surgeon during the pre-operating planning process through our myaprevo application (available via mobile device or desktop). The myaprevo application is a digital tool used to display the personalized digital surgical plan and associated metrics that define the desired correction and alignment. The myaprevo application provides interactive 3D visualizations that the surgeon may share with the patient. Each patient's personalized digital surgical plan and aprevo interbody implants are visualized, reviewed, and approved through the myaprevo application.



- *Intra-Operative*. The proposed personalized digital surgical plan and aprevo interbody implant designs are approved by the surgeon, including the exact implant dimensions, the desired position on the endplate, and their preferred surgical approach. Our patient-specific aprevo interbody implants are then 3D-printed by our CMOs. Our aprevo interbody implants are made of medical-grade titanium and designed with a lattice to promote fusion. Our streamlined DPS allows us to deliver aprevo interbody implants to our customers within six business days of surgical plan approval. The implants are delivered to the operating room in a sterile kit along with single-use surgical instruments. In the operating room, our myaprevo application provides the surgeon and the operating staff with access to the personalized digital surgical plan that aids in the ability to accurately place aprevo interbody implants and predictably achieve the surgical plan.



- *Post-Operative*. Following the spine fusion surgery, we collect each patient's operative and post-operative radiographs. The patient's imaging data is measured and analyzed, and a detailed case report, branded as "aprevo intelligence," is generated. The aprevo intelligence report shows pre-operative, planned, and post-operative alignment parameters. Surgeons can access comprehensive analytics for each surgery, providing the ability to conduct in-depth review and analysis of the surgical outcome against the operative goals. By leveraging the aprevo intelligence reports and post-operative insights, our planning process can be improved to the benefit of future patients.

Data Insights
Patient Analysis

- Using personalized analysis, data from prior cases is used to aid and inform the planning process to enable continuous learning and increased reproducibility.
- Case series reports are presented to surgeons to review preoperative plans and radiographic outcomes.

Key Benefits of the aprevo Technology Platform

We designed the aprevo Technology Platform to address the shortcomings of traditional spine fusion surgery using stock implants. The benefits demonstrated by the aprevo Technology Platform include:

- ***Improved alignment and decreased risk of revision spine surgery***. Post-operative spinal malalignment has been shown to have the greatest negative impact on clinical outcomes in spine fusion surgery. Achieving the necessary alignment to address a patient's condition and improve the chances of a successful outcome requires careful planning and precise execution. The aprevo Technology Platform provides 3D anatomical correction, incorporating coronal alignment, sagittal alignment, and height restoration to help surgeons achieve their planned alignment targets. A large body of evidence supports the clinical benefits of the aprevo Technology Platform for spine fusion, including eight peer-reviewed clinical data publications and 20 peer-reviewed clinical data abstracts. Across the various studies and publications, the aprevo Technology Platform has shown favorable results in two of the most critical success measures in spine fusion surgery: (1) achieving proper post-operative alignment and (2) significantly reducing the need for revision surgery due to implant related complications. We continue to develop our growing base of clinical and patient reported outcomes to serve as evidence of the aprevo Technology Platform's value to all key stakeholders, including patients, clinicians, customers, and payors. For example, we are currently conducting a 338-patient study, our COMPASS Registry, to track clinical outcomes from lumbar procedures using the aprevo Technology Platform in both DDD and ASD patients. Based on interim data from the first 67 ASD patients in our COMPASS Registry, these patients demonstrated improved alignment and reduced mechanical complications post-operatively, with a revision rate of 1.5% at one-year follow-up that were attributable to mechanical complication–related reoperations unrelated to the aprevo interbody implant. A December 2025 publication in the Global Spine Journal reported two-year follow-up data on a retrospective cohort of ASD patients treated with aprevo, comparing the rate of mechanical complication-related reoperations at two years among such patients to the reoperation rate among patients who had been treated using stock implants. The study demonstrated a significantly reduced rate of mechanical complication–related reoperations in the aprevo cohort as compared to the patients who had been treated using stock implants. Patients treated with aprevo had a reoperation rate at two years of 4.3% (n=115) as compared to a two-year reoperation rate of 16.6% (n=997) for patients who had been treated using stock devices ($p<0.001$), representing a 74% relative reduction. The study authors noted that the reoperation rate in the selected comparator was relatively low, as these patients were treated by highly experienced and renowned surgeons. When factoring in three other published studies that were noted in the paper, the average two-year revision rate due to mechanical complications was 24.9%, making the comparative reoperation rate with aprevo even more meaningful. In addition, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of DLL with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up. Other studies have shown patients with unrestored DLL have experienced a 25.9% revision rate for adjacent segment degeneration at minimum two-years follow-up. Separate studies have shown that approximately 40%-80% of short fusion patients present with a low DLL preoperatively. We attribute these results to the improved alignment observed in patients receiving the aprevo Technology Platform.
- ***Outcomes-driven pre-operative planning and post-operative insights***. Our pre-operative, 3D modeling, and AI-enabled algorithms informed by large amounts of data help surgeons plan the surgery that fits with a patient's unique pathology and anatomy. Following the procedure, the patient's post-operative images and outcome data are measured and analyzed to inform results against the surgical plan. These post-operative insights allow surgeons to reconcile their plan against the surgical results. As such, their preferences and objectives can be fine-tuned, which streamlines the planning process in future patient cases and further enhances precision and performance of future surgeries. An aprevo intelligence report containing a dashboard and details showing the surgical outcomes as measured against personalized surgical plans is provided to the surgeon. Our aprevo Technology Platform not only enables direct feedback to the surgeon, but it also collects data that is used to improve our surgical planning process.

- ***Seamless integration and improvement of existing surgical workflows***. The use of the aprevo Technology Platform integrates with, and can improve upon, existing surgical workflow. The aprevo Technology Platform does not require any additional or supplemental pre-surgical imaging beyond what is required for traditional spine fusion surgery. The surgeon can use their preferred surgical access approach and methods as they would with a stock implant without any additional surgical training. Our aprevo interbody implants are compatible with commercially available surgical robots and other accompanying implants, such as rods, screws, and plates. We believe this allows for ease of adoption and integration into the surgeon's workflow and preferences and enables surgeon user acquisition and account penetration. As an improvement to the surgical workflow, the surgeon does not need to test fit various interbody sizes during the surgery while the patient is under anesthesia and the spine is exposed. Instead, the surgeon can deliver the aprevo interbody implant to each planned vertebral level without any trialing required.
- ***On-demand, made-to-order inventory model with short lead times***. Our aprevo interbody implants are manufactured on demand by our CMOs and are specific to each patient, their pathology, and vertebral bone topography. This allows us to maintain a capital-efficient inventory model. Unlike stock implants, our patient-specific aprevo interbody implants and accompanying single-use surgical instruments are delivered sterile to our customers typically within six business days of surgical plan approval. Our surgical kits do not require additional processing at the hospital or ambulatory surgical centers, which eliminates additional expenses for each. Since our aprevo interbody implants and accompanying insertion instruments are made on-demand by our CMOs for each patient, we are able to operate an asset-light business model, requiring limited investments in capital equipment and inventory.

Our 510(k) Submissions

The following table sets forth our 510(k) submissions for our material products and product candidates:

Submission	Device Name	Class	Status
K252894	aprevo Cervical implant specification expansion	II	Cleared
K252611	corra cervical plating system	II	Cleared
K250987	aprevo TLIF	II	Cleared
K250827	aprevo lumbar and cervical devices	II	Cleared
K243802	aprevo anterior and lateral lumbar interbody fusion device, aprevo anterior lumbar interbody fusion device with interfixation	II	Cleared
K242599	aprevo Digital Planning	II	Cleared
K243635	aprevo anterior lumbar interbody fusion device with interfixation	II	Cleared
K242260	aprevo Cervical ACDF; aprevo Cervical ACDF-X; aprevo Cervical ACDF-X NO CAM	II	Cleared
K241477	aprevo anterior lumbar interbody fusion device with interfixation	II	Cleared
K241332	aprevo anterior and lateral lumbar interbody fusion device; aprevo anterior lumbar interbody fusion devices with interfixation; aprevo transforaminal lumbar interbody fusion device	II	Cleared
K241328	aprevo Anterior and Lateral Lumbar Interbody Fusion device (ALIF/LLIF); aprevo Transforaminal Lumbar Interbody Fusion device (TLIF); aprevo Anterior Lumbar Interbody Fusion device with Interfixation (ALIF-X)	II	Cleared
K241019	aprevo TLIF-C Articulating System	II	Cleared

Submission	Device Name	Class	Status
K232282	aprevo anterior and lateral lumbar interbody fusion device, aprevo transforaminal lumbar interbody fusion device	II	Cleared
K231955	aprevo Digital Segmentation	II	Cleared
K231140	aprevo transforaminal lumbar interbody fusion device	II	Cleared
K222195	aprevo Digital Workflow	II	Cleared
K222009	aprevo anterior lumbar interbody fusion device with interfixation	II	Cleared
K222082	aprevo anterior and lateral lumbar interbody fusion devices, aprevo transforaminal lumbar interbody fusion devices	II	Cleared
K210542	aprevo Transforaminal IBF	II	Cleared
K202034	aprevo Intervertebral Body Fusion Device	II	Cleared

Our Clinical Results and Studies

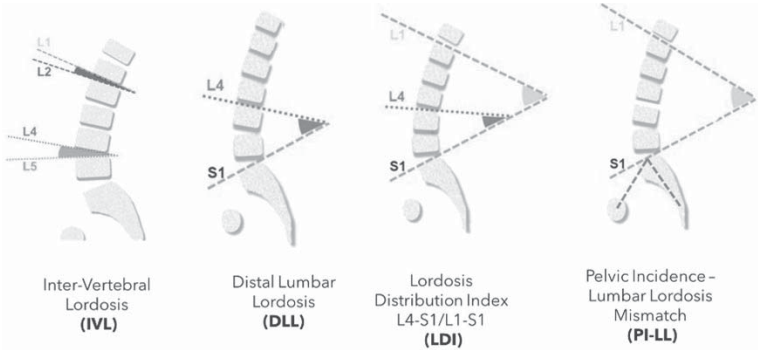
A large body of evidence supports the clinical benefits of the aprevo Technology Platform for spine fusion, including eight peer-reviewed clinical data publications and 20 peer-reviewed clinical data abstracts. We are committed to continuing to develop a strong base of clinical evidence and real-world patient outcomes to further support the aprevo Technology Platform's clinical benefits. We believe that these efforts will help continue to generate a robust cadence of publications, increase awareness of the aprevo Technology Platform and drive commercial adoption.

Across the various studies and publications, the aprevo Technology Platform has shown favorable results in three of the most critical success measures in spine fusion surgery: improved post-operative alignment, improved disc space biomechanics, and reduced need for revision surgery due to implant-related complications.

Improved and More Predictable Post-Operative Alignment. Proper spinal alignment is crucial in spine surgery to achieve optimal patient outcomes, minimize complications, and improve long-term function. In a cohort study of 762 ASD patients, the authors concluded that poor post-operative alignment has the greatest impact on clinical outcomes in ASD patients. Research further indicates that if the spine is, or becomes, malaligned, the patient will likely continue to have symptoms or require revision surgery. The primary measures for evaluating post-operative lumbar spinal alignment include:

- intervertebral lordosis (“IVL”), which measures the angles between the endplates of two adjacent vertebrae;
- DLL, which measures the angle between the upper endplate of the L4 vertebral body and the S1 sacral endplate, which is the upper surface of the first sacral vertebra (“S1”);
- lordosis distribution index (“LDI”), which is defined as the ratio of lower lumbar lordosis (“L4-S1”) to the total lumbar lordosis; and
- pelvic incidence minus lumbar lordosis (“PI-LL mismatch”), which assesses the relationship between pelvic incidence (“PI”), which is the orientation of the pelvis, and lumbar lordosis (“LL”), which describes the curvature of the lower spine.

The following diagram depicts each of these measures:



Several studies have found that procedures using the aprevo Technology Platform can achieve favorable post-operative alignment in short and long construct cases. For example:

- IVL: In a study of 217 patients with ASD or DDD treated with an aprevo interbody implant at one or more levels, 82% of lumbar levels treated (n = 365 implants) achieved IVL alignment within five degrees of target, and 97% of lumbar levels treated achieved IVL alignment within 10 degrees of target. In another published clinical study using stock implants, the authors found no differences in the amount of lumbar lordosis between patients receiving stock interbody devices with an off-the-shelf angle of six degrees versus patients who received stock interbody devices with an off-the-shelf angle of 20 degrees, demonstrating the unpredictability of alignment achieved with stock devices.
- DLL: A study of 72 DDD patients showed that 45% of patients with low DLL (33 of 72 patients) were restored to a normal DLL range after receiving an aprevo interbody implant.The authors of this study compared their results to those reported in a separate study of 335 patients that received stock implants. They noted that, in the other study, correction of low DLL to normal DLL was achieved in only 10% of patients, with the uncorrected patients having 20.2% incidence of revision surgery at a mean follow-up of 6.5 years.
- LDI: In a study of 111 DDD patients, hypolordotic patients (those patients with a reduced or absent inward curve with LDI less than 50%; n=14) treated with an aprevo interbody implant achieved statistically significant improvement in LDI post-operatively. The mean post-operative LDI among these hypolordotic patients was 46%, approaching the normal LDI range (LDI 50-80%). In this study, hyperlordotic patients (those patients with excessive inward curve with LDI greater than 80%; n = 16) had a decrease in LDI trending toward the normal range; however, this decrease did not reach statistical significance. The authors of this study compared their results to those presented in a separate study of 149 DDD patients receiving stock implants and noted that the hypolordotic LDI patients (n = 36) in the other study tended to continue to have abnormally low LDI levels post-operatively and actually worsened as a group. The authors cited multiple studies showing that patients with a post-operative hypolordotic distribution present a greater risk of developing adjacent segment degeneration and are more likely to require revision surgery.

- PI-LL: In a multicenter study of 65 ASD patients receiving an aprevo interbody implant, 44.6% of patients achieved targeted PI-LL within five degrees, and only 15.3% of patients missed targeted PI-LL by greater than 15 degrees. The authors of this study compared their results to those presented in a report from the International Spine Study Group ("ISSG") in a cohort of 266 patients with ASD that received stock implants. The authors noted that, compared with the ISSG cohort, utilization of aprevo interbody implants resulted in significant improvement in achieving PI-LL target within five degrees of the pre-operative plan (44.6% vs. 31.5%, P = 0.046). Furthermore, compared to ISSG cases, utilization of aprevo interbody implants led to a significant reduction in cases in which the PI-LL target was missed by greater than 15 degrees (15.3% vs. 30.8%, P = 0.012). In another multicenter study of 135 DDD patients, among patients who were pre-operatively malaligned, alignment was restored (PI-LL restored to less than 10 degrees) in 44% of the patients (23 of 52 patients) when an aprevo interbody implant was used. The authors of this study compared their results to a multicenter study of 578 patients that received stock implants, where only 29% of pre-operatively malaligned patients experienced PI-LL restoration using stock implants. The authors found that the results using aprevo interbody implants to represent a statistically significant improvement compared with stock implants.

Improved Disc Space Biomechanics. In addition to providing the necessary alignment, interbody fusion devices play a central role in restoring and stabilizing the biomechanics of the disc space. However, the incongruity between an irregularly shaped vertebral endplate and the uniform surfaces of a stock interbody fusion device can create point contact between the interbody device and the endplate, causing uneven load distribution which can lead to implant subsidence or pseudarthrosis. Subsidence of the implant occurs when the interbody device penetrates the vertebral endplate and intrudes into the vertebral body during the post-operative healing process. In these situations, alignment may be altered, and height restoration may be reduced or lost leading to the recurrence of pain. Pseudoarthrosis, which is a failure of the bone graft to fuse the two vertebral bodies into a single unit, can occur if the load on the bone graft is not evenly distributed across the disc space. After a period of time, the failure to achieve a fusion also alters the biomechanics of the disc space and this is most typically manifested by a mechanical failure elsewhere, such as a rod fracture. The goal of the endplate matched design of the aprevo interbody device is to increase the contact area between the irregular surface of the vertebral endplate to distribute loads more evenly across the disc space including loading of the bone graft. Unfortunately, an assessment of contact area across a three-dimensional endplate cannot be performed with conventional 2-dimensional X-rays, rather, a 3D analysis from a post-operative CT is required. Because a CT exposes the patient to harmful radiation, this type of post-operative imaging is relatively infrequent. However, in some situations, post-operative CTs are the standard of care, and these provide a rare and valuable opportunity to analyze endplate to implant contact, as well as assess the occurrence of subsidence and pseudoarthrosis. In a study using one-year post-operative CT imaging to evaluate the implant-endplate contact area, subsidence and fusion in a series of 15 patients receiving 24 aprevo interbody implants, the implant-endplate contact area ratio was determined to be 93.9%, fusion was visible in 100% of levels and 95.8% of levels were free of subsidence. The authors concluded that aprevo interbody implants can provide nearly complete contact with endplate surfaces regardless of the individual endplate morphology, noting that this may contribute to improved interbody fusion rates, less subsidence, maintenance of alignment, and potentially decreased risk of implant-related complications.

Reduced Likelihood of Revision Surgery. Achieving optimal alignment has been shown to prevent mechanical complications and reduce the need for revision surgery, significantly improving patient quality of life. Based on interim data from the first 67 ASD patients in our COMPASS Registry, these patients demonstrated improved alignment and reduced mechanical complications post-operatively, with a revision rate of 1.5% at one-year follow-up that were attributable to mechanical complication–related reoperations unrelated to the aprevo interbody implant. A December 2025 publication in the Global Spine Journal reported two-year follow-up data on a retrospective cohort of ASD patients treated with aprevo, comparing the rate of mechanical complication-related reoperations at two years among such patients to the reoperation rate among patients who had been treated using stock implants. The study demonstrated a significantly reduced rate of mechanical complication–related reoperations in the aprevo cohort as compared to the patients who had been treated using stock implants. Patients treated with aprevo had a reoperation rate at two years of 4.3% (n=115) as compared to a two-year reoperation rate of 16.6% (n=997) for patients who had been treated using stock devices ($p<0.001$), representing a 74% relative reduction. The study authors noted that the reoperation rate in the selected comparator was relatively low, as these patients were treated by highly experienced and renowned surgeons. When factoring in three other published studies that were noted in the paper, the average two-year revision rate due to mechanical complications was 24.9%, making the making the comparative reoperation rate with aprevo even more meaningful. In addition, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of DLL with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up. Other studies have shown patients with unrestored DLL have experienced a 25.9% revision rate for adjacent segment degeneration at minimum two-years follow-up. Separate studies have shown that approximately 40%-80% of short fusion patients present with a low DLL preoperatively.

COMPASS Registry

The COMPASS Registry is an observational, prospective registry designed to collect and evaluate data on patients with degenerative spinal conditions for a period of two years following lumbar surgery using the aprevo Technology Platform. We completed enrollment of 338 patients across 16 centers in the United States in the fourth quarter of 2024 and anticipate complete data to be released in the first half of 2027.

Eligible patients were required to meet inclusion criteria specified for the registry. Generally, patients must be adults who have been diagnosed with a degenerative condition of the lumbar spine that is appropriately treated with a lumbar fusion, and a clinical decision must have been made to use the aprevo Technology Platform in their spine fusion surgery prior to enrollment in the COMPASS Registry. The procedure must include placement of one or more aprevo interbody implants using an anterior, lateral, oblique, or transforaminal approach between the L1 and S1 vertebra. Patients are excluded if they have limited life expectancy for the study duration, have a known allergy to implant materials, are pregnant or intend to be, have an infection or inflammation, or have morbid obesity.

Patients are evaluated at the post-operative time points of six weeks, six months, one year and two years. The primary outcome measures include alignment, complications, and revisions, and the secondary outcome measures are Patient-Reported Outcome Measures to assess pain, function, treatment satisfaction, and quality of life.

- Interim results from the first 67 ASD patients in our COMPASS Registry, from nine centers at 12-week to one-year follow-up with a mean follow-up time of 14.7 months, have been published. Overall, the results demonstrated that ASD patients who were treated with the aprevo Technology Platform obtained favorable post-operative alignment status, with no complications related to the aprevo interbody implant, and low revision rates. Among 44 patients with pre-operative severe overall deformity (based on a combined score of three alignment parameters) 16 improved to moderate deformity and nine to mild deformity. The percentage of patients starting in the severe PI-LL category was reduced from 55% pre-operatively to 12% post-operatively, with 38% improving from pre-operative moderate or severe PI-LL to a PI-LL of zero. Early complications requiring revision surgery consisted of two reoperations for screw malposition within 90 days (unrelated to the aprevo interbody implant). Between 90 days and one year, there was one revision surgery at nine months post-operatively due to proximal junctional kyphosis. This represents a revision rate of 1.5% attributable to a mechanical complication not related to the aprevo interbody implant and the authors of this study noted that this compares favorably to recent publications on traditional spine fusions reporting rates of revision surgery for mechanical complications between 14% and 32% over a mean postoperative period of two years in ASD patients. A December 2025 publication in the Global Spine Journal reported two-year follow up data on a retrospective cohort of ASD patients treated with aprevo, comparing the rate of mechanical complication-related reoperations at two years among such patients to the reoperation rate among patients who had been treated using stock implants. The study demonstrated a significant reduced rate of mechanical complication-related reoperations in the aprevo cohort as compared to patents who had been treated using stock implants. Patients treated with aprevo had a reoperation rate at two years of 4.3% (n=115) as compared to a two-year reoperation rate of 16.6% (n=997) for patients who had been treated using stock devices ($p<0.001$), representing a 74% relative reduction. The study authors noted that the reoperation rate in the selected comparator was relatively low, as these patients were treated with highly experienced and renowned surgeons. When factoring in three other published studies that were noted in the paper, the average two-year revision rate due to the mechanical complications was 24.9% making the comparative reoperation rate associated with aprevo even more meaningful. In addition, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of DLL with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up Other studies have shown patients with unrestored DLL have experienced a 25.9% revision rate for adjacent segment degeneration at minimum two-years follow-up. Separate studies have shown that approximately 40%-80% of short fusion patients present with a low DLL preoperatively.

As of January 2026, there are 324 patients from 16 centers enrolled in the Carlsmed-sponsored COMPASS Registry. The study cohort consists of 181 patients (56%) treated for DDD and 143 patients (44%) treated for ASD. All 324 patients have passed their one-year postoperative milestone, and 216 patients are more than two years postoperative. Among the 324 patients, 11 patients (3.3%) underwent revision surgeries for adjacent segment disease or mechanical complications. Eight of these revisions occurred within the 6-week to 1-year postoperative period and 3 occurred within the 1- to 2- year postoperative period. Among the 181 DDD patients there were 4 such revisions (2.2%) including one for pseudoarthrosis with infection and three for adjacent segment disease. Among the 143 ASD patients there were 7 revisions (4.9%) including one for adjacent segment disease and 6 for proximal junctional kyphosis.

Research and Development

We invest in research and development efforts to continuously improve the aprevo Technology Platform. We believe that investment is critical to achieving our goal of establishing the aprevo Technology Platform as the standard of care for spine fusion and expanding the use of the aprevo Technology Platform into additional disease states. Our research and development initiatives are focused on introducing enhancements and new capabilities aimed at increasing the value provided by the aprevo Technology Platform to patients, surgeons, and payors.

Our research and development team includes engineers and scientists with expertise in biomedical, mechanical, and software design in support of spine surgery solutions. We employ an integrated team approach to product development and emphasize collaboration of team members across various disciplines to design, test, and obtain regulatory clearance and approvals for our products more effectively.

Our research and development efforts are further supported by automation and use of AI in the product improvement process. Our database currently includes over four million de-identified radiographic images and will continue to expand with data from new procedures. We leverage this growing database to continuously improve our digital planning process and will continue to introduce iterations of our AI-enabled algorithms and software to drive further improvements of our platform. We believe that these improvements will strengthen our ability to leverage the post-operative data we collect to improve our planning process and thus help physicians make better decisions earlier on in treatment.

We also invest in developing our technology and products for indication expansions. In November 2024, we received FDA 510(k) clearance for our aprevo interbody implants for cervical spine fusion surgery as part of the aprevo Technology Platform. In July 2025, we successfully completed the first in-human personalized cervical procedure in the United States and commenced commercialization in December 2025. Also in December 2025, we received FDA 510(k) clearance for our personalized cervical plating solutions as part of the aprevo cervical platform. In February 2026, we completed the first personalized plating procedure using the corra Cervical Plating System at the University of California San Francisco and are planning for its commercial launch later this year. We expect to drive adoption with our existing base of surgeons who are actively using the aprevo Technology Platform for lumbar spine fusion surgeries.

In February 2026, we announced the successful completion of the first posterior lumbar spine surgery using our newly developed aprevo lumbar bi-lateral posterior system ("aprevo Lumbar Bi-lateral Posterior System") at the University of Colorado Hospital in Denver, Colorado. The addition of aprevo Lumbar Bi-lateral Posterior System ("PLIF") expands our lumbar offering across multiple spinal fusion techniques and integrates seamlessly with our broader aprevo platform technology. The commercial launch of aprevo PLIF is expected in the first half of 2026.

We continue to explore other potential opportunities to leverage our platform technology, including additional indications and disease states within the spine, such as cervical corpectomy and cervical disc arthroplasty, and other musculoskeletal applications beyond spine.

Sales and Marketing

We market and sell the aprevo Technology Platform to hospitals and ambulatory surgical centers through a combination of our direct sales team and independent sales agents. Our direct sales team consists of Area Vice Presidents, Sales Directors, Account Managers, and Strategic and National Account leadership, who are primarily responsible for marketing the aprevo Technology Platform to surgeons and working with our customers to secure product approval. They are also responsible for recruiting indirect sales agents who cover each surgery, generate leads, and train clinics. Our direct sales team has significant experience launching new technology solutions to accounts and selling innovative spine procedures and products, with established customer relationships in their respective territories.

Our direct sales team is supported by a team of independent sales agents, who are responsible for generating leads, training clinics, and covering cases. Our independent sales agents have deep surgeon relationships, spine expertise, and provide clinical support in aprevo surgical procedures. Each sales agent agreement typically appoints an individual as an independent sales agent on an exclusive basis with respect to specific surgeons and procedures for an initial term of one calendar year, automatically extending for one additional year thereafter unless notice of intent not to renew is provided by either party within 30 days prior to the end of the current term. As an independent sales agent, each individual will receive a standard commission based on sales of aprevo interbody implants. The Company enters into agreements with independent sales agents in the ordinary course of business.

We expect to continue to increase our sales territories and our independent sales agents in the United States to deepen our penetration in the United States in our existing markets and expand into new geographic territories. We believe that the expansion of our U.S. sales force provides us with significant opportunities for future growth as we continue to penetrate existing geographic markets and enter new ones. In addition to our in-house sales team and independent sales agents, our commercial organization includes personnel in product and brand marketing, professional education, strategic accounts contracting support, and sales operations.

We devote significant resources to training and educating our independent sales agents and customers. Our training teams are deployed to new accounts in order to seamlessly integrate the aprevo Technology Platform into each surgeon's clinic and operating room and to drive deeper adoption of our technology by surgeons and customers. We have also developed our aprevo Personalized Spine Provider program, supported by the Carlsmed personalizedspine.com website for patient education materials and access to our aprevo Personalized Spine Provider locator within their geographic area. This tool helps connect patients with surgeons within the aprevo network, increases our exposure, drives brand awareness, and facilitates adoption of the aprevo Technology Platform. We do not incorporate the information contained on, or accessible through, *personalizedspine.com* into this Annual Report and you should not consider it a part of this Annual Report.

Coverage and Reimbursement for aprevo Interbody Implants

In the United States, healthcare providers generally rely on third-party payors, including private insurers, governmental payors, such as Medicare and Medicaid, managed care organizations, and administrative contractors to cover and pay for all or part of the cost of a spine surgery in which the aprevo Technology Platform is used. Hospitals are the primary purchasers of our aprevo interbody implants under the aprevo Technology Platform, which are primarily used in a hospital inpatient setting.

When procedures using the aprevo Technology Platform are performed, both the surgeon or other healthcare provider and the hospital or healthcare facility submit claims for reimbursement to the third-party payor. Generally, the hospital or healthcare facility obtains a lump sum payment, or facility fee, that covers the episode of care, including implant costs. Surgeons are reimbursed separately for their professional time and effort to perform a spine surgery procedure. We do not bill any third-party payors for the aprevo Technology Platform. Instead, we invoice our customers. Third-party payors may deny reimbursement if they determine that a device used in a procedure was not medically necessary or in accordance with cost-effective treatment methods or was used for an unapproved indication. These third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to reimbursement amounts to surgeons, other healthcare providers, hospitals, and healthcare facilities for procedures during which our products are used. No uniform policy for reimbursement for our products exists among third-party payors in the United States. Therefore, reimbursement for devices can differ significantly from payor to payor.

Medicare coverage and reimbursement policies are developed by CMS, the federal agency responsible for administering the Medicare program, and its contractors. CMS establishes these Medicare policies for medical products and procedures, and such policies are periodically reviewed and updated. While private payors vary in their coverage and payment policies, the Medicare program is widely viewed as a benchmark. Medicare payment rates for the same or similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (i.e., teaching or community hospital), and other factors. CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make coverage and payment decisions. Medicaid programs are funded by both federal and state governments and may vary from state to state and from year to year. As a result, the coverage and reimbursement determination process varies widely, with no guarantee that coverage and adequate reimbursement will be applied consistently or obtained in the first place. We therefore cannot provide assurance that government or private third-party payors will cover and provide adequate payment for the procedures in which our products are used. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA") and other reform proposals contain significant changes regarding Medicare, Medicaid, and other third-party payors that may also impact the coverage and reimbursement determination process for our products.

The MS-DRG payments for procedures using the aprevo Technology Platform are intended to cover all hospital inpatient costs associated with treating a patient during his or her hospital stay. The MS-DRGs for lumbar fusions are 402,426, 427, 428, 447, 448, 450, 451, 456, 457, and 458, depending on the number of levels being fused, existence of complicating or comorbid conditions, existence of malignancy or infection, and whether a "custom-made anatomically designed interbody fusion device" is utilized. For the fiscal year beginning October 1, 2025, CMS proposed national average payment amounts for these MS-DRGs ranging between $24,049 and $82,040. Given that most procedures using the aprevo Technology Platform are mapped to the "custom-made anatomically designed interbody fusion device" MS-DRG's, 426, 447 and 450, the incremental CMS reimbursement to the hospital for an aprevo procedure under these MS-DRG's ranges from approximately $12,000 to $50,000. Hospitals receive incremental reimbursement for most aprevo procedures.

In August 2025, CMS announced proposed X-codes for the use of custom-made anatomically designed fusion devices for cervical spine fusion surgeries. In October 2025, the proposed X-codes were finalized, and CMS NTAP was activated, allowing hospitals to receive NTAP of up to $21,125 per qualifying inpatient cervical spine fusion procedure that uses our aprevo cervical interbody implants.

For the year ended December 31, 2025, we estimate that our payor mix was approximately 43% commercial insurance and 57% Medicare and Medicare Advantage insurance. Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. Because there is no uniform policy of coverage and reimbursement among third-party payors in the United States, coverage and reimbursement for procedures can differ significantly from payor to payor. Based on our experience, third-party payors generally reimburse for the procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery, and reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is (i) a covered benefit under its health plan, (ii) appropriate and medically necessary for the specific indication, (iii) cost effective, and (iv) neither experimental nor investigational. See the risk factor titled "*The continued commercialization of the aprevo Technology Platform depends in part on the extent to which third-party payors provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for aprevo interbody implants could limit our ability to market them and decrease our ability to generate revenue*."

Manufacturing and Supply

Our aprevo interbody implants specifically address each patient's pathology and vertebral bone topography for surgical correction, starting with our personalized digital surgical plans. The design and manufacture of our aprevo interbody implants require significant and diverse technical expertise. Accordingly, our manufacturing strategy is a critical component of our success. We rely exclusively on CMOs to manufacture our aprevo interbody implants. To manage this, we have developed two essential value streams within our operations.

Our streamlined DPS manages both the upstream and downstream processes involved in producing these patient-specific aprevo interbody implants. On the upstream side, DPS applies AI to convert the patient's computerized tomography ("CT") scans into a 3D PSM of their spine. It applies the surgeon's desired correction, and designs the corresponding aprevo interbody implants that precisely address the patient's pathology and vertebral bone topography to deliver the optimal alignment for spine fusion surgery. On the downstream side, DPS integrates with both our enterprise resource planning and our CMOs' "shop floor" systems. This integration enables rapid, secure, and accurate information flow and streamlines our "procure-to-pay" processes, ensuring that each aprevo interbody implant design rapidly moves into manufacturing.

We have a streamlined supply chain that, as of February 2026, allows us to timely deliver aprevo interbody implants to our customers within six business days of surgical plan approval. The supply chain integrates all processes in connection with the manufacture of our products. We leverage and rely on a limited number of CMOs to manufacture our products to our specifications and do not own or operate our own manufacturing facilities for clinical or commercial production of aprevo interbody implants. Under this manufacturing model, our CMOs electronically receive the aprevo interbody implant designs, perform all of the various processes in connection with the manufacture of our products, including 3D printing, heat treatment, post-processing, cleaning and packaging, and sterilization, and then ship the completed aprevo surgical kit directly for use in surgery. All of our CMOs are located within the United States. See the risk factor titled "*We rely on a limited number of CMOs for the manufacture, treatment, sterilization, packaging, and distribution of our products. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost and reduces our control over the manufacturing process, which could delay, prevent, or impair our development or commercialization efforts, as well as our ability to timely deliver our aprevo interbody implants.*"

We are registered with the FDA as a medical device manufacturer responsible for development of specifications and complaint handling, and are licensed by the State of California to manufacture and distribute medical devices. We are required to manufacture our products in compliance with the FDA's Quality Management System Regulation under 21 CFR Part 820, as amended effective February 2, 2026, to align more closely with ISO 13485:2016 (the Quality Management System Regulation, or "QMSR"). We have been ISO 13485-certified since February 2025. We are audited annually under these regulations and standards and no major non-conformities have been identified in any external audit to date.

Competition

The medical device industry is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Our currently marketed products, and any future products we commercialize, will compete against manufacturers of conventional spine and orthopedic devices. To our knowledge, there are no other commercially available patient-specific interbody technology platforms widely available for sale in the United States for lumbar and cervical spine fusions. Our products currently compete with stock implants manufactured or developed by other companies, including Medtronic PLC, Johnson & Johnson, and Globus Medical Inc. Some of these competitors are large, well-capitalized companies with greater market share and resources than we have. As a consequence, they may be able to spend more on product development, marketing, sales, and other product initiatives than we can. We also compete with smaller to mid-sized medical device companies, such as Orthofix Medical Inc., Alphatec Holdings, Inc., Highridge, Inc., and VB Spine, LLC. We have no knowledge of, nor can we predict, when devices or solutions in development by our competitors might be available for sale. Additionally, we may also face competition from smaller companies that have developed or are developing similar technologies for our addressable markets.

We believe that the principal competitive factors in our markets include:

- improved outcomes for medical conditions;
- acceptance by surgeons;
- acceptance by the patient community;
- ease of use and reliability;
- product price and qualification for reimbursement;
- technical leadership and superiority;
- effective marketing and distribution; and
- speed to market.

As the first commercially available solution to provide personalized digital surgical plans with patient-specific interbody implants, we believe that the aprevo Technology Platform provides a compelling value proposition to compete favorably in this market.

Intellectual Property

Intellectual property rights are instrumental to the success of our business. We seek to protect the intellectual property and proprietary technology that we consider important to our business by pursuing patent applications that cover our technologies and product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We have developed, and are continuing to develop, a comprehensive intellectual property portfolio related to the aprevo personalized surgery platform.

Our success depends in part on our ability to: (a) obtain, maintain, protect, and enforce intellectual property and other proprietary rights for our current and future technology, inventions, improvements, and know-how that we consider important to our business; (b) preserve the confidentiality of our trade secrets; (c) defend and enforce our intellectual property rights; (d) operate without infringing, misappropriating, or violating the intellectual property and other proprietary rights of others; and (e) prevent others from infringing, misappropriating, or violating our intellectual property and other proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our patent portfolio is intended to cover our surgical planning technology, aprevo personalized surgery platform and software run thereon, personalized spinal implants, and any other inventions that are commercially important to our business. We also rely on trademarks, trade secrets, and know-how to develop and maintain our proprietary position.

Patents have a limited lifespan, and the term of individual patents depends upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, issued patents are granted a term of 20 years from the earliest effective non-provisional filing date. In certain instances, a patent term of a U.S. patent may be adjusted to recapture a portion of delay by the USPTO in examining the patent application or extended to account for term effectively lost as a result of the FDA regulatory review period, or both. The period of extension may be up to five years but cannot extend the remaining term of a patent beyond a total of 14 years from the date of approval. Only one patent among those eligible for an extension and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions may be less than the maximum extension available.

We solely own all of the patents and patent applications in our portfolio. As of December 31, 2025, our patent portfolio contained 45 total issued patents and approximately 120 pending patent applications relating to the aprevo Technology Platform, including our myaprevo application and aprevo devices. The 45 issued patents include 39 issued U.S. patents and six issued foreign patents in the European Union and Japan. These issued patents are expected to expire between 2037 and 2045, without accounting for potentially available patent term adjustments or extensions or terminal disclaimers and assuming payment of appropriate maintenance, renewal, annuity, and other governmental fees. As of December 31, 2025, we also owned approximately 120 pending patent applications, including approximately 54 pending U.S. patent applications and 66 pending foreign patent applications. We are pursuing protection in Australia, Canada, the European Union, Japan, the United Kingdom, the Republic of Korea, Singapore, and other jurisdictions. Any patents that may issue from these pending patent applications are expected to expire between 2037 and 2045, without accounting for potentially available patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity, and other governmental fees.

In addition to patents, we also rely upon trademarks, trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We maintain and will continue to pursue trademark protection for our company name, products, and brand, including the registered trademarks CARLSMED and APREVO in the United States, the European Union, Japan, and other foreign jurisdictions.

We rely on trade secrets to protect certain aspects of our technology related to our current and future proprietary algorithms. However, trade secrets can be difficult to protect. We seek to protect our proprietary information, including trade secrets, in part, by using confidentiality agreements and/or invention assignment agreements with our commercial partners, collaborators, employees, and consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems. See the section titled "*Risk Factors—Risks Related to Our Intellectual Property*" for a more comprehensive description of risks related to our intellectual property.

Government Regulation

Our products and operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the FDA.

U.S. Regulation of Medical Devices

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or approval of a Premarket Approval ("PMA") application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality Management System Regulation (" QMSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, as well as any special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include, among other things, performance standards, post-market surveillance, patient registries, and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA, requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting, and some implantable devices, devices that have a new intended use, or devices that use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring the receipt of a PMA by FDA. Some pre-amendment devices are unclassified but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. The majority of the products that we currently market are classified as Class II devices and have received FDA marketing authorization through the 510(k) clearance process.

FDA Medical Device Marketing Authorization Pathway

To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments), and for which a PMA is not required; a device that has been reclassified from Class III to Class II, or I; or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. FDA collects fees for 510(k) applications and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant 510(k) clearance to commercially market the device within the United States. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "*de novo*" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. The PMA process requires that the manufacturer demonstrate that the device is safe and effective for its intended uses, which generally requires the submission of extensive data, including results from preclinical studies and human clinical trials. A PMA must also contain a full description of the device and its components; the methods, facilities, and controls used for manufacturing and proposed labeling. The PMA process is burdensome, and in practice, the FDA's review of a PMA application may take up to several years following initial submission. We currently do not market any medical devices pursuant to an approved PMA application, nor have we sought or obtained *de novo* classification for our products.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request, or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained or a *de novo* request is granted. In these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Medical Device Clinical Trials

Clinical trials are sometimes required to support 510(k) or *de novo* submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE"), regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a patient. An IDE application must be supported by appropriate data, such as animal and laboratory test results, demonstrating to the FDA satisfaction that the risks of testing the device in subjects would not be outweighed by the anticipated benefits, there are no subject protection concerns that could preclude initiation of the study, and the testing protocol is scientifically sound. An IDE application is approved if the FDA has determined that the sponsor has provided sufficient data to support initiation of a human clinical study, no subject protection concerns preclude initiation of the investigation, and no additional conditions must be met. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, all clinical studies must be approved by, and conducted under the oversight of, an IRB, for each clinical site or under a centralized IRB. The IRB is responsible for the initial and continuing review of the clinical study and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Submission of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials.

During a clinical study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators, and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and record keeping requirements. Additionally, after a trial begins, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, such as a belief or determination that the risks to study subjects outweigh the anticipated benefits. The study sponsor may also suspend or terminate a clinical trial at any time for strategic business decisions.

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and de novo classification. The program is available for medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device Designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff; use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device; opportunities for more efficient and flexible clinical study design; and prioritized review of premarket submissions. When reviewing Breakthrough Device Designation requests, the FDA may require a combination of literature or preliminary bench, animal, or clinical data to demonstrate a reasonable likelihood of clinical and technological success. Receiving a Breakthrough Device Designation from the FDA does not guarantee that the FDA will grant marketing authorization for the device.

Post-Market Regulation

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

- establishment registration and device listing with the FDA;
- QMSR requirements, which currently require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to cleared devices or devices authorized through the de novo classification process that could significantly affect safety or effectiveness, or that would constitute a major change in intended use of such devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal, and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with laws and regulations requiring Unique Device Identifiers on medical devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QMSR, which currently cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QMSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Medical device manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QMSR requirements could result in the shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with marketed medical devices, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

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

- warning letters, untitled letters, “it has come to our attention” letters, fines, injunctions, consent decrees, and civil penalties;
- recalls, withdrawals, or administrative detention or product seizures;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance, *de novo* classification, or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for devices being shipped to foreign markets; or
- criminal prosecution.

We are also subject to regulation by the California Department of Public Health Food and Drug Branch (the “FDB”) through the Medical Device Safety Program. We must maintain a California Medical Device Manufacturing license. Our facilities may be subjected to scheduled or unscheduled inspections by the FDB.

Healthcare Fraud and Abuse Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving, or providing any remuneration, directly or indirectly, overtly or covertly, to induce, reward, or in return for, purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federal healthcare programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious, or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties law, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know that it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program.

HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals such as physician assistants and nurse practitioners, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Several states in which we operate have also adopted fraud and abuse laws similar to those described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any third-party payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement Regulation

In the United States, our commercial success depends in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for aprevo interbody implants. Use of aprevo interbody implants is typically covered and reimbursed under existing physician and hospital codes. These procedures are typically performed in a hospital inpatient setting, where governmental payors such as Medicare reimburse hospitals a single bundled payment based on the MS-DRG system. Failure by surgeons, healthcare systems, and hospitals to obtain adequate reimbursement from third-party payors for services performed with our products, or adverse changes in government and private third-party payors' coverage and reimbursement policies, could adversely impact demand for our products.

Coverage and reimbursement for use of aprevo interbody implants can differ significantly from payor to payor. Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to hospitals under the IPPS. These updates could directly impact the demand for our products.

We believe that the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industries to reduce the costs of products and services. Third-party payors are developing increasingly sophisticated methods of controlling patient access to new technology through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, and exploration of more cost-effective methods of delivering healthcare. In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per-capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

Reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product-specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirements.

Healthcare Reform

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

The implementation of the ACA in the United States, for example, has substantially changed healthcare financing and delivery by both governmental and private insurers and significantly affected medical device manufacturers. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been judicial, executive, and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on its constitutionality.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act, among other things, reduced Medicare payments to providers, effective on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

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

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations, and standards govern the collection, use, disclosure, access to, confidentiality, and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our collaborators, third-party providers, and others upon whom we commercially rely.

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information that could apply to our operations.

In addition, we may in the future become subject to certain foreign laws that govern the privacy and security of personal data, including health-related data.

Privacy and security laws, regulations, and other obligations are constantly evolving; may conflict with each other to complicate compliance efforts and increase both legal risk and compliance costs for us and the third parties upon whom we rely; and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing that could adversely affect our business, financial condition, reputation, and results of our operations.

Finally, the loss of, unauthorized access to, or disclosure of personal information due to a cybersecurity event or otherwise may trigger breach notification statutes and notification obligations under laws in both the United States and other jurisdictions. A cybersecurity event may result in investigations, legal actions, including class action litigation, regulatory inquiries, and regulatory enforcement actions, as well as fines, consent orders, or mandated corrective actions.

Employees and Human Capital Resources

As of December 31, 2025, we had 127 full-time and part-time employees, of which 94 were located at our headquarters in Carlsbad, California and 33 were remote and field-based employees throughout the United States. None of our employees are located outside of the United States. Of these employees, 44 were in sales, marketing or commercial operations; 26 were in manufacturing, operations or quality; 39 were in research and development, clinical or regulatory; and 18 were in general and administration. None of our employees are represented by a labor union or party to a collective bargaining agreement with respect to their employment with us.

We rely on both our internal sales team and independent sales agents to promote and market the aprevo Technology Platform and to solicit sales of our personalized spinal implants. We expect to dedicate meaningful resources to significantly expand our in-house sales force as we continue to expand. We believe that we have a good relationship with our workforce. Our human capital is a key factor in our current and future success, which largely depends upon our continued ability to attract and retain highly skilled employees.

Seasonality

Our business has not historically exhibited material seasonality. However, sales of our products may be influenced by summer vacation and winter holiday periods during which we have experienced fewer surgeries taking place, as well as more surgeries taking place later in the year when patients have met their deductibles under insurance plans.

Corporate Information

We were incorporated under the laws of the State of Delaware in June 2018 under the name Carlsmed, Inc. Our corporate headquarters is located at 1800 Aston Ave., Suite 100, Carlsbad, CA 92008. Our telephone number is (760) 766-1923. We use our website at www.carlsmed.com to communicate important information about our company, including news releases and financial information. We also make available on our investor relations webpage, free of charge, copies of our Securities and Exchange Commission ("SEC") filings and submissions, which can be found at the SEC's website, www.sec.gov, as soon as reasonably practicable after electronically filing or furnishing such documents with the SEC. Stockholders may also request copies of these documents by writing to our Corporate Secretary at the address above. Website references are provided throughout this document for convenience only. The contents of these websites do not constitute a part of this Annual Report and shall not be deemed incorporated by reference into this Annual Report unless expressly noted.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, financial condition, results of operations, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe are not material may also impair our business, financial condition, results of operations, and prospects.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks:

- We depend entirely on sales of aprevo interbody implants for our revenue. If we are unable to successfully achieve substantial market acceptance and adoption of the aprevo Technology Platform, or any of our future products, or if confidence in our products is diminished, our business, financial condition, results of operations, and prospects would be harmed.
- We have a limited operating history and have experienced periods of significant business changes in a short time, making it difficult for you to evaluate our business and future prospects. If we are unable to manage our business and any fluctuations in our business effectively, our business and growth prospects could be materially and adversely affected.
- We have a history of net losses, and we expect to incur additional substantial losses in the foreseeable future.
- Our business and growth strategy depend in part on our ability to broadly commercialize the aprevo Technology Platform for cervical spine fusion surgeries. If we are unable to do so, our future growth would be limited and our business would be harmed.
- Managing our on-demand, customized implant model to address evolving patterns of demand is expensive, time-consuming, and subject to significant uncertainties. If we are unable to manage our CMOs to consistently meet demand on a timely basis, customers and surgeons may choose to use our competitors' products.
- We rely on a limited number of CMOs for the manufacture, treatment, sterilization, packaging, and distribution of our products. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost, and reduces our control over the manufacturing process, which could delay, prevent, or impair our development or commercialization efforts, as well as our ability to timely deliver our aprevo interbody implants.
- If the third parties on which we rely to assist us with premarket development activities for future products do not perform as contractually required or expected, we may not obtain regulatory clearance or approval for our future products or be able to successfully commercialize our future products.
- We operate in a highly competitive industry, and competitive pressures or any new developments by competitors could make the aprevo Technology Platform non-competitive or obsolete and could have a material adverse effect on our business, financial condition, results of operations, and prospects.
- Any future sales in international markets will subject us to additional costs and risks that may have a material adverse effect on our business, financial condition, results of operations, and prospects.
- If we are unable to successfully develop new products and effectively manage their introduction or improve our existing products, our business may be adversely affected.
- We may be subject to product and other liability claims that could require us to pay substantial sums.

- A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.
- The size and expected growth of our total addressable market has not been established with precision and may be smaller than we estimate.
- Discovery of alternative technologies or other personalized spinal implant technologies could materially adversely affect our business, financial condition, results of operations, and prospects.
- Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.
- Macroeconomic conditions could materially adversely affect our business, financial condition, results of operations, and prospects.
- Cybersecurity risks could materially affect our business, operations, or financial condition.
- The continued commercialization of the aprevo Technology Platform depends in part on the extent to which third-party payors provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for aprevo interbody implants could limit our ability to market them and decrease our ability to generate revenue.
- Actual or perceived failures to comply with applicable data privacy and security laws, regulations, standards, and other requirements could adversely affect our business, financial condition, results of operations, and prospects.
- If we fail to comply with healthcare and other governmental regulations, we could face substantial penalties, and our business, results of operations, and financial condition could be adversely affected.
- Our success will depend on our ability to obtain, maintain, enforce, and protect our intellectual property rights.
- Our use and development of AI Technologies presents regulatory, operational, intellectual property, performance, and reputational risks, and evolving AI-related laws could increase compliance burdens.
- We are subject to extensive healthcare fraud and abuse, transparency, and anti-corruption laws (including the Anti-Kickback Statue, False Claims Act, and FCPA), and violations could result in significant penalties or exclusion from government programs.
- We are subject to ongoing FDA oversight, quality system requirements, and post-market reporting obligations, and regulatory changes or enforcement actions could disrupt our operations.
- Our indebtedness under the Customers Loan Agreement subjects us to financial and operational covenants that restrict our flexibility and could trigger default.

Business and Industry Risk Factors

We depend entirely on sales of aprevo interbody implants for our revenue. If we are unable to successfully achieve substantial market acceptance and adoption of the aprevo Technology Platform, or any of our future products, or if confidence in our products is diminished, our business, financial condition, results of operations, and prospects would be harmed.

We expect that revenue from sales of aprevo interbody implants will continue to account for all of our revenue for the foreseeable future. Continued and widespread market acceptance and adoption of the aprevo Technology Platform are critical to our future success. The size of our customer and surgeon user base, our ability to acquire new customers and surgeon users, and our ability to retain existing customers and surgeon users are critical to our success as well. Thus, our commercial success will depend in large part on further adoption of the aprevo Technology Platform by customers and surgeons, and an increase in the number of patients receiving personalized spine surgery with aprevo interbody implants.

Various factors can contribute to the growth in market acceptance of our products and the ability to effectively engage and retain customers and surgeons, and their use of the aprevo Technology Platform. For example, customers and surgeons may be reluctant to purchase or use aprevo interbody implants due to familiarity with stock implants that are well established and known to them. Our ability to grow our sales and drive market adoption will depend on the availability of coverage and adequate reimbursement for procedures using the aprevo Technology Platform from third-party payors, including government payors, or the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government payors. In addition, successfully educating hospitals, ambulatory surgical centers, surgeons, and patients of the relative benefits of the aprevo Technology Platform compared to stock implants, as well as educating such hospitals, ambulatory surgical centers, surgeons, and patients regarding the advantages and limitations of the aprevo Technology Platform, will be essential to our ability to grow sales of aprevo interbody implants and drive market acceptance and adoption. If customers and surgeons do not perceive our products to be useful, effective, reliable, and trustworthy, or if we are unable to provide sufficient training to surgeons, we may not be able to attract or retain customers. Customers and surgeons may perceive the aprevo Technology Platform to be less useful if they lack familiarity or trust in the aprevo Technology Platform. In addition, negative clinical research results or publicity or an adverse change to published or unpublished guidelines or recommendations from third parties (including, without limitation, medical societies) relating to the use, clinical benefit, or risk profile of the aprevo Technology Platform, AI technologies, aprevo interbody implants, or surgical planning software in general could result in negative perception by customers and surgeons, and could affect our brand and reputation. While we constantly work to improve the aprevo Technology Platform, the technologies we work with are novel and complex, and we cannot assure you that there will not be negative reports on the aprevo Technology Platform in the future. Further, patients, customers, or surgeons who are dissatisfied with their experiences with the aprevo Technology Platform may post negative reviews, and we may become the subject of blog, forum, or other social media postings that contain negative statements about us, which are outside of our control and may be inaccurate. Any negative publicity, whether real or perceived, disseminated by word-of-mouth, the general media, electronic or social networking platforms, competitor materials, or other methods, could harm our reputation and brand. Lack of support for our products from customers or surgeons can affect how receptive other surgeons are to use the aprevo Technology Platform for their patients and could result in decreased demand for our products. Negative perception by customers or surgeons could also render us less attractive to future customers, which could result in decreased sales of our products. A number of other factors, including the impacts of economic conditions and regulatory changes on hospitals' and ambulatory surgical centers' budgets and spending patterns, could potentially negatively affect the increase in adoption by customers and surgeons of the aprevo Technology Platform and demand for aprevo interbody implants.

We have a limited operating history and have experienced periods of significant business changes in a short time, making it difficult for you to evaluate our business and future prospects. If we are unable to manage our business and any fluctuations in our business effectively, our business and growth prospects could be materially and adversely affected.

Since our formation in 2018, our efforts have been primarily related to organizing and staffing our company, business planning, raising capital, developing the aprevo Technology Platform, undertaking preclinical studies and clinical studies, obtaining FDA clearance for the aprevo Technology Platform products, establishing our supply chain and network of suppliers and CMOs and commercializing the aprevo Technology Platform. We have a limited operating history, which makes evaluation of our future prospects difficult. Consequently, any predictions you make about our future success, performance, or viability may not be as accurate as they could be if we had more experience or a longer history of successfully developing and commercializing the aprevo Technology Platform. Since our inception, we have had periods of significant growth in revenue and employees, which have required us to scale the size of our organization as our business has rapidly changed. For example, since we began commercializing the aprevo Technology Platform in 2021, we have grown from 24 employees as of December 31, 2021, to 127 employees as of December 31, 2025. Our growth objectives will require us to further expand our sales and marketing and research and development personnel (including those with software and hardware expertise). Our results of operations have fluctuated in the past, and our future quarterly and annual results of operations may fluctuate as we focus on increasing the demand for our products. Among other factors, future changes in the level of reimbursement for procedures using the aprevo Technology Platform could have a significant impact on our results of operations, either positively or negatively. We may need to make business decisions that could adversely affect our results of operations and prospects, such as modifications to our pricing and reimbursement strategy, business structure, or operations.

The challenges we face in managing our business, including the changing reimbursement and regulatory landscapes, place significant demands on our management, financial, operational, manufacturing, technological, and other resources. We expect that managing our business will continue to place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial, and other internal controls, reporting systems, and procedures. In particular, continued growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high-quality product standards and regulatory compliance, and preserving our culture and values. We may not be able to address these challenges in a cost-effective manner, or at all. As we grow, we may also need to invest significant resources to improve and expand our manufacturing partnerships and technology, and we may not be able to do so in a cost-effective manner, or at all. We cannot assure you that any changes in scale, related quality, or compliance assurance, including those related to any future additional improvements and modifications to the aprevo Technology Platform, will be successfully implemented or that appropriate personnel will be available to facilitate the management of, and changes to, our business. Failure to implement necessary quality and compliance procedures, transition to new manufacturing processes or supply chains, or hire or maintain necessary personnel could result in higher costs or an inability to meet demand. In addition, our business is affected by general macroeconomic and business conditions around the world, including the impacts of inflation, increased interest rates, market instability, geopolitical conditions and conflicts, health crises, and natural disasters. If we do not effectively manage our business through the various challenges we face, we may not be able to execute our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy patient and healthcare professional requirements, or maintain high-quality products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have a history of net losses, and we expect to incur additional substantial losses in the foreseeable future.

We have incurred net losses since inception, and we expect to incur additional losses in the near future. For the years ended December 31, 2025 and 2024, we incurred net losses of $29.6 million and $24.3 million, respectively. As of December 31, 2025, we had an accumulated deficit of $100.8 million. We also expect our operating expenses to increase in future periods, and if our revenue growth does not increase to more than offset these anticipated increases in our operating expenses, we may not be able to achieve or maintain profitability, and our business, financial condition, results of operations, and prospects will be harmed. Since inception, we have spent significant amounts to develop the aprevo Technology Platform, to fund clinical studies and gain FDA clearance for the aprevo Technology Platform products, to develop our manufacturing processes, to scale our commercial operations, and to recruit and retain key talent.

We have encountered and will continue to encounter risks and difficulties frequently experienced by growing companies, including increasing expenses as we continue to grow our business. We expect our operating expenses to increase significantly over the next several years as we continue to expand our operations and infrastructure and continue to develop the aprevo Technology Platform, including for any future additional improvements and modifications. In addition to the anticipated costs of growing our business, we also expect to incur additional legal, accounting, and other expert expenses as we grow. These investments may be more costly than we expect, and if we do not achieve the benefits anticipated from these investments, or if the realization of these benefits is delayed, they may not result in increased revenue or growth in our business. If our growth rate were to decline significantly or become negative, it could adversely affect our business, financial condition, results of operations, and prospects.

We cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will be able to sustain or increase profitability. Our prior losses, combined with potential future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our business and growth strategy depend in part on our ability to broadly commercialize the aprevo Technology Platform for cervical spine fusion surgeries. If we are unable to do so, our future growth could be limited and our business could be harmed.

As part of our overall growth strategy, we are developing the aprevo Technology Platform for use in cervical spine fusion surgeries. In November 2024, we received FDA 510(k) clearance for our aprevo Technology Platform for cervical spine fusion surgery and on July 14, 2025, the first in-human personalized cervical procedure using our aprevo Technology Platform was completed. In December 2025, we received FDA 510(k) clearance for our cervical plating system. We have generated limited early sales of aprevo interbody implants for use in cervical spine surgery following a commercial launch in December 2025 and expect to more broadly commercialize our cervical platform, including with the anticipated commercial launch of our corra cervical plating system, in 2026. The successful commercialization of the aprevo Technology Platform for cervical spine fusion surgeries will depend on a number of circumstances, and is subject to the risks and uncertainties identified in these "*Risk Factors*." One or more of these factors, many of which are beyond our control, could impair the successful commercialization of the aprevo Technology Platform for use in cervical spine fusion surgeries. Failure to successfully commercialize our cervical platform could have a material adverse effect on our business, financial condition, results of operations and prospects and could significantly impact our growth and growth strategy.

Managing our on-demand, customized implant model to address evolving patterns of demand is expensive, time-consuming, and subject to significant uncertainties. If we are unable to manage our CMOs to consistently meet demand on a timely basis, customers and surgeons may choose to use our competitors' products.

We currently market the aprevo Technology Platform directly to hospitals, ambulatory surgical centers, and surgeons in the United States, where we face the risk of significant changes in the demand for the aprevo Technology Platform. Our business model depends on our ability to timely deliver aprevo interbody implants in order to allow surgeons to maintain their surgical schedule. We rely entirely on CMOs to produce and deliver our aprevo interbody implants. A sudden increase in demand could cause delays in delivering aprevo interbody implants to surgeons and customers. If we are not able to manage our CMOs, or if our CMOs are not able to consistently deliver aprevo interbody implants on a timely basis, surgical schedules may be put in jeopardy and cause surgeons to use our competitors' products, even if they are inferior to ours, which could cause harm to our reputation and cause our sales to decline. Any increase or decrease in demand would put pressure on our CMOs and their supply and manufacturing processes. For example, a sudden increase in demand could require increased production of aprevo interbody implants so that our surgeons can timely use aprevo interbody implants with their patients. Unlike our competitors, we operate an asset-light business model given that aprevo interbody implants are manufactured on-demand by our CMOs and customized for each patient. As a result, in the event of a sudden increase in demand, our CMOs may lack sufficient capital equipment and materials or inventory on hand to create aprevo interbody implants and deliver them to our customers within six business days of surgical plan approval. Adapting to changes in demand inherently lags behind the actual changes because it takes time to identify the change that the market is undergoing and to implement any measures to take as a result. Finally, capacity adjustments are inherently risky because there is imperfect information, and sales trends may rapidly intensify, ebb, or even reverse. We may be unable to accurately or timely predict trends in demand and customer behavior or to take appropriate measures to mitigate risks and react to opportunities resulting from such trends. Any inability in the future to identify or to adequately and effectively react to changes in demand could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We rely on a limited number of CMOs for the manufacture, treatment, sterilization, packaging, and distribution of our products. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost, and reduces our control over the manufacturing process, which could delay, prevent, or impair our development or commercialization efforts, as well as our ability to timely deliver our aprevo interbody implants.

Our business model depends on our ability to timely deliver aprevo interbody implants in order to allow surgeons to maintain their surgical schedule. We do not own or operate manufacturing facilities for production of aprevo interbody implants. We have limited experience in medical device manufacturing and lack the resources and the capability to manufacture aprevo interbody implants on a commercial scale. Our products are manufactured to our specifications by CMOs who meet our manufacturer qualification standards. We have developed a streamlined DPS that manages both the upstream and downstream processes involved in producing our aprevo interbody implants; however, we rely entirely on a limited number of CMOs, only one of which is vertically integrated, to perform all the various processes in connection with the manufacture of our aprevo interbody implants. Under this manufacturing model, our CMOs electronically receive the aprevo interbody implant design; perform all of the various processes in connection with the manufacture of our products, including 3D printing, heat treatment, post-processing, cleaning and packaging, and sterilization; and then ship the completed aprevo interbody implant and accompanying single-use surgical instruments directly for use in surgery. If our CMOs are unable to produce our products in the amounts, timing, or pricing that we require, we may not be able to coordinate with alternative CMOs to manufacture our products on a timely basis and in the quantities or pricing we require. Additionally, if our CMOs are not able to consistently deliver aprevo interbody implants on a timely basis, surgical schedules may be put in jeopardy and cause surgeons to use our competitors' products, even if they are inferior to ours, which could cause harm to our reputation and cause our sales to decline. We expect to depend on CMOs for the foreseeable future.

Our CMOs are critical to us, and there are relatively few alternative sources of supply. Most of our CMOs are not currently under long-term contracts with us. Our CMOs may experience delays or issues, discontinue production of aprevo interbody implants, increase the prices they charge us, or elect to terminate their relationships with us. In any such cases, we could encounter a delay of several months to identify and evaluate suitable alternative manufacturing partners, qualify them, and perform audits to ensure that their processes comply with the FDCA. Supply delays may, and the loss of our vertically integrated CMO likely would, result in our inability to timely deliver aprevo interbody implants to our customers within six business days of surgical plan approval, resulting in surgeons having to rely on stock implants to complete the procedures. These events could materially and adversely affect our ability to retain and attract customers and surgeons and could have a material negative impact on our operations, business, financial results, and financial condition.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our CMOs for compliance with current Good Manufacturing Practice ("cGMP") regulations applicable to our products, including compliance with the FDA's QMSR. CMOs may not be able, or may fail, to comply with cGMP regulations. If our CMOs cannot successfully manufacture aprevo interbody implants that conform to our specifications and the strict regulatory requirements of the FDA, they will not be able to secure and/or maintain registration for their manufacturing facilities.

We also do not have complete control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel. The failure of our CMOs to maintain acceptable quality requirements could result in quality issues, including recalls of our products. If one of our CMOs fails to maintain acceptable quality requirements or perform as agreed, we may have to identify and qualify a new supplier or develop in-house manufacturing capabilities, which could require significant capital investments. Although we require our CMOs to supply us with aprevo interbody implants that meet our specifications and comply with applicable provisions of the QMSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing, or other acceptance activities in an effort to ensure that they meet our requirements, there is a risk that they may not supply aprevo interbody implants that meet our requirements or supply them in a timely manner. Moreover, our failure, or the failure of our CMOs, to comply with applicable cGMP requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our financial position.

The number of CMOs with the necessary regulatory expertise and facilities to produce aprevo interbody implants is limited, and qualification of a new CMO may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The added time and cost to arrange for alternative CMOs could harm our business. Obtaining the necessary FDA or international marketing authorizations or other qualifications under applicable regulatory requirements could result in a significant interruption of supply and could require the new supplier to bear significant additional costs that may be passed on to us.

Our current and anticipated future dependence upon others for the manufacture of our products may adversely affect our future profit margins and our ability to commercialize our products on a timely and competitive basis.

If the third parties on which we rely to assist us with premarket development activities for future products do not perform as contractually required or expected, we may not obtain regulatory clearance or approval for our future products or be able to successfully commercialize our future products.

We often must rely on third parties to assist in conducting our pre-market development activities for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory obligations, or meet expected deadlines, or if these third parties need to be replaced, or if the quality or accuracy of the work product, including data, they produce is compromised due to failing to adhere to clinical protocols, to applicable regulatory requirements, or otherwise, our premarket development activities may be extended, delayed, suspended, or terminated. Under these circumstances, we may not be able to obtain regulatory clearance or approval for our future products or be able to successfully commercialize our future products on a timely basis, if at all, and our business, operating results, and prospects may be materially and adversely affected.

We operate in a highly competitive industry, and competitive pressures or any new developments by competitors could make the aprevo Technology Platform non-competitive or obsolete and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The medical device industry is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Our currently marketed products, and any future products we commercialize, will compete against manufacturers of conventional spine and orthopedic devices.

Many of our competitors, which primarily include manufacturers of stock implants, may be able to develop products, manufacturing processes, or surgical plans competitive with, or superior to, our own. Our competitors may also have stronger intellectual property portfolios; broader spinal surgery product offerings and products supported by significantly more extensive clinical data; more established distribution networks; significantly greater name recognition and more recognizable trademarks for products similar to the products we sell; more established relationships with hospitals, ambulatory surgical centers and surgeons; greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancement; and greater experience in launching, marketing, and selling products than we do.

The introduction by competitors of products that are, or claim to be, superior to aprevo interbody implants, or that are alternatives to our existing or planned products, may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine surgery market generally. Additionally, the failure of procedures using the aprevo Technology Platform to present a cost-effective alternative to procedures using stock implants, including as a result of changes to the spine fusion reimbursements applicable to aprevo interbody implants, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the spine and orthopedic medical device industry in which we compete is characterized by rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products developed by other companies are regularly introduced into the market, which may render the aprevo Technology Platform non-competitive or obsolete.

If we are unable to meet customer demands for new technology, or if the technologies we introduce are viewed less favorably than our competitors' products, our results of operations and future prospects may be negatively affected.

For us to remain competitive, it is essential to be at the forefront of new technologies, including in the rapidly evolving area of AI. If we are unable to meet customer demands for new technology, or if the technologies we introduce are viewed less favorably than our competitors' products, our results of operations and future prospects may be negatively affected. To meet our customers' needs in these areas, we must continuously work on our product design, develop our algorithms, and invest in and develop new technologies to improve the aprevo Technology Platform. We will also need to anticipate customer and surgeon demand with respect to these technologies and which technological advances are most desirable in personalized surgery plans and aprevo interbody implants and any future additional products that we may market. This need will result in requiring our employees to continue learning and adapting to new technologies, and us competing for highly skilled talent in a competitive market. Our operating results depend to a significant extent on our ability to anticipate and adapt to technological changes in the spinal surgery and implant market, maintain and protect innovation, maintain a strong product pipeline, and reduce or maintain low costs for producing high-quality surgical plan and spinal implant products. Any inability to do so could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business and growth strategy depend on our ability to maintain and expand our aprevo Personalized Spine Provider program. If we are unable to do so, our future growth would be limited, and our business would be harmed.

Our achievement of rapid organic adoption of the aprevo Technology Platform among hospitals, ambulatory surgical centers and surgeons is dependent upon our continued ability to maintain and grow our network of established surgeons. If we are unable to maintain and grow our network of surgeons who have interest in the aprevo Technology Platform, it would harm our business and ability to grow and would adversely affect our results of operations. Our ability to develop and maintain satisfactory relationships with these providers also may be negatively impacted by other factors not associated with us, such as changes in Medicare and/or Medicaid reimbursement levels and other pressures on surgeons and consolidation activity among hospitals, physician groups, and healthcare providers. The failure to maintain or to secure new surgeons with interest in the aprevo Technology Platform may result in a loss of or inability to grow our customer and surgeon base, higher costs, healthcare provider network disruptions, less-attractive service for our customers, and/or difficulty in meeting regulatory or accreditation requirements, any of which could harm our business.

Any future sales in international markets will subject us to additional costs and risks that may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We intend to pursue regulatory clearances and establish a commercial pathway in attractive international markets in the near term, and there are significant costs and risks inherent in conducting business in international markets. Upon our expansion into foreign markets, we will be subject to new business risks, in addition to regulatory risks. We can give no assurance as to the timing of regulatory authorizations in any markets or that such efforts will be successful. See the risk factor titled "*We face risks related to obtaining necessary foreign marketing authorizations*." In addition, expansion into foreign markets will impose additional burdens on our executive and administrative personnel, finance and legal teams, sales and marketing teams, and general managerial resources.

We have limited experience with international regulatory regimes and market practices, and we may not be able to penetrate or successfully generate sales in new markets. We may also encounter difficulty expanding into international markets because of limited brand recognition in certain parts of the world and our limited experience with international manufacturing and distribution, leading to delayed acceptance of our products by potential customers in these international markets. Regulatory frameworks and guidance applicable to our products may continue to evolve in certain jurisdictions, and regulatory authorities may not always have well-established or consistent approaches for reviewing and classifying our technology. As a result, we may experience delays, increased costs, additional clinical or technical requirements, or other obstacles in obtaining or maintaining regulatory approvals necessary to commercialize our products internationally. In addition, international markets may have different reimbursement pathways that present additional challenges and make those markets less commercially viable. If we are unable to expand internationally and manage the complexity of international sales operations successfully, it could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our efforts to introduce our products into foreign markets are not successful, we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

If we fail to attract and retain senior management and other key personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, sales and marketing, and research and development personnel, including those with hardware expertise and software expertise, in particular in the area of AI and machine learning. We are highly dependent upon our senior management team as well as our senior technology personnel. We are also dependent on our direct sales team. We have experienced, and may in the future experience, planned or unplanned departures of members of our senior management team, our senior technology personnel, and our direct sales team. Any loss of services, whether planned or unplanned, of any of the members of our senior management team could adversely affect our business until a suitable replacement can be found.

Competition for qualified personnel in the medical device field in general and the personalized surgery field specifically is intense, due to the limited number of individuals who possess the training, skills, and experience required by our industry. We intend to continue to review and, where necessary, strengthen our senior management as the needs of our business develop, including through internal promotion and external hires. However, there may be a limited number of people with the requisite competencies to serve in these positions, and we cannot assure you that we will be able to locate or employ such qualified personnel on terms acceptable to us, or at all. We also face significant competition for personnel where our sole office is located in San Diego County, California. We also intend to continue to increase our sales territories, and we may not be successful in attracting qualified personnel to staff our direct sales team in our desired new territories. To attract and maintain key personnel, we need to remain competitive in our “total rewards” offers to employees, including attractive cash compensation, equity, and benefits packages. While we regularly assess market trends for any changes in compensation across all functions, we need to remain diligent in our compensation benchmarking, especially for key personnel, to ensure that we are providing attractive offers to new employees and compensating existing employees well. Therefore, the loss of one or more of our key personnel, whether planned or unplanned, or our failure to attract and retain additional key personnel, could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, to the extent that we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited, that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We rely on our independent sales agents to generate revenue, which subjects us to various risks.

We rely on, and expect to continue to rely on, the efforts of both our direct sales team and our independent sales agents to promote and market the aprevo Technology Platform to solicit sales of our aprevo interbody implants, and we expect to continue to rely on our direct sales team with the support of independent sales agents to generate a substantial portion of our net sales in the future while we continue to dedicate meaningful resources to significantly grow our direct sales force as we continue to expand. The impairment or termination of our relationships with our independent sales agents for any reason, or the failure of these parties to diligently promote, market, and sell the aprevo Technology Platform and aprevo interbody implants and comply with applicable laws and regulations could materially and adversely affect our ability to generate revenue and profits. Because our independent sales agents control the relationships with certain of our end customers or surgeon users of our products, if our relationship with any independent sales agent ends, we may also lose our customer and surgeon relationships. Furthermore, our success is partially dependent on the willingness and ability of the independent sales agents and other employees of our independent sales agents to diligently sell our aprevo interbody implants. However, we can make no assurances that our independent sales agents will be successful in promoting and marketing our products or in providing adequate support to surgeon users. In addition, because our independent sales agents do not sell aprevo interbody implants exclusively, they may focus their sales efforts and resources on other products that produce better margins or greater commissions for them or are incorporated into a broader strategic relationship with a partner. Because we do not control the independent sales agents and other employees of our independent sales agents, we cannot guarantee that our sales processes, regulatory compliance, and other priorities will be consistently communicated and executed. While we may take steps to mitigate the risks associated with non-compliance by our independent sales agents, there remains a risk that they will not comply with regulatory requirements or our requirements and policies. Actions by the sales representatives and other employees of our independent sales agents that are beyond our control could adversely impact sales in that territory or result in harm to our reputation or our products or legal liability, any of which could have a material adverse effect on our business, financial condition, and results of operations. In addition to the risk of losing customers, the operation of local laws and our agreements with our independent sales agents may make it difficult for us to replace an independent sales agent that we believe is underperforming.

We expect to continue to increase our sales territories and our independent sales agents in the United States to deepen our penetration in the United States in our existing markets and expand into new geographic territories. However, we may not be successful in doing so. If we are unable to establish new independent sales agent relationships and maintain our relationships with our existing independent sales agents on commercially reasonable terms, we may be unable to increase sales of aprevo interbody implants, which, in turn, could materially and adversely affect our business, financial condition, and results of operations.

If we are unable to successfully develop new products and effectively manage their introduction or improve our existing products, our business may be adversely affected.

We must successfully manage introductions of new or enhanced medical devices or new or enhanced features of the aprevo Technology Platform, including those related to any future indications. Introductions of new medical devices or features of the aprevo Technology Platform could also adversely impact the sales of our existing medical devices. For instance, the introduction or announcement of new aprevo interbody implants or an advanced aprevo Technology Platform could cause sales channel conflicts to arise or shorten the life cycle of our existing aprevo interbody implants or reduce demand for them, potentially reducing any benefits of successful new product or enhancement introductions and leading to challenges in managing the portfolio of existing aprevo Technology Platform products. In addition, new or enhanced medical devices may have higher manufacturing, marketing, information technology, or other costs than our existing medical devices, or lower pricing, market acceptance or adoption, which could negatively impact our gross margins and operating results. As the technological complexity of the aprevo Technology Platform products increases, the infrastructure to support them, such as our design and manufacturing processes and technical support for our products, may also become more complex. Accordingly, if we fail to effectively manage introductions of new or advanced medical devices, our business may be adversely affected.

We spend significant amounts on marketing and brand-building initiatives to acquire and retain customers, which may not be successful or cost effective.

We spend significant amounts in marketing initiatives to increase market awareness of the aprevo Technology Platform and the benefits of a personalized surgery plan and aprevo interbody implants. We believe our marketing programs are essential to increasing adoption of the aprevo Technology Platform by our customers and surgeons and expanding the use of the aprevo Technology Platform to a greater number of patients.

While we have developed robust marketing initiatives, we may fail to identify marketing opportunities that satisfy our anticipated return on marketing spend or accurately predict customer acquisition or product-related concerns. If any of our marketing efforts prove less successful than anticipated in attracting new or retaining existing customers, we may not be able to recover our marketing spend, and our rates of customer acquisition and/or customer retention may fail to meet market expectations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our marketing efforts may not result in increased sales of our products, and we may be unable to compete effectively in the long term.

In addition, we believe that building a strong brand and developing and achieving broad awareness of the aprevo Technology Platform is critical to achieving market success. If any of our brand-building activities prove less successful than anticipated, or such activities are inhibited by the negative perceptions of surgeons, including with respect to AI technologies, including proprietary artificial intelligence and machine learning algorithms and models (collectively, "AI Technologies"), aprevo interbody implants, surgical planning software, or lack of confidence in our processes in general, or the safety, reliability, and efficacy of the aprevo Technology Platform, our ability to attract new and retain existing customers and the rate of use of our products by existing customers could be materially adversely impacted. If this were to occur, we may not be able to recover our brand-building spend, and our rates of customer acquisition and retention and product usage may fail to meet market expectations, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to product and other liability claims that could require us to pay substantial sums.

We are subject to an inherent risk of, and adverse publicity associated with, product liability and other liability claims, whether or not such claims are valid. Lumbar spine and cervical spine surgeries involve significant risk of serious complications, including bleeding, tissue injury, nerve injury, paralysis, and even death. In addition, if surgeons are not sufficiently trained in the use of aprevo interbody implants, they may misuse or ineffectively use them, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

Product liability claims are expensive to defend, divert our management's attention, and, if we are not successful in defending the claim, can result in substantial monetary awards against us or costly settlements. Further, successful product liability claims made against one or more of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Any product liability claim brought against us, with or without merit and regardless of the outcome or whether it is fully pursued, may result in decreased demand for our products, injury to our reputation, significant litigation costs, product recalls, loss of revenue, the inability to commercialize new products or product candidates, and adverse publicity regarding our products. Any of these may have a material adverse effect on our reputation with existing and potential customers and on our business, financial condition, and results of operations. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

We maintain product liability insurance coverage in amounts and scope that we believe are reasonable and adequate. There can be no assurance, however, that product liability or other claims will not exceed our insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful product liability claim that exceeds our insurance coverage limits could require us to pay substantial sums and could have a material adverse effect on our financial condition. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. See the risk factor titled "*Our insurance may not cover all potential losses or liabilities that may arise*."

The off-label use of aprevo interbody implants may harm our reputation in the marketplace or result in injuries that lead to fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, either of which could have a material adverse effect on our business, financial condition, and results of operations.

Our products and any marketing authorization we may receive for future products are, and will be, cleared by the FDA for specific indications. We train our direct sales team and independent sales agents to not promote aprevo interbody implants for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a surgeon from using aprevo interbody implants off-label, when in the surgeon's or healthcare provider's independent professional medical judgment he or she deems it appropriate. In addition, there may be increased risk of injury to patients if surgeons attempt to use aprevo interbody implants off-label. Furthermore, the use of our products for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons, healthcare providers, and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or trainings constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of a warning or untitled letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action under another regulatory framework, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products based on a finding that there is reasonable probability that the device could cause serious, adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found or if they believe that the product could be in violation of the FDCA. Even if voluntary, the FDA requires that a medical device manufacturer report to the FDA any corrective action or removal of a device initiated to reduce a risk to health posed by the device. A government-mandated or voluntary recall could occur as a result of risk to health, component failures, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall, or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Any of our products and technologies may have unforeseen adverse events or undesirable side effects, which may require our products to be taken off the market, require our products to include safety warnings, or otherwise limit sales of our products.

Unforeseen adverse events or undesirable side effects related to the use of any of our products or technologies may arise either during clinical development, to the extent applicable, or, if cleared or approved, after the product has been marketed. If we or others identify unforeseen adverse events or undesirable side effects caused by one or more of our products or technologies:

- sales of the affected product may decrease significantly, and we may not achieve the anticipated market share;

- regulatory authorities may require changes to the labeling of the affected product, which may include the addition of labeling statements, specific warnings, and contraindications, and issuing field alerts to surgeons and patients;
- we may be required to modify the affected product, change instructions regarding the way the product is used, or, if applicable, conduct additional clinical trials;
- we may be subject to limitations on how we may promote the affected product;
- regulatory authorities may require us to take our approved affected product off the market (temporarily or permanently) or to conduct other field safety corrective actions; and
- we may be subject to fines, litigation costs, or product liability claims; and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating sufficient revenue to achieve or sustain profitability.

The size and expected growth of our total addressable market has not been established with precision and may be smaller than we estimate.

Our estimated total addressable market is based on the SmartTRAK Report's previously published projections for 2025 and the data and assumptions underlying such projections, including a CAGR of approximately 1.5% in the spinal fusion market. This is consistent with historical growth, resulting from, among other things, an aging U.S. population, which is expected to drive an increase in fusion procedures performed. Our total addressable market is the total overall revenue opportunity that we believe is available for the aprevo Technology Platform in the United States if we achieve 100% market share and is not a representation that we will achieve such market share. While we believe that the data underlying our estimates is reasonable, these assumptions are inherently uncertain. If there was a material difference to actuals in one ore more of: (i) our estimate of the number of patients that we believe could benefit from the aprevo Technology Platform, (ii) our future average revenue per procedure compared to its current levels, or (iii) the total addressable market size, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Discovery of alternative technologies or other personalized spinal implant technologies could materially adversely affect our business, financial condition, results of operations, and prospects.

If medical research were to lead to the discovery of alternative technologies or devices that address the same indications as the aprevo Technology Platform in a way that is or is perceived to be more accurate, reliable, cost-effective, or otherwise improved relative to the aprevo Technology Platform, for example, through alternative analysis and surgical planning software or other personalized implant technologies or devices, the demand for our products could decrease significantly, leading to a material adverse effect on our business, financial condition, results of operations, and prospects.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, profitability, and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- market acceptance of the aprevo Technology Platform and other products and solutions that we may develop in the future;

- our ability to obtain marketing approval for the aprevo Technology Platform in relevant markets or for other products and solutions that we may develop in the future, and the timing and scope of any such approvals that we may receive;
- the availability of reimbursement for aprevo interbody implants at acceptable reimbursement rates;
- the cost of manufacturing of aprevo interbody implants, which may vary depending on the quantity of production and the terms of our agreements with manufacturers and other vendors;
- our ability to attract, hire, train, and retain qualified personnel;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our future pricing policies or those of our competitors;
- the level of demand for the aprevo Technology Platform;
- general economic, industry, and market conditions, or extraordinary external events, such as a recession;
- changes in our regulatory environment;
- expenses associated with unforeseen product quality issues;
- the timing and success or failure of clinical trials or post-approval studies (to the extent applicable) for the aprevo Technology Platform or competing product candidates;
- any other change in the competitive landscape of our industry, including consolidation amongst our competitors or partners;
- litigation or other claims against us for intellectual property infringement or otherwise;
- expenses associated with indemnification obligations to third parties that are subject to litigation or claims, including in relation to intellectual property infringement, or incur other losses as a result of their use of our products;
- our ability to obtain additional financing as necessary; and
- advances and trends in new technologies and industry standards.

Our business has not historically exhibited material seasonality. However, sales of our products may be influenced by summer vacation and winter holiday periods during which we have experienced fewer surgeries taking place, as well as more surgeries taking place later in the year when patients have met their deductibles under insurance plans.

Macroeconomic conditions could materially adversely affect our business, financial condition, results of operations, and prospects.

Macroeconomic conditions, such as persistent inflation, changes to monetary policy, high interest rates, volatile currency exchange rates, credit and debt concerns, decreasing consumer confidence and spending, including capital spending, concerns about the stability and liquidity of certain financial institutions, the introduction of or changes in tariffs or trade barriers, pandemics and other health crises, and global recessions can adversely impact demand for our products, which could negatively impact our business, financial condition, results of operations, and prospects. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies and monetary and financial uncertainties, including with respect to tariffs imposed against U.S. trading partners.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. In addition, spine surgery procedures are often considered elective procedures, depending on the level of disability or pain of the patient. The frequency of spine surgery procedures considered to be discretionary expenditures may be influenced by macroeconomic conditions, such as higher inflation in the United States and globally. As a result of recent inflationary pressure, individuals have started to reprioritize their discretionary expenditures, which could potentially result in patients reducing their demand for elective spine surgeries. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, supply chain constraints, logistics challenges, liquidity concerns in the broader financial services industry, and fluctuations in labor availability.

In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. A higher inflationary environment can also negatively impact equipment, material, and logistics costs that, in turn, may increase the costs of producing and distributing our products.

Also, we may experience supply chain constraints, including difficulties obtaining a sufficient supply or increased prices of equipment and materials used in the manufacture of our products by our manufacturing partners. Increased interest rates may make access to credit more difficult, which may result in the insolvency of key suppliers, which would exacerbate supply chain challenges. Such supply chain constraints could cause us to fail to meet product demand or maintain our margins.

Cybersecurity risks could materially affect our business, operations, or financial condition.

Our business depends on the availability, reliability, and security of our information technology systems and the confidentiality of proprietary, patient, consumer, customer, vendor, and employee data. We face cybersecurity risks common to companies in our industry, including risks arising from unauthorized access to systems or data, malicious cyber activity, human error, insider threats, software vulnerabilities, and disruptions caused by third-party service providers. Cybersecurity incidents could result in the loss, unauthorized disclosure, or corruption of sensitive information, interruptions to our operations, delays in product development or commercialization, damage to our reputation, and increased costs related to remediation, regulatory inquiries, litigation, or insurance.

In addition, we are subject to evolving healthcare, privacy, and data protection laws and regulations, including HIPAA, as well as contractual and industry-standard obligations related to information security. A cybersecurity incident, or failure to maintain effective security controls, could result in regulatory enforcement actions, fines or penalties, contractual liabilities, reputational harm, and increased scrutiny from regulators or customers. While we have implemented, and continue to enhance, cybersecurity and data protection measures and maintain an information security program informed by recognized industry standards and practices, these efforts may not be sufficient to prevent or detect all cybersecurity incidents. As cyber threats continue to evolve in sophistication and frequency, we may be required to devote significant additional resources to cybersecurity risk management, and such efforts may not be successful in preventing material adverse effects on our business, results of operations, or financial condition.

Risk Related to Regulatory Matters

The continued commercialization of the aprevo Technology Platform depends in part on the extent to which third-party payors provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for aprevo interbody implants could limit our ability to market them and decrease our ability to generate revenue.

While third-party payors generally currently cover and provide reimbursement for procedures using the aprevo Technology Platform, there is significant uncertainty related to the commercial payor coverage and reimbursement of newly approved products that have not yet been launched. In the United States, the level of reimbursement that hospitals and ambulatory surgical centers receive from third-party payors, including commercial and governmental payors such as the Medicare and Medicaid programs, has a substantial impact on the prices that we are able to charge to our customers and how widely the aprevo Technology Platform is accepted. The Medicare and Medicaid programs increasingly are used as models in the United States for how commercial payors and other governmental payors develop their coverage and reimbursement policies for medical devices. Some third-party payors may require pre-approval of coverage for new or innovative devices before they will reimburse healthcare providers who use such devices.

Our aprevo interbody implants used in lumbar spinal procedures are typically used in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patient's principal diagnosis, up to 24 additional diagnoses, and up to 25 procedures performed during the stay. Cases are classified into MS-DRGs for payment under the Medicare Inpatient Prospective Payment System ("IPPS") for all items and services provided to the patient during a single hospitalization, regardless of whether procedures utilizing the aprevo Technology Platform are performed during such hospitalization. The MS-DRG codes to which procedures using the aprevo Technology Platform are assigned provide premium reimbursement for procedures that utilize aprevo interbody implants relative to those that use stock implants. Reimbursement for professional services performed at the hospital by physicians is reported under a separate billing code and different payment methodology.

Although they are not required to, commercial third-party payors often follow Medicare's coverage and payment policies. Payment rates of other third-party payors may be consistent with Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. As a result, hospitals,' ambulatory surgical centers' and physicians' access to adequate reimbursement by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products on a profitable basis if third-party payors refuse to cover procedures using the aprevo Technology Platform or reduce their current levels of reimbursement, or if our costs of production increase faster than increases in reimbursement levels.

aprevo cervical is currently reimbursed under the same payor reimbursement methodology as stock interbody implants. We believe Medicare-aged patients receiving multi-level ACDF surgeries are uniquely addressed by aprevo cervical. Based on our internal data, a majority of these procedures are performed in inpatient setting; however, the remaining are performed in hospital outpatient departments and ambulatory surgery centers. Our requested Transitional Pass-Through ("TPT") payment for aprevo cervical in outpatient settings was not approved by CMS in the November 2025 OPPS Final Rule, despite our analysis and documentation for its qualification. Although we will continue to explore opportunities with CMS for various pathways including TPT and New Technology Ambulatory Payment Classification ("APC") to appropriately reimburse our customers' cost of providing aprevo interbody implants in cervical fusion procedures, there can be no assurance that such efforts will be successful.

In addition, customers and surgeons that use aprevo interbody implants may be subject to reimbursement claim denials upon submission of their claims. Customers and surgeons may also be subject to recovery of overpayments if a third-party payor makes payment for the claim and subsequently determines that such payor's coding, billing, or coverage policies were not followed. These events, or any other decline in the amount that payors are willing to reimburse our customers, could make it difficult for existing customers to continue using or to adopt the aprevo Technology Platform and could create additional pricing pressure for us. If we are forced to lower the price that we charge for aprevo interbody implants, our gross margins will decrease, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to satisfy governmental and other third-party payors that procedures using the aprevo Technology Platform should be covered and reimbursed. In addition, third-party payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products. There can also be no assurance that third-party payor policies will provide coverage for procedures using the aprevo Technology Platform.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets, which may impact utilization of our products and have a material adverse effect on our business, financial condition, results of operations, and prospects. Third-party coverage and reimbursement for our products or any of our products in development for which we may receive regulatory clearance, certification, or approval may not be available or adequate in either the United States or international markets. If demand for our products is adversely affected by third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to certain federal and state fraud and abuse laws and transparency laws, and any failure to comply could subject us to substantial penalties or other adverse consequences. In addition, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and transparency laws regarding payments and other transfers of value made to physicians and other healthcare professionals. Our business practices and relationships with providers are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual for, or the purchase, order, or recommendation, of any item or service for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of medical device manufacturers. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. In addition, certain marketing practices that, for example, induce providers to up-code to a higher reimbursement service or site of service may also violate false claims laws. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Private individuals can bring False Claims Act “qui tam” actions on behalf of the government, and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal Health Care Fraud Statute, which prohibits, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain applicable manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and to report annually ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and
- analogous state law equivalents of each of the above federal laws, state anti-kickback, and false claims laws; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing, and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, that we may have with customers and surgeons. In particular, these laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements, as well as interactions with customers and surgeons through consultant and advisory board arrangements, product training, sponsorships, or other activities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. We have entered into advisory board and consulting agreements with physicians, including some who have ownership interests in us and/or influence the ordering of or use our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. It is possible that governmental authorities will conclude that these and other business practices, including our aprevo Personalized Spine Provider program and use of independent sales agents, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management’s attention from the business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties. In addition, as a result of these investigations and qui tam actions, we may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have a material adverse effect on our business, financial condition, results of operations, and prospects. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the federal and state laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm, oversight if we become subject to a consent decree or corporate integrity agreement, or disgorgement, and we could be required to curtail, restructure, or cease our operations. Any of the foregoing consequences will have an adverse effect on our business, financial condition, results of operations, and prospects.

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

We are exposed to the risk that our employees, independent sales agents, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, or negligent conduct or other unauthorized activities that violate the regulations of the FDA or other regulatory authorities (both domestic and foreign), including those that require the reporting of true, complete, and accurate information to such regulatory authorities, manufacturing standards, healthcare fraud and abuse laws, or other regulations in the United States and internationally. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. It is not always possible to identify and deter misconduct by our employees, independent sales agents, consultants, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, oversight if we become subject to a consent decree or corporate integrity agreement, and curtailment of operations, any of which could adversely affect our business, financial condition, results of operations, and prospects. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and suffer reputational harm, and defending ourselves against any of these claims or investigations would divert the attention of management.

We may be subject to damages resulting from claims that we or our employees or our independent sales agents have wrongfully used or disclosed alleged trade secrets or proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Many of our independent sales agents market, promote, and sell, or in the past have marketed, promoted, and sold, products of our competitors. We may be subject to claims that we, our employees, or our independent sales agents have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable personnel. Any future litigation or the threat thereof may adversely affect our ability to hire additional members of our direct sales team or engage additional independent sales agents. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations, and financial condition.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the United States, there have been and continue to be a number of legislative and regulatory initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce patient access to new technology may limit coverage of or lower reimbursement for the procedures using the aprevo Technology Platform. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

By way of example, in the United States, the ACA made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models and expanded the eligibility criteria for Medicaid programs. There have been executive, judicial, and congressional challenges to certain aspects of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011 (the "Budget Control Act"), among other things, reduced Medicare payments to providers, effective on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or how any future legislation or regulation in the United States may negatively affect our business, financial condition, results of operations, and prospects. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve or maintain profitability, and the availability of capital. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could harm our business.

Our products are regulated as medical devices in the United States. Medical devices and their manufacturers and product developers are subject to extensive regulation in the United States, including by the FDA. The FDA regulates, among other things, with respect to medical devices: design, development, and manufacturing; testing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; establishment registration, and device listing; marketing, sales, and distribution; premarket clearance, classification, and approval or certification; recordkeeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we are subject are complex and burdensome to understand and apply and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs, or lower than anticipated sales. The FDA enforces its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or any of our CMOs will be found compliant in connection with any future FDA or foreign inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; import alerts; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; and, in the most serious cases, criminal penalties.

Failure to maintain marketing authorizations for our products, or to timely obtain necessary marketing authorizations for our future products, may have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the United States, before we can market a new medical device, or a new use of, or other significant modification to, an existing, marketed medical device, we must first receive either clearance under Section 510(k) of the FDCA, approval of a PMA, or grant of a *de novo* classification request from the FDA, unless an exemption applies. In the 510(k)-clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance, and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k)-clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a *de novo* classification request. Despite the time, effort, and cost, a device may not obtain marketing authorization by the FDA. We have obtained 510(k) clearances for our commercialized medical devices, and we must obtain marketing authorization for any future devices we develop, unless they are exempt. Marketing authorizations for any of our future products, if granted, may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

In the United States, any modification to a medical device for which we have obtained marketing authorization may require us to submit a new 510(k) premarket notification and obtain clearance, to submit a PMA and obtain FDA clearance, or to submit a *de novo* request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new clearances or approvals are necessary. We have made and expected to continue making certain modifications or add additional features in the future to our medical devices that we believe do not require a new 510(k) clearance, *de novo* classification request, or approval of a PMA. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA can delay, limit, or deny marketing authorization of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our products are substantially equivalent to a predicate device for their intended uses, or otherwise satisfy applicable requirements for clearance, de novo classification, or approval;
- FDA disagreement with our proposed indications for use, technological characteristics, performance testing strategy, or labeling, including determinations that additional information is required or that a different regulatory pathway is appropriate;
- FDA concerns arising from adverse events, complaints, product performance issues, or other post-market information related to our products or similar products;
- deficiencies in our premarket submissions, including with respect to clinical, non-clinical, bench, software, or other performance data, or the FDA's determination that additional testing or data are necessary;
- the manufacturing process or facilities that we use may not meet applicable requirements, including the QMSR, or the manufacturing processes or facilities of our suppliers or CMOs; and
- the potential for FDA marketing authorization regulations to change significantly in a manner rendering our performance data or regulatory filings insufficient for marketing authorization.

In addition, even though we have received Breakthrough Device Designation and FDA clearance with respect to the development or use of certain patient-specific interbody devices for specific indications in the correction of adult lumbar spinal deformity and degenerative cervical conditions, we can provide no assurances that we will obtain Breakthrough Device Designation or FDA clearance in connection with our future products, which could have an adverse impact on our results of operations. Breakthrough Device Designation provides certain benefits, including more interactive and timely communications with FDA staff, potential use of post-market data collection to facilitate expedited development and review, opportunities for more efficient and flexible clinical study design, and prioritized review of premarket submissions. However, even if we obtain Breakthrough Device Designation for any future product candidate, there can be no guarantee that these benefits will materialize or significantly impact our development and regulatory approval process. We may not experience a faster development process, review, or approval compared to conventional FDA procedures. Breakthrough Device Designation does not alter the regulatory standards for marketing authorization or guarantee that we will ultimately obtain FDA marketing authorization. Furthermore, the FDA may rescind Breakthrough Device Designation if it believes that the designation is no longer supported by data from our clinical development program.

There is risk that future trials and studies of the aprevo Technology Platform may fail to replicate the positive results observed as of the date of this Annual Report. Although our studies to date have involved patient populations which we believe were appropriately sized and which were designed to demonstrate statistical significance against matched cohorts, most such studies were conducted or sponsored by us. Independent studies with larger samples or different designs may not replicate results observed as of the date of this Annual Report. Furthermore, others, including healthcare professionals and regulators, may perceive a conflict of interest with studies supported, sponsored, or funded by us or conducted by our employees or consultants, and may not find results of such studies to be compelling or credible. As a result of the foregoing, we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those that we have planned. The initiation and completion of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in any clinical studies or trials we may conduct for a number of reasons, which could adversely affect the costs, timing, or successful completion of any such clinical studies or trials, including related to the following, to the extent applicable:

- regulators may disagree as to the design or implementation of our clinical studies or trials;
- regulators and or IRBs or other bodies may not authorize us or our investigators to commence a clinical study or trial, or to conduct or continue a clinical study or trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with third-party researchers, clinical sites, or prospective contract research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different researchers, sites, and CROs;
- the number of subjects or patients required for clinical studies or trials may be larger than we anticipate, enrollment in these clinical studies or trials may be insufficient or slower than we anticipate, and the number of clinical studies or trials being conducted at any given time may be high and result in fewer available patients for any given clinical study or trial, or patients may drop out of these clinical trial studies or at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies or trials for various reasons, including occurrence of adverse events or other findings that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical study or trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or other bodies and/or regulatory authorities for re-examination;
- regulators, IRBs, other bodies, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or non-compliance with regulatory requirements;
- the cost of clinical studies or trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical study or trial;
- we may be unable to recruit a sufficient number of clinical sites;
- regulators, IRBs, or other bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies; the supply of devices or other materials necessary to conduct clinical studies or trials may be insufficient, inadequate, or not available at an acceptable cost; or we may experience interruptions in supply;
- marketing authorization or regulations of the FDA may change in a manner rendering our clinical data insufficient for marketing authorization;

- we may be required to submit an investigational device exemption IDE application to the FDA, which must become effective prior to commencing certain human clinical studies or trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical studies or trials, or place restrictions on the conduct of such efforts; similar requirements may apply in foreign jurisdictions; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing authorization of any medical device.

Patient enrollment in clinical studies or trials and completion of patient follow-up, if applicable, depend on many factors, including the size of the patient population, the nature of the protocol, the eligibility criteria for the clinical study or trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product being studied. Patients participating in our clinical studies or trials (if applicable) may drop out before completion or experience adverse medical events unrelated to an investigational device. Delays in patient enrollment or failure of patients to continue to participate in a clinical study or trial may delay commencement or completion of the clinical study or trial, cause an increase in the costs of the clinical study or trial and delays, or result in the failure of the clinical study or trial.

Clinical studies or trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and IRBs, or other bodies at the medical institutions where the clinical studies or trials are conducted. In addition, clinical studies or trials must be conducted with supplies produced under cGMP or similar foreign requirements and other regulations applicable to the location where the clinical study or trial is conducted. We rely on third-party researchers and clinical sites, and may in the future rely on CROs, to ensure the proper and timely conduct of our clinical studies, and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on these third parties to conduct our clinical studies in compliance with the requirements of their medical institutions. To the extent that they fail to enroll participants for our clinical studies, fail to conduct the study to institutional standards, or are delayed for a significant time in the execution of the studies, including achieving full enrollment, we may be affected by increased costs, delays, or both. In addition, if we conduct clinical studies or trials in other countries in the future, we may be subject to further delays and expenses as a result of increased shipment costs and additional regulatory requirements, and the engagement of non-U.S. third-party contractors may expose us to risks associated with clinical investigators who are unknown to the FDA and different standards of diagnosis, screening, and medical care. See the risk factor titled "*If the third parties on which we rely to assist us with premarket development activities for future products do not perform as contractually required or expected, we may not obtain regulatory clearance, approval, or a CE Certificate of Conformity for our future products or be able to successfully commercialize our future products.*"

Interim, "top-line," or preliminary data from clinical studies or trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line, or preliminary data from clinical studies or trials concerning or involving our products, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial or additional data collected at a later time. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same study or trial, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Interim, top-line, or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line, or preliminary data that we previously announced. As a result, interim, and top-line, preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in our share price.

Further, others, including regulatory agencies or other bodies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular study, or the approvability or potential for commercialization of the particular medical device. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. The interim, top-line, or preliminary data that we report may differ from final results, and regulatory authorities and other bodies may disagree with the conclusions reached, which may harm our ability to obtain marketing authorization for, and commercialize, our future products, which could harm our business, financial condition, results of operations, and prospects.

We are subject to ongoing regulatory review and scrutiny. Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

We are subject to ongoing and extensive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, medical device manufacturers must submit certain reports to the FDA and keep required records as a condition of obtaining and maintaining marketing authorization. These reports include information about failures and certain adverse events potentially associated with the device after its marketing authorization. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations, and the FDA and state regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state regulatory authorities, which may include any of the following or other sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees, and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;

- delays in or refusal to grant our requests for future clearances, *de novo* classifications or approvals, or comparable foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of any granted marketing authorizations, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in negative publicity, higher than anticipated costs or lower than anticipated sales, and could have a material adverse effect on our reputation, business, financial condition, results of operations, and prospects.

In addition, the FDA may change its marketing authorization policies affecting future products, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any products under development or impact our ability to modify any products authorized for market on a timely basis. Such changes may also occur in foreign jurisdictions where we may market our products in the future. Such changes could impose additional requirements upon us that could delay our ability to obtain future marketing authorizations, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations that we have obtained. See the risk factor titled "*Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products*."

Our products must be manufactured in accordance with applicable laws and regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's cGMPs for medical devices under 21 CFR Part 820, known prior to February 2026 as the QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. However, on February 2, 2024, the FDA issued a Final Rule to amend the QSR to align more closely with the International Organization for Standardization ("ISO") standards. Specifically, this Final Rule, which became effective on February 2, 2026, replaces the QSR with the Quality Management System Regulation ("QMSR"), and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in FDA's prior QSR, it is unclear the extent to which this Final Rule could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. Furthermore, we are required to verify that our suppliers and third-party manufacturers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces these requirements through periodic announced or unannounced inspections of medical device manufacturing facilities. Our products are also subject to similar state regulations governing manufacturing. In addition, because some of our products include AI-enabled device software functions, FDA's evolving expectations and guidance regarding the use of predetermined change control plans ("PCCPs") for certain anticipated modifications could affect the timing and process for implementing software or algorithm updates and could increase our compliance costs. Further, evolving FDA cybersecurity requirements for certain devices and device software functions, including requirements applicable to "cyber devices" under section 524B of the FDCA, could increase our compliance burden and adversely affect the timing or outcome of FDA review of new or modified products.

Failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions, or civil penalties; suspension or withdrawal of marketing authorizations; voluntary market withdrawals or stock recoveries; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products or similar decisions by foreign regulatory authorities or notified bodies; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims, and we could lose customers and experience reduced sales and increased costs.

aprevo interbody implants may cause or contribute to adverse medical events that we may be required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, results of operations, and prospects. In addition, the discovery of serious safety issues with aprevo interbody implants, or a recall of them either voluntarily or at the direction of the FDA, could have a negative impact on us.

It is possible that there may be side effects and adverse events associated with the use of our medical devices or any future devices we develop. For example, aprevo interbody implants may be rejected by a patient's body, migrate, or fracture, resulting in an adverse event. The FDA's medical device reporting regulations require us to assess reportability of adverse events that come to our attention and report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the event as well as the nature of the event. We may fail to report events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. The FDA may also disagree with our determinations that an event was not reportable. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our marketing authorizations, seizure of our products, or delay in obtaining marketing authorizations for our future products.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found or if we believe that the product could be in violation of the FDCA. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require us to, or we may decide, that we will need to, obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us, and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation, business, financial condition, results of operations, and prospects.

Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any future products under development or impact our ability to modify any products for which we have already obtained marketing authorizations on a timely basis. It is unclear the extent to which any other legislative or regulatory proposal, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, or revisions or reinterpretations of existing regulations may make it more difficult and costly to manufacture, market, or distribute our commercialized products, or may impose additional costs, lengthen marketing authorization review times, or make it more difficult to obtain marketing authorizations for any future products we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel and prevent new or modified products from being developed, reviewed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels; statutory, regulatory, and policy changes; the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees; and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products, or modifications to cleared or approved products, to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed toward reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, the FDA has, at various times, adjusted the timing and manner of domestic and foreign inspections in response to operational disruptions, public health emergencies, travel restrictions, funding constraints, and staffing limitations. If a prolonged government shutdown occurs, or if public health emergencies , funding shortages, or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We face risks related to obtaining necessary foreign marketing authorizations.

Upon our expansion into foreign markets, we will be subject to foreign regulatory requirements that we have limited experience with and vary widely from country to country and from the United States. The time required to obtain authorizations required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory authorizations and may also incur significant costs in attempting to obtain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products in new jurisdictions, or if we fail to receive these approvals, we may be unable to market our products in international markets in a timely manner, if at all, which could materially impact our international expansion and adversely affect our business as a whole. If any of these risks were to materialize, they could limit our expected international growth and profitability, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Failure to comply with the Foreign Corrupt Practices Act (the "FCPA"), economic and trade sanctions regulations, and similar laws could subject us to penalties and other adverse consequences.

We are, or will in the future be, subject to the FCPA and other laws in the United States and elsewhere that prohibit improper payments or offers of payments to foreign governments and their officials and political parties for the purpose of obtaining or retaining business. Certain countries in which we may in the future do business are known to experience corruption. Business activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, contractors, or agents that could be in violation of various laws, including the FCPA and anti-bribery laws in these countries, even though these parties are not always subject to our control. While we have implemented policies and procedures designed to discourage these practices by our employees, consultants, and agents, and to identify and address potentially impermissible transactions under such laws and regulations, we cannot assure you that none of our employees, consultants, or agents will take actions in violation of our policies, for which we may be ultimately responsible.

We are also subject to certain economic and trade sanctions programs that are administered by the U.S. Department of the Treasury's Office of Foreign Assets Control which prohibit or restrict transactions to or from or dealings with specified countries, their governments, and, in certain circumstances, their nationals, and with individuals and entities that are specially designated nationals of those countries, narcotics traffickers, and terrorists or terrorist organizations.

Failure to comply with any of these laws and regulations or changes in this regulatory environment, including changing interpretations and the implementation of new or varying regulatory requirements by the government, may result in significant financial penalties or reputational harm, which could adversely affect our business, financial condition, results of operations, and prospects.

Data Privacy Risk Factors

Actual or perceived failures to comply with applicable data privacy and security laws, regulations, standards, and other requirements could adversely affect our business, financial condition, results of operations, and prospects.

The global data protection landscape is rapidly evolving, and we, and the third-party service providers on which we rely, are or may become subject to numerous U.S., state, federal, and/or foreign laws, requirements, and regulations, in addition to contractual obligations and research protocols governing privacy and data security, including the collection, use, disclosure, retention, processing, maintenance, transfer, and security of personal information, such as information that we and our third-party service providers collect in connection with the use and development of the aprevo Technology Platform and algorithm and in clinical trials or studies, including patient data. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability; or impose additional costs on us. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Our actual or perceived failure to comply with privacy and data security regulation could lead to regulatory inquiries or enforcement actions, litigation, fines and penalties, disruptions to our business operations, reputational harm, loss of revenue business changes or delays, and other adverse business consequences.

In the United States, numerous state and federal laws, regulations, standards, and other legal obligations, including consumer protection laws and regulations, which govern the collection, dissemination, use, access to, confidentiality, security, transfer, disclosure, and processing of personal information and health-related information could apply to our operations or the operations of our partners. For example, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the regulations that implement both laws ("HIPAA"), imposes privacy, security, and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining, or transmitting individually identifiable health information for or on behalf of such covered entities and their covered subcontractors. Among other requirements, HIPAA requires business associates to develop and maintain policies with respect to the protection, use, and disclosure of protected health information ("PHI"), including the adoption of administrative, physical, and technical safeguards that govern the protection of PHI, as well as certain notification requirements in the event of a breach of unsecured PHI (i.e., requirements to report breaches of unsecured PHI to covered entities, affected individuals, and the Department of Health and Human Services, if applicable). Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations.

Further, states continue to adopt new laws or amend existing laws related to data privacy, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA"), gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. As such, the CCPA requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches, which may increase data breach litigation. Additional states, such as Virginia, Colorado, Connecticut, and Utah, have each passed similar comprehensive privacy legislation which imposes similar obligations to those in the CCPA. Further, other states, such as Nevada and Washington, have enacted privacy laws specifically governing consumer health information, with Washington providing for a private right of action. Although many of these laws currently exempt certain health-related information and other personal information that we process, the laws may increase our compliance costs and potential liability related to our data processing activities. Similar laws have been proposed in other states and at the federal level, and, if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

Additionally, the Federal Trade Commission (the "FTC") has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information, or engage in other unfair or deceptive practices that harm customers or that may violate Section 5 of the FTC Act. Further, the FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information that it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce under the FTC Act.

Additionally, we may in the future become subject to rapidly evolving data protection laws, rules, and regulations in foreign jurisdictions, including foreign laws governing the privacy and security of personal data, many of which have developed privacy and data protection requirements that impose requirements that differ from those that apply within the United States. For example, in Europe, the European Union General Data Protection Regulation (the "EU GDPR") governs the collection, use, disclosure, transfer, and other processing of personal data of individuals within the European Economic Area (the "EEA") and imposes stringent requirements for data processors and controllers of such personal data or in the context of their activities within the EEA. Companies that must comply with the EU GDPR face increased compliance obligations and risk, including robust regulatory enforcement of data protection requirements and potential fines for non-compliance of up to €20 million or 4% of the annual global revenues of the non-compliant undertaking, whichever is greater. In addition to fines, a breach of the EU GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), and/or civil claims (including class actions).

The United Kingdom General Data Protection Regulation and Data Protection Act 2018 (the "UK GDPR") imposes separate but similar obligations to those under the EU GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a non-compliant company's global annual revenue for the preceding financial year, whichever is greater.

As we expand into foreign countries and jurisdictions, we will become subject to additional laws and regulations that will affect how we conduct business, and we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. Our operations could suffer additional costs, complaints, and regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Compliance with applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with new data protection rules. Failure or perceived failure to comply with the EU GDPR, the UK GDPR, or any such laws or regulations, to the extent such laws or regulations become applicable to us, would put us at risk of facing significant fines and penalties that could adversely affect our business, financial condition, reputation, and results of our operations. Furthermore, conflicting requirements across applicable privacy and data security laws would complicate our compliance efforts and increase both legal risk and compliance costs for us and the third parties upon whom we rely.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations, research protocols, and other obligations, any actual or perceived failure by us or our employees, representatives, contractors, consultants, or other third parties to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in, among other adverse impacts, damage to our reputation, loss of customer confidence in our security measures, withdrawal or withholding of customer consent for using patient data, government investigations, and enforcement actions and litigation and claims by third parties, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may face risks associated with our use and development of AI models.

We use and develop AI Technologies in our business, and are making significant investments in this area. For example, we use AI Technologies to power the aprevo Technology Platform and drive continuous improvements in the production and performance of the platform. New products that we develop, including expansion into new indications, are also likely to incorporate AI Technologies.

We expect that increased investment will be required in the future to continuously improve our use and development of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining, and deploying these technologies, and there can be no assurance that the usage of or our investments in such technologies will always enhance our products or be beneficial to our business, including our efficiency or results of operations.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased, or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; misused or used outside of scope of applicable regulatory authorizations; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats, or material performance issues, the performance of our products and business, as well as our reputation and the reputations of our customers, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party, regulatory enforcement actions, or civil claims.

With respect to our products or services that incorporate AI Technologies, the market for such products and services is rapidly evolving, and important assumptions about the characteristics of targeted markets, pricing, sales cycles, cost, performance, and perceived value associated with our services or products may be inaccurate. We cannot be sure that the market will continue to grow or that it will grow in ways that we anticipate. In addition, market acceptance and consumer perceptions of products and services that incorporate AI Technologies are uncertain. Our failure to successfully develop and commercialize our products or services involving AI Technologies could depress the market price of our stock and impair our ability to: raise capital; expand our business; provide, improve, and diversify our product offerings; continue our operations and efficiently manage our operating expenses; and respond effectively to competitive developments.

For the aprevo Technology Platform, as well as for any potential future AI Technology-driven products, performance of the algorithms is generally assessed by comparing the output of the algorithms against a clinically derived reference standard ("ground truth") for a specified dataset. This applies to internal evaluation of an algorithm's performance, supporting external presentations and publications, and testing to support regulatory submissions. The aprevo Technology Platform output will not always agree with the opinion of a surgeon or healthcare professional, and in some cases, multiple surgeons will not agree with each other. However, while the AI Technologies we work with are novel and complex, and while we constantly work to improve our products and algorithms, we cannot assure you that our AI Technologies will be able to perform as intended under all circumstances.

If we are deemed to not have sufficient rights to the data we use to train our generative AI Technologies, we may be subject to litigation by the owners of the content or other materials that comprise such data, similar to the litigation that is currently pending in various U.S. courts against other developers of generative AI Technologies, and in which the outcome of such litigation is uncertain. If we are unable to obtain sufficient rights to use such data under applicable regulatory frameworks or our agreements with our customers, or our customers were to withdraw or withhold their data from us, our ability to continue to develop our products and services to our customers, and our revenue prospects, could be materially adversely impacted.

We are in varying stages of development in relation to our products and platforms involving AI Technologies. The continuous development, maintenance, and operation of our AI Technologies is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects, or errors. For instance, the models underlying AI Technologies can experience decay (also known as "model drift") in which its performance and accuracy decreases over time without further human intervention to correct such decay.

We may not be successful in our ongoing development and maintenance of these technologies in the face of novel and evolving technical, reputational, and market factors. Our efforts to develop proprietary AI models could increase our operating costs. Our ability to develop proprietary AI models may be limited by our access to processing infrastructure or training data, and we may be dependent on third-party providers for such resources.

A number of aspects of intellectual property protection in the field of AI and machine learning are currently under development, and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI and machine learning systems and relevant system input and outputs. The law is also uncertain across jurisdictions regarding the copyright ownership of content that is produced in whole or in part by generative AI tools. If we fail to obtain protection for the intellectual property rights concerning our AI Technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products that could adversely affect our business, reputation, and financial condition.

Given the long history of development of AI Technologies, other parties may have (or in the future may obtain) patents or other proprietary rights that would prevent, limit, or interfere with our ability to make, use, or sell our own AI Technologies.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. The FDA has issued guidance documents relating to the incorporation of AI Technologies into medical devices. In addition, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies, or could be rescinded or amended as new administrations take differing approaches to evolving AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet completely determine the impact that future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

Certain existing legal regimes (e.g., relating to FDA submissions or data privacy) regulate certain aspects of AI Technologies, and new laws regulating AI Technologies either entered into force around the globe or are expected to enter into force in the coming years. In the United States, the current Presidential administration rescinded an executive order relating to AI Technologies that was previously implemented by the former Presidential administration. Further, legislation and regulations related to AI Technologies have been contemplated at the federal level and are advancing at the state level. For example, the California Privacy Protection Agency has finalized regulations under the CCPA regarding the use of automated decision-making. The state of California also enacted numerous laws that further regulate use of AI Technologies and provide consumers with additional protections around companies' use of AI Technologies, such as requiring companies to disclose certain uses of generative AI. Other states have also passed AI-focused legislation, such as Colorado's Artificial Intelligence Act, which requires developers and deployers of "high-risk" AI systems to implement certain safeguards against algorithmic discrimination, and Utah's Artificial Intelligence Policy Act, which establishes disclosure requirements and accountability measures for the use of generative AI in certain consumer interactions. Such additional laws may impact our ability to develop, use, and commercialize AI Technologies in the future.

It is possible that further new laws, regulations, and executive orders will be adopted in the United States and in other non-U.S. jurisdictions in which we may in the future do business, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our system and business and the way in which we use AI Technologies. We may need to expend resources to adjust our system in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions, and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our business and operations may suffer in the event of information technology system failures, cyberattacks, or deficiencies in our cybersecurity.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, transmit, and process large amounts of confidential information, including intellectual property, proprietary business information, clinical data, and personal information of clinical study participants, patients, healthcare professionals, consumers, vendors, and our employees and contractors (confidentially, "Confidential Information"). We may also share Confidential Information with our partners or other third parties in conjunction with our business, which we must do in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Our information technology systems and those of our customers, third-party service providers, manufacturers, and other contractors or consultants are vulnerable to attack, damage, and interruption from computer viruses and malware (e.g., ransomware), misconfigurations, "bugs" or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, unauthorized access, fraud, denial or degradation of service attacks, and sophisticated nation-state and nation-state-supported actors. We have also outsourced elements of our information technology infrastructure, and, as a result, a number of third-party vendors may or could have access to our confidential information. There can also be no assurance that our and our customers', third-party service providers', contractors', and consultants' cybersecurity risk management programs and processes, including policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our systems, networks, and Confidential Information.

If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, the costs associated with the investigation, remediation, and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss, or the loss of or damage to intellectual property or other proprietary information. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', and collaborators' cybersecurity risk management program and processes, including policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our systems, networks, and Confidential Information.

We and certain of our customers and service providers may be subject to cyberattacks and security incidents from time to time. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience data security incidents, which, without proper detection, monitoring, and alerting technologies in place, may remain undetected for an extended period. Even if identified, we may face challenges in investigating or remediating data security incidents due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Any adverse impact to the availability, integrity, or confidentiality of our or third-party information technology systems or Confidential Information, whether actual or perceived, could result in liability, legal claims, or proceedings (such as class actions), regulatory investigations and enforcement actions, fines, and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation, and future compliance costs, any of which could materially and adversely affect our business, financial condition, results of operations, and prospects.

While, to date, we have no evidence that we have experienced any significant system failure, accident, or security incident, if such an event were to occur and cause interruptions to our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure or misappropriation of our trade secrets, personal information, patient data collected from our customers, or other Confidential Information or other similar disruptions. It could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could require us to devote significant financial and other resources to address and mitigate such incident, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical and technical safeguards, further training of employees, evaluating, and, if needed, altering third-party vendor control practices, and engaging third-party subject matter experts and consultants to address any such incident. If a security incident were to result in the unauthorized access to or unauthorized use, disclosure, release, or other processing of personal information, including the patient data of our customers, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws and the costs associated with the investigation, remediation, and potential notification of the incident to third parties and data subjects could be material. For example, in the United States, all 50 states and several territories have laws requiring entities to notify individuals, and, in most jurisdictions, regulators, of security incidents of information involving certain personal information.

Notifications and responsive actions related to a data security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any data breach, disruption, or security incident were to result in any loss, destruction, or alteration of, damage, unauthorized access to, or inappropriate or unauthorized disclosure or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, we could be exposed to litigation and governmental investigations and inquiries, the further development and commercialization of our products could be delayed, and we could be subject to significant fines or penalties for any non-compliance with applicable state, federal, and foreign privacy and security laws, rules, regulations, and standards.

Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security incidents to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our customers and service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks), and the mishandling of data, then our reputation, business, financial condition, results of operations, and prospects could be materially and adversely affected.

Risks Related to Our Intellectual Property

Our success will depend on our ability to obtain, maintain, enforce, and protect our intellectual property rights.

Our success and ability to compete depends in part on our ability to obtain, maintain, enforce, and protect issued patents, trademarks, trade secret, and other intellectual property rights and proprietary technology in the United States and elsewhere. If we cannot adequately obtain, maintain, and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses. We generally seek to protect our proprietary position by filing patent applications that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications or other intellectual property or proprietary rights from third parties. If we are unable to obtain or maintain patent protection with respect to any proprietary technology, our business, financial condition, results of operations, and prospects could be materially harmed.

We rely on a combination of contractual provisions, confidentiality procedures, and patent, trademark, copyright, trade secret and other intellectual property laws to protect the proprietary aspects of the aprevo Technology Platform, our aprevo interbody implants, software, brand, technologies, trade secrets, know-how, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property rights and proprietary information. In addition, although various extensions may be available, the term of a patent, and the protection it affords, is limited. In the United States, for example, the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Even if patents covering our technologies or products are obtained, once the patent term has expired, we may be open to competition. In addition, although upon issuance in the United States, a patent's term can be increased based on certain delays caused by the U.S. Patent and Trademark Office (the "USPTO"), this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Our success will also depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how, and obtaining, maintaining, and enforcing other intellectual property rights. We may not be able to obtain, maintain, and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

The patent prosecution process is expensive, time consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Moreover, pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover relevant product, service, or the technology. There can be no assurance that our current or future patent applications will result in patents being issued or that our issued patents will afford sufficient protection against competitors or other third parties with similar products, services, or technologies competitive with ours, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our intellectual property or other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property or other proprietary rights relating to our products, services, and technologies could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications, and patent applications in certain foreign territories will be considered patentable by the USPTO courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged. Our ability to obtain and maintain valid and enforceable patents depends in part on whether our inventions are eligible for patent prosecution and, if so, whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Additionally, regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our products, services, technologies, or activities. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or in-licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Failure to obtain, maintain, and/or enforce intellectual property rights necessary to our business and failure to protect, monitor, and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we may in the future depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our patents, trademarks, data, technology, and other intellectual property rights by others, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated by others.

The degree of future protection for our intellectual property rights is uncertain, and we cannot ensure that:

- others will not develop, manufacture, and/or commercialize similar or alternative products, services, or technologies that do not infringe, misappropriate, or violate any patents or other intellectual property rights that we own or have rights to;
- any patents issued to us will provide a basis for an exclusive market for our products, services, or technologies; will provide us with any competitive advantages; or will not be challenged, invalidated, modified, revoked, or circumvented by third parties;
- any of our challenged patents will ultimately be found to be valid and enforceable;
- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products, services, or technologies;
- any of our pending patent applications will issue as patents;
- we will be able to successfully develop, manufacture, and commercialize our products, services, or technologies on a substantial scale before relevant patents we may have expire;

- we were the first to make the inventions covered by each of our patents and pending patent applications, or we were the first to file patent applications for such inventions;
- we will develop additional proprietary inventions, products, services, or technologies that are separately patentable; or
- our commercial activities, products, services, or technologies will not infringe upon the patents of others.

If we fail to identify our patentable inventions or adequately protect our patent rights, the commercial value of our products, services, or technologies may be adversely affected, and our competitive position may be harmed.

We rely in part on our portfolio of issued patents and pending patent applications in the United States and other countries to protect our intellectual property and competitive position. However, it is also possible that we may fail to identify patentable aspects of inventions made in the course of the development, manufacture, and commercial activities conducted by or on behalf of us before it is too late to obtain patent protection on such inventions. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee of a third party's patents or patent applications, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained, and/or enforced in a manner consistent with the best interests of our business. While we expect that we will generally apply for patents in commercially significant countries other than the United States, where we will intend to make, use, import, offer for sale, or sell our products or services, or otherwise practice our technology, we may not accurately predict all of the countries where patent protection will ultimately be desirable. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from importing, using, manufacturing, and/or commercializing our own products or services, or otherwise practicing our own technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue; the breadth of any resulting patent; whether any of the issued patents will be found to be infringed, invalid, or unenforceable, or will be threatened or challenged by third parties; or which of our issued patents have, or whether any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products, services, or technology. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our issued patents will be sufficient to stop a competitor from developing, manufacturing, and commercializing one or more products, services, or technologies in a non-infringing manner that would be competitive with one or more of our products, services, or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed, or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we own or in-license may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

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

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

Changes in U.S. or foreign patent laws or their interpretations could diminish the value of our patents in general, thereby impairing our ability to protect our current and future products, services, or technologies, and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.

Our ability to obtain patents and the breadth of any patents obtained are uncertain in part because, as of the date of this Annual Report, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other countries. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products, services, and technologies.

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on actions by the U.S. congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business, financial condition, results of operations, and prospects.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. We cannot predict future changes in the interpretation of patent laws in the United States and other countries or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

In June 2023, the European Unitary Patent system and the European Unified Patent Court (“UPC”) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent, which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice and deciding whether to opt in or opt out of Unitary Patent practice entails strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt in or opt out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

The legal systems in certain countries may also favor state-sponsored or companies headquartered in particular jurisdictions over our first-in-time patents and other intellectual property protection. We are aware of incidents where such entities have stolen the intellectual property of domestic companies in order to create competing products, and we believe that we may face such circumstances ourselves in the future. For example, through its “Annual Special 301 Report on Intellectual Property,” the Office of the United States Trade Representative has been reporting on the adequacy and effectiveness of intellectual property protection in a number of foreign countries that are U.S. trading partners and their protection and enforcement of intellectual property rights. Placement of a country on the Priority Watch List indicates that particular problems exist in that country with respect to intellectual property protection, enforcement, or market access for persons relying on intellectual property rights. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the specific problem areas. It is possible that we will not be able to enforce our intellectual property rights against third parties that misappropriate our proprietary technology in those countries.

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

Filing, prosecuting, and defending patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and the requirements for patentability may differ in certain countries, particularly in developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, services, or technologies and, further, may export otherwise infringing products, services, or technologies to territories where we have patent protection, including importing competing products or transmitting competing technology into the United States. Patent enforcement in foreign jurisdictions is often not as strong as that in the United States. These products, services, or technologies may compete with our products, services, or technologies, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

Various companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries may not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices and related services and technologies, which could make it difficult for us to stop the infringement of our patents or marketing of competing products, services, and technologies in violation of our intellectual property and proprietary rights. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than the United States, including, for example, imposing a high standard for making claim amendments and for the submission of supplemental experimental data during patent examination. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions, even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent rights at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Various countries outside the United States, including certain countries in Europe, India, and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner in such countries may have limited remedies in certain circumstances, which could materially diminish the value of such patent. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied predictably. As such, we do not know the degree of worldwide uniform protection that we will have on our technologies and products in the future.

If we cannot successfully enforce our intellectual property rights, the commercial value of our products, services, or technologies may be adversely affected, and our competitive position may be harmed.

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate, or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming, and unsuccessful. We regularly monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek to enforce our rights against potential infringement, misappropriation, or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation, or violation of our intellectual property rights. In certain circumstances, it may not be practicable or cost effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products, services, or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product, services, or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products, services, and technologies. We may in the future become involved in lawsuits to protect or enforce our intellectual property rights. An adverse result in any litigation proceeding could harm our business. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to stop the other party from manufacturing, commercializing, using, or importing the product, service, offering, or technology at issue on grounds that our intellectual property rights do not cover, and the other party is not infringing, violating, or otherwise misappropriating our intellectual property, through the manufacture, commercialization, use, or importation of the product, service, offering, or technology in question. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us, alleging that we infringe, misappropriate, or otherwise violate their intellectual property rights. If we initiate legal proceedings against a third party to enforce a patent covering a product, service, offering, or technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Mechanisms for such challenges include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In a patent or other intellectual property proceeding, a court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly, or refuse to stop the other party from manufacturing, commercializing, using, or importing the product, service, offering, or technology at issue on the grounds that our patents or other intellectual property do not cover the manufacture, commercialization, use, or importation of the product, service, offering, or technology in question. Furthermore, even if our patents or other intellectual property rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead may grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business, financial condition, results of operations, and prospects. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time consuming, and unsuccessful, and could interfere with our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

Our commercial success depends, in part, on our ability to develop, manufacture, commercialize, import, or use our products, services, and technologies without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. Our industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. While we take steps to ensure that we do not infringe upon, misappropriate, or otherwise violate the intellectual property rights of others, there may be other more pertinent rights of which we are presently unaware.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights. The outcomes of such proceedings are uncertain and could have a negative impact on the success of our business. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products, services, and technologies, or that we may be accused of misappropriating third parties' trade secrets or infringing third parties' trademarks. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products, services, or technologies, including interference proceedings, post-grant review, and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Furthermore, we may also become involved in other proceedings, such as reexamination, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents, which our current or future products, services, or technologies infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe.

There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe that such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid and enforceable, and infringed by the use of our products, services, or technologies, which could have a negative impact on the commercial success of our current and any future products, services, or technologies. If we were to challenge the validity of any such third party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third-party claim of patent infringement.

Our defense of any litigation or interference proceedings may fail, and, even if successful, defending such claims brought against us would cause us to incur substantial expenses and distract our management and other employees. If such claims are successfully asserted against us, we could be forced to pay substantial damages. Further, if a patent infringement or other intellectual property rights-related lawsuit were brought against us, we could be forced, including by court order, to cease developing, manufacturing, commercializing, importing, or using the infringing product, service, or technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Although patent, trademark, trade secret, and other intellectual property disputes have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may not be able to obtain licenses on commercially reasonable terms or at all, in which event, our business would be materially and adversely affected. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors and other third parties gaining access to the same intellectual property. Ultimately, if we are unable to obtain such licenses or make any necessary changes to our products, services, or technologies, we could be forced to cease some aspect of our business operations, which could harm our business significantly.

A finding of infringement or an unfavorable interference or derivation proceedings outcome could prevent us from developing, manufacturing, commercializing, importing, or using our products, services, or technologies, or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. We could encounter delays in product introductions while we attempt to develop alternative products or technologies.

If third parties assert infringement, misappropriation, or other claims against our customers, these claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products, services, or technologies they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, services, or technologies.

Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, import, and/or export our products, services, or technologies. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us may increase. Moreover, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," purchase patents, and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices, or "invitations to license," or may be the subject of claims that our products, services, or technologies and business operations infringe, misappropriate, or otherwise violate the intellectual property rights of others. These matters can be time consuming, be costly to defend in litigation, divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. In addition, we purchase equipment or materials, including hardware and software, from suppliers, and the design of these equipment or materials may be outside of our direct control. These suppliers may not indemnify us in the event that a third party alleges that the use of such components infringes its intellectual property rights.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our intellectual property. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop developing, making, selling, importing, or using products, services, or technologies that allegedly infringe, misappropriate, or otherwise violate the asserted intellectual property right;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating;
- redesign those products, services, or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive, and infeasible; and attempt to obtain a license to the relevant intellectual property rights from third parties, which may not be available on commercially reasonable terms or at all, or from third parties who may attempt to license rights that they do not have;
- lose the opportunity to license our intellectual property rights to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses; or
- pay the attorneys' fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating.

Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products, services, or technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products, services, or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, even if resolved in our favor, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property rights.

We may also be subject to claims that our current or former employees, contractors, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants, or others who were or are involved in developing our products, services, or technologies. Although it is our policy to require our employees and contractors who may be involved in the conception or development of inventions to execute agreements assigning such inventions and intellectual property rights therein to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops inventions that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of inventions may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership of inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property rights, and other owners may be able to license their interest in such intellectual property rights to other third parties, including our competitors. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, we may be subject to claims from third parties challenging inventorship or ownership of intellectual property rights that we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign their inventions and intellectual property rights therein to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights therein to another employer, to a former employer, or to another person or entity. Many of our current and former employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees and consultants have executed with such previous employment or engagements confidential information non-disclosure and non-use agreements and inventions assignment agreements, which may have included non-competition provisions. Although we try to ensure that such employees and consultants do not use or otherwise disclose confidential information or intellectual property rights of others in their work for us without such other person's consent, we may be subject to claims that we or our current or former employees or consultants have, inadvertently or otherwise, infringed, violated, or otherwise misappropriated the confidential information or the intellectual property rights of these former employers, clients, or other third parties. To the extent that our current or former employees or consultants disclose or use confidential information or intellectual property rights owned by others in their work for us, disputes may arise as to the rights in any related or resulting inventions, and litigation may be necessary to defend against these claims. It may also be necessary, or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim; however, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from manufacturing, commercializing, using, or importing the product, service, or technology features or practicing other intellectual property rights that are essential to our business, which could have a material adverse effect on our competitive position as well as our business, financial condition, results of operations, and prospects. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and our employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with collaborators, partners, services providers, or contractors. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture, commercialize, import, or use our products, services, or technologies, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

We depend on certain intellectual property rights that are licensed to us. We may be unsuccessful in licensing or acquiring intellectual property rights from third parties that may be necessary to develop, manufacture, commercialize, import, or use our current and/or future products, services, or technologies.

We make use of a certain computer code, which we in-license and use in the aprevo Technology Platform development process. Our rights to use such intellectual property rights in our business are subject to the continuation of and our compliance with the terms of the software license agreements between us and each of our licensors. In addition, the agreements under which we in-license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have in-licensed, or in-license in the future, prevent, or impair our ability to maintain our current or future licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology generated or covered by these license agreements. If these in-licenses are terminated, this could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development, manufacture, commercialization, import, or use of our current and/or future products, services, or technologies, in which case, we would need to acquire or obtain a license to such intellectual property rights from such third party. A third party that perceives us to be a competitor may be unwilling to license or assign its intellectual property rights to us. In addition, the licensing or acquisition of third-party intellectual property rights is a competitive area, and other companies may also pursue similar strategies to license or acquire such third party's intellectual property rights. Some of these companies may have a competitive advantage over us due to their size, capital resources and greater development, manufacturing, and commercialization capabilities. We also may be unable to license or acquire third party intellectual property rights on commercially reasonable terms that would allow us to make an appropriate return on our investment, or we may be unable to obtain any such license or acquire such intellectual property rights at all. If we are unable to successfully license or acquire necessary third-party intellectual property rights, we may not be able to develop, manufacture, commercialize, or use our current and/or future products, services, or technologies, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to protect the disclosure and use of our confidential information and trade secrets, the value of our products, services, and technologies and our business and competitive position could be harmed.

In addition to patent protection, we also rely on other intellectual property rights, including trade secrets, know-how, and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To protect and maintain the confidentiality of our trade secrets and other proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, and other third parties. We generally enter into confidentiality and/or inventions assignment agreements with our employees, consultants, and applicable third parties upon their commencement of a relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and we may not enter into such agreements with all employees, consultants, and third parties who have been involved in the development of our inventions. Although we generally require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets.

In addition, despite the protections that we place on our intellectual property and our other proprietary rights, monitoring unauthorized use and disclosure by employees, consultants, and other third parties who have access to such intellectual property or other proprietary rights is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors, or third parties, despite the existence of our protections, including non-disclosure and use restrictions. These agreements may not provide meaningful protection against the unauthorized disclosure or use of our trade secrets, know-how, or other proprietary information in the event that the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how or other proprietary information that we fail to detect. There can be no assurances that such employees, consultants, advisors, or third parties will not intentionally or unintentionally breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by third parties, including our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that information to compete with us. In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant, or other third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, consultant, or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition, results of operations, and prospects. In particular, a failure to protect our proprietary rights may allow competitors to copy our products, services, or technologies, which could adversely affect our pricing and market share. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products, services, or technologies that we consider proprietary. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality, non-disclosure, and non-use provisions, and outcomes of such litigation are unpredictable. Enforcing a claim that a party illegally disclosed, used, or misappropriated a trade secret can be difficult, expensive, and time consuming, and the outcome is unpredictable. While we use commonly accepted security measures, trade secret protections are often a combination of federal and state laws in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, we may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Some courts outside of the United States are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable at all in certain cases. Finally, even if we were to be successful in the enforcement of our claims, we may not be able to obtain adequate remedies.

It is also possible that others may independently develop information or technologies that are the same as or similar to our trade secrets or other proprietary technologies without obtaining access to our trade secrets or other proprietary information, in which case we could not assert any intellectual property rights, including trade secret rights, against such parties in a manner that would allow for legal recourse by us. If we fail to obtain or maintain trade secret protection, or if any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or used by others without our consent or otherwise misappropriated, or if any such information was independently developed by a competitor, or if our competitors obtain our trade secrets or independently develop products, services, or technologies that are the same as or similar to ours, our competitive market position could be materially and adversely harmed.

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

Our trademarks could be challenged, opposed, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, be declared generic or descriptive, or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our company, products, services, or technologies, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We rely on our trademarks, trade names, and brand names, such as our aprevo mark, to distinguish our products, services, and technologies from the products, services, and technologies of our competitors, and have registered or applied to register many of these trademarks in the United States and certain countries outside the United States; however, we have not yet registered all of our trademarks in the United States and other potential markets. There can be no assurance that all of our trademark applications will be approved for registration. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties have opposed, and may in the future oppose, our trademark applications and may seek to cancel trademark registrations or otherwise challenge our use of the trademarks. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. While we may be able to continue the use of our trademarks in the event that registration is not available, particularly in the United States, where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court. IIf we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Our products contain third-party open-source software components, and failure to comply with the terms of the underlying open-source software licenses could restrict our ability to sell our products, affect our ability to protect our proprietary information, and subject us to possible litigation.

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

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

Risks Relating to Financial and Accounting Matters

Our ability to use our net operating loss carryforwards and other tax attributes may be limited due to certain provisions of the Internal Revenue Code of 1986, as amended, or state tax law.

We have incurred substantial losses during our history and may never achieve profitability. U.S. federal net operating loss carryforwards ("NOLs") may be carried forward indefinitely, but may only be used to offset 80% of our taxable income annually for tax years beginning after December 31, 2017. As of December 31, 2025, we had NOLs of approximately $69.0 million for federal income tax purposes and $57.6 million for state income tax purposes. Realization of these NOLs depends on future taxable income, and there is a risk that our existing NOLs for state income tax purposes could expire unused and be unavailable to offset future state taxable income, which could adversely affect our results of operations.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change federal NOLs and other tax attributes (such as tax credits) to offset its post-change taxable income and taxes may be limited. In general, an "ownership change" occurs if there is a greater than 50 percentage-point change (by value) in a corporation's equity ownership by certain stockholders over the testing period, which is generally the three-year period preceding any potential ownership change. The completion of our initial public offering, together with any private placements and other transactions that have occurred since our inception, may result in an ownership change. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, our ability to use pre-change federal NOLs and other tax attributes to offset future taxable income and taxes could be subject to limitations. Similar provisions of state tax law may also apply. For these reasons, even if we achieve profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations, or rates; structural changes in our business; new accounting pronouncements or changes to existing accounting pronouncements, non-deductible goodwill impairments; changing interpretations of existing tax laws or regulations; changes in the relative proportions of revenue and income before taxes in the various jurisdictions in which we operate that have different statutory tax rates; the future levels of tax benefits of equity-based compensation; changes in overall levels of pretax earnings; or changes in the valuation of our deferred tax assets and liabilities. Additionally, we could be challenged by state and local tax authorities as to the propriety of our sales tax compliance, and our results could be materially impacted by these compliance determinations.

Changes in tax laws or tax rulings could adversely affect our effective tax rates, results of operations, and financial condition.

Tax laws, regulations, and administrative practices in various jurisdictions are evolving and may be subject to significant changes due to economic, political, and other conditions. Changes in tax laws or treaties, issuance of new tax rulings, or changes in interpretations of existing laws could cause us to be subject to additional income-based taxes and non-income-based taxes, including payroll, sales, use, value-added, digital, net worth, property, and goods and services taxes, which in turn could adversely affect our results of operations and financial condition. These factors, together with the ambiguity of tax laws and regulations, the subjectivity of factual interpretations, and uncertainties regarding the geographic mix of earnings in any period, can affect our estimates of our effective tax rate and income tax assets and liabilities, result in changes in our estimates and accruals, and have a material adverse effect on our business results, cash flows, or financial condition. We are unable to predict what tax reforms may be proposed or enacted in the future or what effect such changes would have on our business, but such changes could potentially result in higher tax expense and payments, along with increasing the complexity, burden, and cost of compliance.

Our tax burden could increase as a result of ongoing or future tax audits.

We may be subject to periodic tax audits by tax authorities. Tax authorities may not agree with our interpretation of applicable tax laws and regulations. As a result, such tax authorities may assess additional tax, interest, and penalties. We regularly assess the likely outcomes of these audits and other tax disputes to determine the appropriateness of our tax provision and establish reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of any tax audit or other tax dispute or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves. As such, the actual outcomes of these disputes and other tax audits could have a material adverse effect on our business results or financial position.

The terms of the Customers Loan Agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility.

We are party to the Customers Loan Agreement with Customers Bank. As of December 31, 2025, $15.6 million in aggregate principal amount of the Term Loan was outstanding under the Customers Loan Agreement.

The Customers Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions, as well as financial covenants requiring us to maintain at least $20.0 million in unrestricted cash with the lender and to comply with certain minimum revenue amounts. These covenants limit our ability to, among other things:

- sell, transfer, lease, or dispose of our assets subject to certain exclusions;
- create, incur, assume, guarantee, or assume additional indebtedness, other than certain permitted indebtedness;
- encumber or permit liens on any of our assets other than certain permitted liens;
- make restricted payments, including paying dividends on, repurchasing, or making distributions with respect to any of our capital stock;
- make specified investments;
- consolidate, merge with, or acquire any other entity, or sell or otherwise dispose of all or substantially all of our assets; and
- enter into certain transactions with our affiliates.

See the section under Part II. Item 7. titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations— Liquidity and Capital Resources*" for more information regarding the covenants under the Customers Loan Agreement. The covenants in the Customers Loan Agreement limit our ability to take certain actions and, in the event that we breach one or more covenants, the lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding of the aggregate principal amount, plus accrued interest, and foreclose on the collateral granted to it to secure such indebtedness. Such repayment could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our cash deposits with financial institutions exceed insured limits.

We maintain the majority of our cash and cash equivalents in accounts with one or more U.S. financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of financial institutions. There is no guarantee that, in the event of the closure of banks or financial institutions in the future, depositors would be able to access uninsured funds or that they would be able to do so in a timely fashion. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner, or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial condition.

Risks Relating to Ownership of Our Common Stock

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an "emerging growth company" until the earliest to occur of:

- the last day of the fiscal year during which our total annual revenue equals or exceeds $1.235 billion (subject to adjustment for inflation);
- the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering ("IPO");
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

As a result of our "emerging growth company" status, we may take advantage of exemptions from various reporting requirements that would otherwise be applicable to public companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We also are a "smaller reporting company" as defined in the Exchange Act. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less-active trading market for our common stock, and the market price of our common stock may be adversely affected and more volatile.

We incur increased costs and are subject to additional regulations and requirements as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We have also incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and the exchange on which our securities are listed. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing.These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors (the "Board of Directors"), on our board committees, or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action, and potentially civil litigation.

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

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second annual report on Form 10-K, we will be required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to the rules and regulations of the SEC regarding compliance with Section 404 of the Sarbanes-Oxley Act. The process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly, and complicated. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. Further, if we identify one or more material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we, or if required, our auditors, are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which could require additional financial and management resources. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our Board of Directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, prospects, financial condition, contractual restrictions, and capital requirements. In addition, our ability to pay cash dividends on our capital stock is limited by the terms of the Customers Loan Agreement and may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into. Accordingly, investors must for the foreseeable future rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

If our operating and financial performance in any given period does not meet the guidance provided to the public or to the expectations of investment analysts, the market price of our common stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to the risks and uncertainties described in this Annual Report and in our other public filings and public statements. The ability to provide this public guidance, and the ability to accurately forecast our results of operations, will be impacted by a number of factors, many of which are out of our control. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic or regulatory uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance provided or the expectations of investment analysts or investors generally, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future.

Future sales and issuances of our securities, including to support business growth or pursuant to our equity incentive plans, may cause dilution to our stockholders or decrease our stock price.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and opportunities, including the need to develop new products, enhance our existing products, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. In order to achieve these objectives, we may make future commitments of capital resources. Accordingly, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. In addition, the incurrence of indebtedness would increase our fixed obligations and include covenants or other restrictions that would impede our ability to manage our operations. Further, if additional financing is needed, we may not be able to obtain additional financing on terms favorable to us or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and responding to business challenges and opportunities.

Furthermore, pursuant to our 2025 Equity Incentive Plan (the "2025 Plan"), our management is authorized to grant stock options, restricted stock units and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2025 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2026 and continuing through and including January 1, 2035, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our Board of Directors. In addition, pursuant to our 2025 Employee Stock Purchase Plan (the "2025 ESPP"), the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2026 and continuing through and including January 1, 2035, by 1% of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of the automatic increase or a lesser number of shares determined by our Board of Directors. Unless our Board of Directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2025, our executive officers, directors, owners of more than 5% of our capital stock, and their respective affiliates beneficially owned approximately 66.3% of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or change in our management without the consent of our Board of Directors. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board of Directors;

- provide that our Board of Directors will be classified into three classes of directors, divided as nearly as equal in number as possible;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors constituting the Board of Directors, and not by our stockholders; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

In addition, we are also subject to the anti-takeover provisions contained in Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the Board of Directors has approved the transaction.

Claims for indemnification by our directors, officers, and other employees or agents may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. We also maintain customary directors' and officers' liability insurance.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors, officers, and certain other employees provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner that such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our Board of Directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaws provisions to reduce our indemnification obligations to directors, officers, employees, and agents.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or stockholders to us or to our stockholders, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time), or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States is the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees, or agents and arising under the Securities Act of 1933, as amended (the "Securities Act"). Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware (a "Foreign Action"), in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

We believe that these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums, and protection against the burdens of multi-forum litigation. However, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, results of operations, and prospects.

The market price of our common stock may be volatile, which could cause the value of your investment to decline.

The market price of our common stock may be highly volatile and could be subject to wide fluctuations. Securities markets worldwide experience significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions, could reduce the market price of our common stock regardless of our operating performance. In addition, our results of operations could be below the expectations of public market analysts and investors due to a number of potential factors, including variations in our quarterly results of operations, additions or departures of key management personnel, failure to meet analysts' earnings estimates, publication of research reports about our industry, litigation and government investigations, data privacy and security-related events, changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business, adverse market reaction to any indebtedness we may incur or securities we may issue in the future, changes in market valuations of similar companies or speculation in the press or investment community, announcements by our competitors, adverse publicity about the medical device industry, or individual scandals, and, in response, the market price of our common stock could decrease significantly.

Stock markets experience extreme price and volume fluctuations. In the past, following periods of volatility in the overall market and the market price of a company's securities, securities class action litigation has often been instituted against these companies. Such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced, in part, by the research and reports that industry or securities analysts publish about us or our business. Because we became a public company relatively recently, we may be slow to attract research coverage by securities and industry analysts. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

General Risk Factors

If we engage in acquisitions or strategic partnerships, it may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary offerings, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property, and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing operations in pursuing such a strategic merger or acquisition;
- loss of key personnel and uncertainties in our ability to maintain key business relationships;
- uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or future products and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition or partnership opportunities, and even if we do locate such opportunities, we may not be able to successfully bid for or obtain them due to competitive factors or lack of sufficient resources. This inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We or the third parties we depend on may be adversely affected by natural disasters and other catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious natural disaster or other catastrophic event. Any interruption in our operations or the operations of our CMOs may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Severe weather, natural disasters, and other catastrophic events, including pandemics or other public health crises, earthquakes, tsunamis, hurricanes, floods, fires, explosions, accidents, power outages, cyberattacks, telecommunications failures, mechanical failures, unscheduled downtimes, civil unrest, strikes, transportation interruptions, unpermitted discharges or releases of toxic or hazardous substances, other environmental risks, wars or other conflicts (including conflicts in Ukraine and the Middle East), sabotage, terrorist attacks, or other intentional acts of vandalism or misconduct could severely disrupt our operations, or the operations of our CMOs, and have a material adverse effect on our business, financial condition, results of operations, and prospects.

If a natural disaster or other catastrophic event occurs that prevents us or our CMOs from using all or a significant portion of our or their headquarters or other facilities, that damages critical infrastructure, or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar catastrophic event. The potential impact of any disruption would depend on the nature and extent of the damage caused by a disaster. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, our corporate headquarters and one of our CMO's facilities are located in Carlsbad, California, near major earthquake faults and fire zones. We do not carry earthquake insurance. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to risks from legal and arbitration proceedings that may prevent us from pursuing our business activities or require us to incur additional costs in defending against claims or paying damages.

We may become subject to legal disputes and regulatory proceedings in connection with our business activities involving, among other things, product liability, product defects, intellectual property infringement, employment matters, and/or alleged violations of other applicable laws in various jurisdictions. We may not be insured against all potential damages that may arise out of any claims to which we may be party in the ordinary course of our business. A negative outcome of these proceedings may prevent us from pursuing certain activities and/or require us to incur additional costs in order to do so and pay damages. In addition, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, results of operations, and prospects. Additionally, the significant increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

The outcome any potential future legal and arbitration proceedings is difficult to predict with certainty. In the event of a negative outcome of any material legal or arbitration proceeding, whether based on a judgment or a settlement agreement, we could be obligated to make substantial payments, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, the costs related to litigation and arbitration proceedings may be significant, and any legal or arbitration proceedings could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports that we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement, causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our insurance may not cover all potential losses or liabilities that may arise.

We are not insured against all potential losses or liabilities that may arise, as insurance coverage may be unavailable, not cost-effective, or subject to significant limitations. For example, we are not insured against business interruptions suffered by third parties that we depend on, environmental liabilities, or patent infringement, among other types of risks. Furthermore, no assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. If a loss or liability occurs that is not fully covered by insurance, we may be required to pay substantial amounts, which could adversely affect our cash position and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have established processes designed to identify, assess, and manage risks from cybersecurity threats that could affect our information systems, products, operations, or sensitive data. These processes are integrated into our broader enterprise risk management framework and are intended to help protect the confidentiality, integrity, and availability of our information assets.

Our cybersecurity risk management program includes, among other things, risk assessments, employee training, incident response planning, and the use of technical safeguards designed to prevent, detect, and respond to cybersecurity incidents. We also engage third-party service providers to support certain aspects of our information technology infrastructure and evaluate cybersecurity risks associated with such third parties as part of our vendor management processes.

We design our cybersecurity and data protection practices to support compliance with applicable data protection regulations. Our information security program is aligned with recognized industry standards and frameworks, including ISO/IEC 27001, which informs our policies, procedures, and controls for managing information security risks. We are in the process of implementing additional controls and documentation as part of an effort to achieve ISO/IEC 27001 certification; however, we cannot provide assurance regarding the timing or outcome of such certification efforts.

We face cybersecurity risks common to companies in our industry, including risks related to unauthorized access to proprietary information, patient or customer data, intellectual property, and disruptions to business operations. While we believe our processes are designed to reduce cybersecurity risks, compliance with regulatory requirements and alignment with industry standards do not eliminate these risks, and we may not be able to anticipate or prevent all cybersecurity incidents.

Governance

Management is responsible for the day-to-day oversight and implementation of our cybersecurity risk management processes. This oversight is led by the office of Chief Technology Officer (CTO) and the members of the information technology and security functions, who have relevant experience managing information security and technology risks. These individuals coordinate cybersecurity efforts across the organization, including incident response planning, risk assessments, and employee awareness initiatives, and report relevant matters to senior management and the Board as appropriate.

Our Board of Directors is responsible for overseeing our risk management processes and has delegated to the audit committee of our Board of Directors (the "Audit Committee") oversight of management’s implementation of our cybersecurity risk management policies, strategies and mitigation measures. The Audit Committee receives periodic updates from management regarding cybersecurity risks, incidents (if any), and mitigation efforts.

Cybersecurity Incidents

As of the date of this Annual Report, we have not identified any cybersecurity incidents that have materially affected, or are reasonably likely to materially affect our business strategy, results of operations, or financial condition. However, we cannot provide assurance that future cybersecurity incidents will not have a material impact on the Company.

Item 2. Properties.

Our corporate headquarters is in Carlsbad, California, where we lease a facility totaling approximately 23,000 rentable square feet under a lease agreement that expires on June 30, 2028.

Our existing facility will continue to support our research and development, finance, marketing, and administrative teams. We believe that our existing facility is adequate for our current needs and that suitable additional or alternative space would be available for lease, if and when required, on commercially reasonable terms.

Item 3. Legal Proceedings.

For discussion regarding legal proceedings, please refer to "Note 9 – Commitments and Contingencies" in the accompanying notes to our Financial Statements included elsewhere in this Annual Report.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "CARL".

Holders of Record

As of February 23, 2026, there were approximately 79 registered holders of record of our common stock. The actual number of holders is greater than this number and includes stockholders who are beneficial owners but whose shares are held in "street name" by banks, brokers, and other financial institutions. This number of record holders also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. The terms of the Customers Loan Agreement also limit our ability to pay dividends, and we may enter into additional credit agreements or other borrowing arrangements in the future that may restrict our ability to declare or pay cash dividends on our capital stock. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on our results of operations, financial condition, capital requirements, and other factors deemed relevant by our Board of Directors.

Use of Proceeds from our Initial Public Offering

On July 24, 2025, we completed our IPO, in which we issued and sold 6,700,000 shares of our common stock, at a price to the public of $15.00 per share. The net proceeds to the Company from the IPO were approximately $88.1 million, after deducting underwriting fees and offering costs.

The net proceeds from our IPO have been used and will be used, together with our existing cash and cash equivalents: (i) to support the commercialization of the aprevo Technology Platform and expand and improve our product offerings, including approximately $25 million to support our increased sales and marketing efforts and approximately $46 million to fund our research and development activities to advance the aprevo Technology Platform, including the continued development of the aprevo Technology Platform for use in cervical spine fusion surgeries, and (ii) the remainder for working capital and general corporate purposes.

There has been no material change in the intended use of proceeds from our IPO as described in our prospectus dated July 22, 2025 (File No. 333-288339), as filed with the Securities and Exchange Commission (the "SEC") on July 24, 2025 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act").

Recent Sales of Unregistered Securities

In January 2025, we completed a subsequent closing of the sale of 1,117,743 shares of Series C convertible preferred stock at a price of $10.74 per share for gross cash proceeds of $12.0 million. Each share of our Series C convertible preferred stock converted into shares of our common stock immediately prior to the closing of the IPO.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this discussion and analysis in conjunction with our audited financial statements and related notes included in this Annual Report. Unless the context otherwise requires, references to "Carlsmed," the "Company," "we," "us," and "our" refer to Carlsmed, Inc., a Delaware corporation. This discussion contains forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions, and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report. See the section titled "Special Note Regarding Forward-Looking Statements." Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

Company Summary

We are a commercial-stage medical technology company pioneering AI-enabled personalized spine surgery solutions with a focus on becoming the standard of care for spine fusion surgery. Our mission is to improve outcomes and decrease the cost of healthcare for spine surgery and beyond. The aprevo Technology Platform was designed to address the limitations of traditional lumbar and cervical spine fusion surgery and aims to optimize patient outcomes and reduce the need for revision surgeries.

Our technology is powered by AI-enabled, outcome-based algorithms that provide personalized surgical plans for spine fusion. The aprevo surgical kit delivered to customers includes interbody implants for a custom vertebral fit for each patient's unique pathology and vertebral bone topography, and single-use surgical instruments. The aprevo Technology Platform supports surgeons in achieving proper spinal alignment for patients with degenerative disc disease, which can improve clinical outcomes and reduce the likelihood of revision surgeries. We currently market the aprevo Technology Platform for lumbar and cervical spine fusion surgeries.

We market the aprevo Technology Platform to hospitals and ambulatory surgical centers in the United States through a combination of our direct sales team and independent sales agents. Our direct sales team consists of Area Vice Presidents, Sales Directors, Account Managers, and Strategic and National Account leadership, who are primarily responsible for promoting the aprevo Technology Platform to surgeons and working with customers to secure required approvals for our products. Our direct sales team is also responsible for recruiting independent sales agents who cover each aprevo surgery.

Since we began commercializing the aprevo Technology Platform in 2021, we have experienced sequential quarterly and annual revenue growth from its rapid commercial adoption. For the year ended December 31, 2025 and 2024, we recognized revenue of $50.5 million and $27.2 million, respectively, representing period-over-period growth of 85.9%.

Our business model depends on our ability to timely deliver aprevo interbody implants in order to allow surgeons to maintain surgical schedules for their patients. In November 2024, we launched our enhanced digital production system ("DPS"), which enabled us to deliver our aprevo interbody implants to customers within 10 business days or less of surgical plan approval. Starting in February 2026, this lead time has been reduced to six business days. Our implants are manufactured to our specifications by CMOs who meet our manufacturer qualification standards. Our streamlined DPS manages both the upstream and downstream processes involved in producing our implants.

Initial Public Offering

On July 24, 2025, we completed our initial public offering of 6,700,000 shares of our common stock, at a price to the public of $15.00 per share. We received net proceeds of $93.5 million from the IPO, after deducting underwriting discounts and commissions and before additional offering expenses of $5.4 million paid by us.

Regulatory Overview

aprevo Lumbar

In July 2020, the FDA awarded us a Breakthrough Device Designation, indicating that aprevo lumbar interbody implants are likely to provide a more effective treatment than the use of stock implants. In December 2020, the FDA, through its 510(k) regulatory clearance pathway, cleared our aprevo interbody implants for lumbar fusions to correct adult spinal deformity. After FDA clearance, we commenced the limited clinical release of the aprevo Technology Platform, with the first U.S. aprevo patient procedure completed in February 2021. In August 2022, the FDA, through its 510(k) regulatory clearance pathway, cleared the aprevo Technology Platform for the treatment of patients with several degenerative conditions of the lumbar spine.

aprevo Cervical

In September 2023, the FDA granted us a Breakthrough Device Designation for aprevo in cervical spine fusion. In November 2024, we received FDA 510(k) clearance for our aprevo Technology Platform for cervical spine fusion surgery. In July 2025, the first aprevo cervical procedure was successfully completed at UC San Diego Health. Through December 31, 2025, 92 aprevo cervical procedures have been successfully completed by 28 spine surgeons as part of our clinical evaluation program and our recent commercial launch of this indication in December 2025.

Key Factors Affecting Our Results of Operations and Performance

Our financial performance has been driven by the following key factors that we believe will persist for the foreseeable future. While each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties.

Market Adoption and Clinical Evidence

Since its full commercial launch in October 2021, the aprevo Technology Platform for spine fusion surgery has been used to treat more than 3,200 patients through December 31, 2025. We estimate there are approximately 4,000 spine surgeons across the United States whose patients could benefit from using our platform. Through December 31, 2025, 253 surgeons have been trained on the aprevo Technology Platform and have completed at least one aprevo procedure, an increase of 101 surgeons as compared to December 31, 2024.

Over time, we expect to meaningfully grow the base of surgeons using the aprevo Technology Platform and its penetration with existing surgeon users. To achieve this, we plan to grow our commercial infrastructure and expand various initiatives, including supporting medical education programs, fellowships, and surgeon training at top academic institutions.

We are also committed to building upon our strong foundation of clinical evidence demonstrating the efficacy of our aprevo Technology Platform. Clinical data publications are important tools for surgeon education and patient awareness of the potential benefits of our personalized solution as compared to stock implants.

Our COMPASS Registry is generating ongoing real-world evidence of patient outcomes from lumbar spine surgery with the aprevo Technology Platform. For example, a study on 90 COMPASS patients with DDD published at the 2025 Congress of Neurological Surgeons meeting demonstrated that aprevo significantly improved restoration of DLL with zero revision surgeries for adjacent segment degeneration at 20-month median follow-up.

In December 2025, the Global Spine Journal published peer-reviewed two-year follow-up data on a retrospective cohort of ASD patients treated with aprevo, demonstrating a 74% reduced rate of mechanical complication–related reoperations compared to patients who had been treated using stock implants.

Expansion of Our Product Portfolio and Investments in Research and Development

Our research and development initiatives are focused on introducing new products, enhancements and capabilities aimed at increasing the value provided by our aprevo Technology Platform to patients, surgeons, and payors. We are developing new iterations of our algorithm and software platform to drive further improvements in surgical planning and in turn help surgeons to make more informed decisions to best treat their patients.

In November 2024, we received FDA 510(k) clearance for our aprevo interbody implants for cervical spine fusion surgery as part of the FDA-cleared aprevo Technology Platform and commenced commercialization in December 2025. Also in December 2025, we received FDA 510(k) clearance for our accompanying personalized cervical plating solutions as part of the aprevo cervical platform. In February 2026, we completed the first personalized plating procedure using the corra Cervical Plating System at the University of California San Francisco and are planning for its commercial launch later this year. We expect to drive adoption with our existing base of surgeons who are actively using the aprevo Technology Platform for lumbar spine fusion surgeries.

In February 2026, we announced the successful completion of the first bi-lateral posterior lumbar spine surgery using our newly developed aprevo PLIF at the University of Colorado Hospital in Denver, Colorado. The addition of aprevo PLIF expands our lumbar offering across multiple spinal fusion techniques and integrates seamlessly with our broader aprevo platform technology. The commercial launch of aprevo PLIF is expected in the first half of 2026.

We also believe that our platform technology has the potential to be utilized across various spinal indications and disease states such as cervical corpectomy and cervical disc arthroplasty. Additional FDA clearances would be required for these or any other new indications.

Hospital and Outpatient Reimbursement

Future changes in the level of reimbursement that hospitals and outpatient facilities receive from payors for lumbar and cervical fusion surgical procedures could have a significant impact on our results of operations. The level of payors' reimbursement for procedures using our aprevo Technology Platform depends substantially on our continued ability to generate clinical evidence, garner support from key opinion leaders, and gain advocacy for patient access to our technology with CMS and commercial payors.

aprevo Lumbar

Procedures using our aprevo Technology Platform are covered by Medicare, Medicare Advantage, and commercial payors. Effective October 2024, CMS adopted a new MS-DRG coding system which reassigns MS-DRG codes for certain lumbar spine fusion procedures when “custom-made anatomically designed interbody fusion devices” (such as our aprevo Technology Platform) are utilized. This provides additional reimbursement for our hospital customers compared to the reimbursement for fusion procedures that use stock implants. We believe this, among other factors, will support our customers' continued demand for use of our technology in lumbar spine fusion surgeries.

aprevo Cervical

Inpatient Procedures

We believe Medicare-aged patients receiving multi-level ACDF surgeries are uniquely addressed by aprevo cervical. Based on our internal data, a majority of these procedures are performed in an inpatient setting. Effective October 1, 2025, cervical fusion procedures utilizing aprevo personalized interbody implants for traditional Medicare beneficiaries are eligible for NTAPs from CMS. The NTAP program provides additional reimbursement to hospitals that use designated new medical technologies in the first few years of market introduction. These new technologies must demonstrate significant clinical improvement in the diagnosis or treatment of Medicare beneficiaries compared to existing alternatives or be designated by the FDA as Breakthrough technology. CMS created unique ICD-10-PCS codes to identify cervical fusion procedures using "custom made anatomically designed interbody fusion devices" such as our aprevo Technology Platform. Reimbursement claims submitted with these unique ICD-10-PCS procedure codes may qualify hospitals for up to an additional $21,125 in NTAP reimbursement for eligible inpatient procedures.

Outpatient Procedures

aprevo cervical currently has the same payor reimbursement methodology as stock interbody implants for hospital outpatient departments and ambulatory surgery centers. Our requested Transitional Pass-Through ("TPT") payment for aprevo cervical in outpatient settings was not approved by CMS in its November 2025 OPPS Final Rule, despite our analysis and documentation for its qualification. We will continue to explore opportunities with CMS for various pathways including TPT and New Technology APC to appropriately reimburse our customers' costs of providing aprevo interbody implants in cervical fusion procedures.

Key Components of Our Results of Operations

Revenue

We sell our aprevo interbody implants and accompanying inserter instruments to customers under standard pricing schedules. We typically recognize revenue in the period of its use within a spine fusion surgical procedure.

Cost of Sales

Cost of sales includes the costs of creating patient-specific digital surgical plans and the manufacturing costs of our aprevo interbody implants and the accompanying inserter instruments. These costs of sales include allocations for personnel, software, contract manufacturing and other third-party services, packaging, shipping, provision for excess and obsolete inventory, and overhead cost allocations. We expect that our cost of sales will continue to increase in proportion to recognized revenue.

Gross Profit and Gross Margin

Gross profit (i.e., revenue *less* cost of sales) and gross margin (i.e., gross profit as a *percentage of* revenue) have been, and will continue to be, affected by various factors. These include potential changes to our average revenue per procedure, sales volumes, third-party manufacturing costs, direct labor costs, software costs, and provisions for excess and obsolete inventory. We expect our gross margin to remain relatively constant over the short term to our 2025 full year results and to modestly increase over the medium and long term with economies of production scale, increased leverage of our AI technologies, and other planned manufacturing efficiencies.

Operating Expenses

Research and Development Expenses

Research and development expenses include personnel costs (i.e., salaries, bonuses, stock-based compensation expense, and benefits), allocated facility costs, product prototype materials and testing, clinical studies aimed at potential new products, allocated software license amortization expenses, and consulting and other service fees. We recognize research and development expenses in the periods in which they are incurred. We expect our research and development expenses to increase as we continue to accelerate product and software innovation, develop additional clinical data, and expand manufacturing capabilities.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of personnel costs (i.e., salaries, commissions, bonuses, stock-based compensation expense, benefits, and travel), independent sales agent commissions, costs associated with generic surgical instruments we may provide to our independent sales agents, various digital and print initiatives to increase market awareness of our product and technology, conference and trade show fees, consulting fees, and medical education expenses.

We expect our sales and marketing expenses to increase in the foreseeable future as we continue to increase the size of our sales organization and scope of our marketing efforts in the United States and into other geographies, expand the indications for our aprevo Technology Platform, and establish international sales channels. While we expect sales and marketing expenses to continue to increase in absolute value, we expect that these costs will decrease as a percentage of revenue over time.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs (i.e., salaries, bonuses, stock-based compensation expense, and benefits) for executive, legal, finance, and human resources roles. Other significant costs include legal fees relating to intellectual property and corporate matters, consultant and professional fees, insurance, and facility-related costs. We recognize general and administrative expenses in the periods in which they are incurred. We anticipate that our general and administrative expenses will increase in the future to support our anticipated business growth as a publicly traded company. These increased costs include accounting, audit, legal, regulatory, tax, insurance, investor relations, and compliance with exchange listing and SEC requirements. While we expect general and administrative expenses to continue to increase in absolute value, we expect that these costs will decrease as a percentage of revenue over time.

Interest Expense

Interest expense consists of interest coupon payments and non-cash amortization of debt issuance costs as part of the Customers Loan Agreement.

Interest Income

Interest income is attributable to bank interest on our cash and cash equivalents and interest earned on our short-term investments in certificates of deposit.

Change in Fair Value of Warrant Liabilities

Prior to the closing of the IPO on July 24, 2025, we had issued warrants for the purchase of our convertible preferred stock in conjunction with the loan and security agreement with Customers Bank (the "Customers Loan Agreement"). On the closing of the IPO, all warrants issued to Customers Bank under the Customers Loan Agreement became exercisable into common stock, with certain warrants continuing to be classified as liabilities. Upon the execution of the Fifth Amendment to the Customers Loan Agreement on October 29, 2025, there were no warrants that remained classified as liabilities as a result of the cancellation of 15,831 shares of common stock that were exercisable contingent on loan draw milestones. We accounted for these liability-classified warrants, initially measured at fair value, in accordance with *ASC Topic 480*. Changes in fair value of warrant liabilities have been recognized in the Statements of Operations and Comprehensive Loss. See *Note 2—Summary of Significant Accounting Policies* in the notes to our Financial Statements for information regarding the Series B Warrant and the Series C Warrant in connection with the Customers Loan Agreement.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following tables set forth our results of operations, variances versus the prior period, and percentage of revenue for each presented caption. The period-to-period comparison is not necessarily indicative of financial results to be achieved in future periods.

	Year Ended December 31,		$	%	Percentage of Revenue	
	2025	2024	Change	Change	2025	2024
(in thousands, except percentages)						
Revenue	$ 50,511	$ 27,165	$ 23,346	85.9 %	100.0 %	100.0 %
Cost of sales	12,471	7,117	5,354	75.2 %	24.7	26.2
Gross profit	38,040	20,048	17,992	89.7 %	75.3	73.8
Operating expenses:						
Research and development	17,019	14,304	2,715	19.0 %	33.7	52.7
Sales and marketing	35,027	21,472	13,555	63.1 %	69.3	79.0
General and administrative	16,568	8,394	8,174	97.4 %	32.8	30.9
Total operating expenses	68,614	44,170	24,444	55.3 %	135.8	162.6
Loss from operations	(30,574)	(24,122)	(6,452)	26.7 %	(60.5)	(88.8)
Other income (expense):						
Interest expense	(1,430)	(1,321)	(109)	8.3 %	(2.8)	(4.9)
Interest income	2,698	1,330	1,368	102.9 %	5.3	4.9
Change in fair value of warrant liabilities	(328)	(144)	(184)	127.8 %	(0.7)	(0.5)
Total other income (expense), net	940	(135)	1,075	(796.3)%	1.8	(0.5)
Net loss and comprehensive loss	$ (29,634)	$ (24,257)	$ (5,377)	22.2 %	(58.7)%	(89.3)%

Revenue

Revenue was $50.5 million and $27.2 million for the years ended December 31, 2025 and 2024, respectively. The increase of $23.3 million, or 85.9%, was primarily driven by increased sales of aprevo interbody implants during the year ended December 31, 2025 as compared to the year ended December 31, 2024, with our average revenue per procedure substantially constant.

Cost of Sales and Gross Margin

Cost of sales was $12.5 million and $7.1 million for the years ended December 31, 2025 and 2024, respectively. The increase of $5.4 million, or 75.2%, was primarily driven by increased sales of aprevo interbody implants and the associated increase in contract manufacturing costs for the year ended December 31, 2025 with this sales volume, as compared to the year ended December 31, 2024.

Gross margin was 75.3% for the year ended December 31, 2025, as compared to 73.8% for the year ended December 31, 2024. This increase was primarily driven by enhanced manufacturing efficiencies and additional process improvements.

Research and Development Expenses

Research and development expenses were $17.0 million and $14.3 million for the years ended December 31, 2025 and 2024, respectively. The increase of $2.7 million, or 19.0%, was primarily due to an increase in personnel costs of $3.0 million to support product development and AI initiatives. This increase was partially offset by decreased costs for external services, prototype parts and materials, and reduced COMPASS registry costs following enrollment completion in the second half of 2024.

Sales and Marketing Expenses

Sales and marketing expenses were $35.0 million and $21.5 million for the years ended December 31, 2025 and 2024, respectively. The increase of $13.6 million, or 63.1%, was primarily driven by investments to support revenue growth. This included an increase in personnel-related costs for new headcount and employee commissions of $5.9 million and sales agent commissions increase of $4.7 million, both tied to our sales growth. The increase also reflects expanded marketing activities and other commercial support costs of $2.9 million associated with scaling our commercial organization. These increases were partially offset by lower professional service fees during the year ended December 31, 2025.

General and Administrative Expenses

General and administrative expenses were $16.6 million and $8.4 million for the years ended December 31, 2025 and 2024, respectively. The increase of $8.2 million, or 97.4%, was primarily driven by professional service and legal costs of $4.3 million for our IPO and intellectual property matters, as well as increased personnel-related costs of $3.1 million as part of administrative support and compliance requirements as a public company.

Interest Expense

Interest expense was $1.4 million and $1.3 million for the years ended December 31, 2025 and 2024, respectively. The increase of $0.1 million, or 8.3%, was primarily attributable to a higher average balance of borrowings outstanding under the Customers Loan Agreement during the year ended December 31, 2025 compared to the year ended December 31, 2024.

Interest Income

Interest income was $2.7 million and $1.3 million for the years ended December 31, 2025 and 2024, respectively. The increase of $1.4 million, or 102.9%, was due to an increase in bank interest on our higher daily average cash and cash equivalent balances resulting from the proceeds from our IPO in July 2025 and purchases of short-term investments during the year ended December 31, 2025.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities increased by $0.2 million during the year ended December 31, 2025 compared to the year ended December 31, 2024.

Non-GAAP Financial Measures

In addition to our results determined in accordance with GAAP, we utilize and present financial measures that are not calculated and presented in accordance with GAAP. Our non-GAAP financial measures include EBITDA and Adjusted EBITDA, each of which is described below. We use our non-GAAP financial measures in evaluating our operating performance and for internal planning purposes. We believe that these non-GAAP financial measures, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding our performance by excluding certain items that may not be indicative of our business, results of operations, or outlook. We believe that the presentation of our GAAP and non-GAAP financial measures, in combination, is helpful to investors in assessing our trending business performance in the currently reported period and versus prior periods. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool, and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business.

EBITDA and Adjusted EBITDA

EBITDA and Adjusted EBITDA are non-GAAP financial measures used by management as a supplemental measure in evaluating our operating performance. EBITDA and Adjusted EBITDA should not be considered as alternatives to, or more meaningful than, net loss or any other measure as determined in accordance with GAAP. Our computation of EBITDA and Adjusted EBITDA may not be comparable to EBITDA and Adjusted EBITDA of other companies.

We define "EBITDA" as net income (loss), adjusted to exclude: (i) net interest (income) expense, (ii) income tax expense (benefit), (iii) depreciation expense from property and equipment, and (iv) amortization expense from long-lived assets. We define "Adjusted EBITDA" as EBITDA adjusted to exclude stock-based compensation expense and change in fair value of warrant liabilities.

The following tables present a reconciliation of EBITDA and Adjusted EBITDA to the GAAP financial measure of net loss for each of the periods indicated:

	Year Ended December 31,		$	%
	2025	2024	Change	Change
(in thousands, except percentages)				
Net loss	$ (29,634)	$ (24,257)	$ (5,377)	22.2 %
Interest income, net	(1,268)	(9)	(1,259)	**
Income taxes	—	—	—	—
Depreciation and amortization	281	145	136	93.8 %
EBITDA	(30,621)	(24,121)	(6,500)	26.9 %
Stock-based compensation	1,927	253	1,674	661.7 %
Change in fair value of warrant liabilities	328	144	184	127.8 %
Adjusted EBITDA	$ (28,366)	$ (23,724)	$ (4,642)	19.6 %

**Change not meaningful

Unaudited Quarterly Results of Operations Data

The following tables set forth selected quarterly results of operations data for the three months ended for each quarter of the fiscal years ended December 31, 2025 and 2024, as well as the percentage of revenue that each line item represents for each quarter. The unaudited quarterly financial information has been prepared in accordance with GAAP on the same basis as our financial statements included elsewhere in this Annual Report. In the opinion of management, these tables fairly present our quarterly financial results that include normal recurring adjustments, necessary for the proper presentation of the results of operations for these periods. This data should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report. These historical quarterly operating results are not necessarily indicative of any future period.

	Three Months Ended (unaudited, in thousands)							
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
Revenue	$ 5,086	$ 6,081	$ 6,590	$ 9,408	$ 10,189	$ 12,083	$ 13,074	$ 15,165
Gross profit	$ 3,664	$ 4,562	$ 4,798	$ 7,024	$ 7,636	$ 8,869	$ 9,927	$ 11,608
Total operating expenses	$ 8,993	$ 10,881	$ 12,575	$ 11,721	$ 13,355	$ 15,371	$ 18,962	$ 20,926
Loss from operations	$ (5,329)	$ (6,319)	$ (7,777)	$ (4,697)	$ (5,719)	$ (6,502)	$ (9,035)	$ (9,318)
Net loss	$ (5,447)	$ (6,277)	$ (7,813)	$ (4,720)	$ (5,729)	$ (6,766)	$ (8,526)	$ (8,613)

All values from the results of operations data, expressed as a percentage of revenue, were as follows:

	Three Months Ended (unaudited, in thousands)							
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
Revenue	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %
Gross profit	72.0 %	75.0 %	72.8 %	74.7 %	74.9 %	73.4 %	75.9 %	76.5 %
Total operating expenses	176.8 %	178.9 %	190.8 %	124.6 %	131.1 %	127.2 %	145.0 %	138.0 %
Loss from operations	(104.8) %	(103.9) %	(118.0) %	(49.9) %	(56.1) %	(53.8) %	(69.1) %	(61.4) %
Net loss	(107.1) %	(103.2) %	(118.6) %	(50.2) %	(56.2) %	(56.0) %	(65.2) %	(56.8) %

Selected Quarterly Trends

Revenue

Our quarterly revenue increased sequentially in each of the periods presented due to increased unit sales of aprevo interbody implants with an average selling price that remained relatively constant in each period. We believe that this sales ramp is due to our ongoing sales and marketing efforts for new surgeon adoption of the aprevo Technology Platform and deepened penetration with our existing surgeons.

Gross Profit

Gross profit generally trended upward over the periods presented, primarily driven by increased sales of our aprevo interbody implants and associated per unit production costs.

Total Operating Expenses

Total operating expenses generally increased sequentially in each of the quarters presented, primarily driven by variable sales expenses that correspond with increased sales of aprevo interbody implants, product development activities, clinical data collection costs, marketing investments, personnel additions across various departments to support our ongoing revenue and business growth, and expenses associated with operating as a publicly traded company.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception. We have historically financed operations primarily through the net proceeds that we have received from the sale of shares of our convertible preferred stock, borrowings under our debt facilities, and cash generated from the sales of aprevo interbody implants. On July 24, 2025, we completed our IPO and received $93.5 million in net proceeds, after deducting underwriting discounts and commissions and before additional offering expenses of $5.4 million paid by us. As of December 31, 2025, we had $109.9 million of cash, cash equivalents, restricted cash and short-term investments, $15.6 million of principal outstanding under the Term Loan of the Customers Loan Agreement, and an accumulated deficit of $100.8 million.

Our losses primarily resulted from the costs incurred in the development and sales and marketing of our products and providing general and administrative support for our operations. We may continue to incur losses and expend significant amounts of cash in the foreseeable future as we continue to scale our business, invest in research and development activities, increase sales and marketing expenses to support commercial expansion, and increase general and administrative expenses associated with operating as a publicly traded company.

Customers Loan Agreement

In December 2022, we entered into a loan and security agreement with Signature Bank, which was later succeeded by Customers Bank (the "Customers Loan Agreement"). The Customers Loan Agreement had an initial maturity date of December 2026 and provided for $12.5 million in principal funding.

On March 7, 2024, we executed a Third Amendment to the Customers Loan Agreement (the "Third Amendment"), increasing the credit facility size from $12.5 million to $18.8 million and extending the maturity up to December 2027, subject to achievement of certain revenue and other milestones.

On December 30, 2024, we entered into a Fourth Amendment to the Customers Loan Agreement (the "Fourth Amendment"), expanding the facility to $27.5 million through the addition of two new tranches, one of which was a revenue milestone-based tranche. The Fourth Amendment also extended the maturity date to October 31, 2029.

On October 29, 2025, we amended the Customers Loan Agreement (the "Fifth Amendment") to expand this credit facility to include (i) a term loan in the principal amount of up to $50.0 million (the "Term Loan"), $17.5 million of which is contingent upon the achievement of requisite revenue milestones, and (ii) a $10.0 million non-formula revolving line of credit (the "Non-Formula Revolving Line"), subject to an aggregate borrowing limit for both the Term Loan and the Non-Formula Revolving Line of $50.0 million.

The maturity date of the Term Loan was extended to October 15, 2030, with an interest-only period through October 15, 2027, followed by principal repayment over 36 months thereafter. Upon achievement of certain revenue milestones, the interest-only period and repayment terms of the Term Loan may be extended through April 15, 2028 followed by principal repayment over 30 months, and upon achievement of an additional milestone, may be further extended through October 15, 2028, followed by principal repayment over 24 months thereafter. The Non-Formula Revolving Line will mature on October 15, 2028. The applicable per annum interest rate did not change as a result of the Fifth Amendment and remains as the *greater of* (a) WSJ Prime Rate + 0.25% or (b) 5.25%.

On December 23, 2025, we amended the Customers Loan Agreement (the "Sixth Amendment") to permit us to maintain certain limited deposit accounts outside of Customers Bank. No other terms of the Customers Loan Agreement were affected by the Sixth Amendment.

As of December 31, 2025, $15.6 million of principal was outstanding under the Term Loan that matures on October 31, 2030 and there were no borrowings outstanding under the Non-Formula Revolving Line. As of December 31, 2025, an aggregate $26.9 million remained available for borrowing under the Term Loan and Non-Formula Revolving Line, net of amounts outstanding. See *Note 4—Debt* in the accompanying notes to our Financial Statements for additional information regarding the Customers Loan Agreement.

Future Funding Requirements

Based on our current operating plan, we believe our existing cash, cash equivalents and short-term investments, the expected cash generated from sales of our aprevo interbody implants, and amounts currently available for future borrowings under our Customers Loan Agreement will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside of our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock.

Our future capital requirements will depend on many factors, including, but not limited to:

- market acceptance of the aprevo Technology Platform and other products and solutions we may develop in the future;
- our ability to obtain marketing approval for the aprevo Technology Platform in relevant markets or for other products and solutions we may develop in the future, and the timing and scope of any such approvals we may receive;
- the availability of reimbursement for aprevo interbody implants at acceptable reimbursement rates;
- the cost of manufacturing of aprevo interbody implants, which may vary depending on the quantity of production and the terms of our agreements with manufacturers and other vendors;
- our ability to attract, hire, train, and retain qualified personnel;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our product pricing policies or those of our competitors;
- the level of demand for aprevo Technology Platform;
- general economic, industry, and market conditions or extraordinary external events, such as a recession;
- changes in our regulatory environment;
- expenses associated with unforeseen product quality issues;
- the timing and success or failure of studies or trials for the aprevo Technology Platform or competing product candidates;
- any other change in the competitive landscape of our industry, including consolidation amongst our competitors or partners;
- litigation or other claims against us for intellectual property infringement or otherwise;
- expenses associated with indemnification obligations to third parties that are subject to litigation or claims, including in relation to intellectual property infringement, or that incur other losses as a result of their use of our products;
- our ability to obtain additional financing as necessary; and
- advances and trends in new technologies and industry standards.

If these sources of cash are insufficient to satisfy our liquidity requirements, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity or convertible debt securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. In addition, the incurrence of indebtedness would increase our fixed obligations and include covenants or other restrictions that would impede our ability to manage our operations.

Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and fluctuations in interest rates. If additional financing is needed, we may not be able to obtain additional financing on terms favorable to us, or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and responding to business challenges and opportunities.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,	
	2025	2024
(in thousands)		
Net cash provided by (used in):		
Net cash flows used in operating activities	$ (28,977)	$ (25,466)
Net cash used in investing activities	$ (25,483)	$ (180)
Net cash flows provided by financing activities	$ 100,128	$ 58,499

Operating activities

For the year ended December 31, 2025, net cash used in operating activities was $29.0 million, consisting primarily of a net loss of $29.6 million. Cash payments to vendors during the year ended December 31, 2025, for our operating expenses totaled $46.9 million, and payroll-related cash payments totaled $27.6 million. This net cash used in operating activities for the year ended December 31, 2025, was partially offset by $45.5 million of cash received from our customers for sales of aprevo interbody implants. We recognized $50.5 million of revenue in 2025, based on the timing of the use of aprevo interbody implants in surgical procedures.

For the year ended December 31, 2024, net cash used in operating activities was $25.5 million, consisting primarily of a net loss of $24.3 million. Cash payments to vendors during the year ended December 31, 2024, for our operating expenses totaled $31.9 million, and payroll-related cash payments totaled $16.7 million. This net cash used in operating activities for the year ended December 31, 2024, was partially offset by $23.1 million of cash received from our customers for sales of aprevo interbody implants. We recognized $27.2 million of revenue in 2024, based on the timing of the use of aprevo interbody implants in surgical procedures.

Investing activities

For the year ended December 31, 2025, net cash used in investing activities was $25.5 million and consisted primarily of purchases of short-term investments of $24.0 million, capitalized software costs of $0.7 million, purchases of property and equipment of $0.6 million, and payment of initial direct costs of $0.1 million for an office lease that was executed in May 2025.

For the year ended December 31, 2024, net cash used in investing activities was $0.2 million and consisted primarily of purchases of property and equipment.

Financing activities

For the year ended December 31, 2025, net cash provided by financing activities was $100.1 million, consisting primarily of proceeds from our IPO of $93.5 million, net of underwriting discounts and commissions, net proceeds from the issuance of Series C convertible preferred stock of $11.9 million and proceeds from the exercise of stock options of $0.2 million. This was partially offset by payments for deferred offering costs of $5.4 million in connection with our IPO and $0.1 million of term loan issuance costs.

For the year ended December 31, 2024, net cash provided by financing activities was $58.5 million, consisting primarily of net proceeds from the issuance of Series C convertible preferred stock of $52.3 million and borrowings under the Customers Loan Agreement of $6.2 million.

Contractual Obligations and Other Material Cash Commitments

Our contractual obligations as of December 31, 2025, include:

Debt

Total principal outstanding under the Customers Loan Agreement as of December 31, 2025, was $15.6 million under the Term Loan. The Term Loan matures on October 15, 2030, with an interest-only period through October 15, 2027, followed by principal repayment over 36 months thereafter. Upon achievement of certain revenue milestones, the interest-only period and repayment terms may be further extended to an interest-only period through October 15, 2028, followed by principal repayment over 24 months thereafter. The applicable per annum interest rate is the *greater of* (a) WSJ Prime Rate + 0.25% or (b) 5.25%.

Operating leases

As of December 31, 2025, contractual obligations for operating lease payments (substantially related to our Carlsbad, California office leases with lease terms to June 30, 2028) totaled $2.3 million and are due over 30 months after December 31, 2025.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, stock-based compensation, and other fair value measurements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in *Note 2* to our audited financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Revenue Recognition

We recognize revenue from our aprevo interbody implant sales in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Conditions ("ASC") Topic 606, *Revenue from Contracts with Customers*, which requires the amount and timing of revenue recognition to align with the completed transfer of promised goods or services to customers and our entitled contractual consideration in return.

Revenue is typically recognized in the period that an aprevo interbody implant is used in a surgical procedure and is based on standard pricing arrangements with our customers. The consideration we are entitled to for sales of aprevo is fixed based on the stated contractual amount with our customers. Our sales process includes contracted independent sales agents that cover each surgery and we have determined that we are the principal in these transactions for purposes of gross versus net revenue presentation. We recognize revenue at "gross" (i.e., our reported revenue is not reduced for sales agent fees that are reported in "sales and marketing" expenses) since we are responsible for product fulfillment and customer acceptability, carry the inventory risk, and have sole discretion in setting the price for our products.

Excess and Obsolete Inventory

We maintain minimal inventories because aprevo interbody implants are made specific to each patient's anatomy and pathology and are not otherwise made-to-stock. Inventories are stated at actual cost. Work-in-process inventory consists of titanium alloy implants for spine fusion surgical procedures, pending sterilization and packaging. Finished goods inventory is ready for shipment and use in spine fusion surgical procedures.

Inventories are valued at the lower of cost or net realizable value. At each balance sheet date, we evaluate our inventories for obsolescence, based on notification of permanently canceled surgeries, and our estimates of additional permanent cancellations. We record the corresponding charge for this obsolete inventory through "cost of sales". The estimation of obsolete inventory requires management's judgment for future cancellations that correspond to on-hand patient-specific aprevo interbody implants. These estimates can be influenced by a variety of factors and could materially affect our financial results if actual results differ.

Stock-Based Compensation

We recognize stock-based compensation expense for equity awards granted to employees, consultants, and members of our Board of Directors. Stock option awards are granted at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. The grant date is the date that the terms of the award are formally approved by our Board of Directors. We use the Black-Scholes option pricing model to estimate the fair value of stock option awards as of the date of grant.

The measurement of the fair value of stock option awards, and recognition of stock-based compensation expense requires the use of certain assumptions within the Black-Scholes option pricing model by management. While the model includes several inputs, the estimates that involve inherent uncertainties and the application of management's judgment consist primarily of:

- *Fair Value of Common Stock.* Prior to the completion of our IPO, we estimated the fair value of the shares of our common stock underlying our stock-based awards. Our Board of Directors considered numerous objective and subjective factors to determine the fair value of our common stock as discussed in "—Common Stock Valuation" below. Subsequent to the completion of our IPO, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant on the Nasdaq stock exchange.
- *Volatility.* Since we had been privately held prior to our IPO, we did not have any trading history for our common stock. Therefore, the expected volatility is estimated based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle, or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

The judgments and estimates related to stock-based compensation are subject to uncertainty due to the reliance on subjective assumptions and a complex valuation model. The estimation of the fair value of common stock and volatility involves significant judgment and is sensitive to changes in market conditions and company-specific factors. These assumptions are inherently uncertain and can vary based on future market conditions, making the estimation process complex and introducing variability into the reported stock-based compensation expense. Changes to these assumptions and estimates could have a material impact on the amount of stock-based compensation.

See *Note 6* to our audited financial statements included elsewhere in this Annual Report for more information concerning specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options.

Common Stock Valuation

Prior to the completion of our IPO, the fair value of our common stock was determined by our Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the "Practice Aid"). In doing so, our Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our products, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and medical device sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm's-length transactions and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and medical device industry sectors.

Our Board of Directors determined the fair value of our common stock by first determining the enterprise value of our business and then allocating the value among the various classes of our equity securities to derive a per share value of our common stock. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In allocating enterprise value among the various classes of stock, we utilized a hybrid method, which is a combination of the Option Pricing Method ("OPM") and the Probability-Weighted Expected Return Method ("PWERM"). Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering a number of discrete possible outcomes of the business, as well as the economic and control rights of each share class. Under the hybrid method, we considered expected initial public offering liquidity scenarios as well as other market-based non-initial public offering scenarios in the event a near-term initial public offering does not occur. Additionally, in determining the estimated fair value of our common stock prior to the completion of our IPO, our Board of Directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

Significant judgments and estimates were inherent in the determination of the fair value of our common stock prior to the completion of our IPO. These judgments and estimates included assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event, and the determination of the appropriate valuation methods.

For valuations after the completion of our IPO, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant on the Nasdaq stock exchange.

Recently Issued and Adopted Accounting Pronouncements

See "Note 2 – Summary of Significant Accounting Policies" in the accompanying notes to our Financial Statements included elsewhere in this Annual Report for information about recent accounting pronouncements, the timing of their adoption, and our assessment, if any, of their potential impact on our financial condition and results of operations.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"); and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. In addition, the JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to "opt out" of this provision, and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period is irrevocable.

We are also a "smaller reporting company," because the market value of our shares held by non-affiliates is less than $700.0 million, and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time that we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

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INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Carlsmed, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Carlsmed, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.
San Diego, California
February 25, 2026

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CARLSMED, INC.
BALANCE SHEETS
(in thousands, except for share and par value amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 85,793	$ 40,125
Restricted cash	100	100
Short-term investments	24,000	—
Accounts receivable, net of allowances of $1,653 and $1,239, as of December 31, 2025 and December 31, 2024, respectively	11,362	6,766
Inventory	1,845	995
Prepaid expenses and other current assets	3,573	1,365
Total current assets	126,673	49,351
Property and equipment, net	1,487	260
Operating lease right-of-use assets	1,826	1,644
Other assets	134	569
Total assets	$ 130,120	$ 51,824
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,481	$ 2,412
Accrued liabilities	3,287	2,687
Accrued compensation	5,760	3,270
Short-term operating lease liabilities	752	449
Total current liabilities	14,280	8,818
Long-term portion of term loan, net	15,346	15,414
Long-term operating lease liabilities	1,316	1,317
Warrant liabilities	—	457
Other long-term liabilities	309	222
Total liabilities	31,251	26,228
Commitments and contingencies (*Note 9*)		
Series A convertible preferred stock, $0.00001 par value; zero shares authorized, issued, and outstanding and zero liquidation preference as of December 31, 2025; 4,902,814 shares authorized, issued, and outstanding, and $13,767 liquidation preference as of December 31, 2024	—	13,578
Series B convertible preferred stock, $0.00001 par value; zero shares authorized, issued, and outstanding and zero liquidation preference as of December 31, 2025; 4,393,481 shares authorized, 4,335,051 shares issued and outstanding, and $30,000 liquidation preference as of December 31, 2024	—	29,801
Series C convertible preferred stock, $0.00001 par value; zero shares authorized, issued, and outstanding and zero liquidation preference as of December 31, 2025; 4,910,500 shares authorized, 4,890,123 shares issued and outstanding, and $52,500 liquidation preference as of December 31, 2024	—	52,847
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and zero shares issued and outstanding as of December 31, 2025; zero shares authorized, issued, and outstanding as of December 31, 2024	—	—
Common stock, $0.00001 par value; 600,000,000 shares authorized, 26,664,243 shares issued, and 26,604,505 shares outstanding as of December 31, 2025; 21,835,801 shares authorized, 4,234,798 shares issued, and 4,139,219 shares outstanding as of December 31, 2024	—	—
Additional paid-in capital	199,674	541
Accumulated deficit	(100,805)	(71,171)
Total stockholders' equity (deficit)	98,869	(70,630)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 130,120	$ 51,824

The accompanying notes are an integral part of these Financial Statements.

CARLSMED, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Revenue	$ 50,511	$ 27,165
Cost of sales	12,471	7,117
Gross profit	38,040	20,048
Operating expenses:		
Research and development	17,019	14,304
Sales and marketing	35,027	21,472
General and administrative	16,568	8,394
Total operating expenses	68,614	44,170
Loss from operations	(30,574)	(24,122)
Other income (expense):		
Interest expense	(1,430)	(1,321)
Interest income	2,698	1,330
Change in fair value of warrant liabilities	(328)	(144)
Total other income (expense), net	940	(135)
Net loss and comprehensive loss	(29,634)	(24,257)
Deemed dividend to preferred stockholders	(584)	(592)
Net loss attributable to common stockholders	$ (30,218)	$ (24,849)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.12)	$ (6.11)
Weighted-average number of common shares used to compute basic and diluted net loss per share	14,221,991	4,066,395

The accompanying notes are an integral part of these Financial Statements.

CARLSMED, INC.

STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except for share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance as of December 31, 2023	**4,902,814**	**$ 13,578**	**4,335,051**	**$ 29,801**	**—**	**$ —**	**3,970,811**	**$ —**	**$ 784**	**$ (46,914)**	**$ (46,130)**
Issuance of Series C convertible preferred stock, net of issuance costs of $245	—	—	—	—	4,890,123	52,847	—	—	—	—	—
Deemed dividend related to issuance of Series C convertible preferred stock	—	—	—	—	—	—	—	—	(592)	—	(592)
Issuance of common stock	—	—	—	—	—	—	29,121	—	6	—	6
Vesting of early exercised stock options	—	—	—	—	—	—	47,789	—	56	—	56
Exercise of vested stock options	—	—	—	—	—	—	91,498	—	34	—	34
Stock-based compensation expense	—	—	—	—	—	—	—	—	253	—	253
Net loss	—	—	—	—	—	—	—	—	—	(24,257)	(24,257)
Balance as of December 31, 2024	**4,902,814**	**$ 13,578**	**4,335,051**	**$ 29,801**	**4,890,123**	**$ 52,847**	**4,139,219**	**$ —**	**$ 541**	**$ (71,171)**	**$ (70,630)**
Issuance of Series C convertible preferred stock, net of issuance costs of $80	—	—	—	—	1,117,743	12,503	—	—	—	—	—
Deemed dividend related to issuance of Series C convertible preferred stock	—	—	—	—	—	—	—	—	(584)	—	(584)
Conversion of convertible preferred stock into common stock on initial public offering	(4,902,814)	(13,578)	(4,335,051)	(29,801)	(6,007,866)	(65,350)	15,245,731	—	108,729	—	108,729
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering costs of $12,446	—	—	—	—	—	—	6,700,000	—	88,054	—	88,054
Reclassification of warrants from liability classified to equity classified	—	—	—	—	—	—	—	—	760	—	760
Cashless exercise of warrants	—	—	—	—	—	—	25,184	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	35,841	—	42	—	42
Exercise of vested stock options	—	—	—	—	—	—	458,530	—	205	—	205
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,927	—	1,927
Net loss	—	—	—	—	—	—	—	—	—	(29,634)	(29,634)
Balance as of December 31, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**26,604,505**	**$ —**	**$ 199,674**	**$ (100,805)**	**$ 98,869**

The accompanying notes are an integral part of these Financial Statements.

CARLSMED, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (29,634)	$ (24,257)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	281	145
Stock-based compensation	1,927	253
Non-cash interest	206	206
Loss on remeasurement of warrant liabilities	328	144
Non-cash lease expense	536	375
Provision for credit losses	414	368
Provision for excess and obsolete inventory	1,839	1,378
Other non-cash items	17	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,010)	(3,969)
Inventory	(2,689)	(1,798)
Prepaid expenses and other assets	(2,342)	(720)
Accounts payable	2,323	297
Accrued liabilities	627	1,208
Accrued compensation	2,490	1,214
Lease liabilities	(290)	(310)
Net cash used in operating activities	**(28,977)**	**(25,466)**
Cash flows from investing activities:		
Purchase of short-term investments	(24,000)	—
Purchase of property and equipment	(642)	(180)
Capitalized software costs	(715)	—
Payment of initial direct costs related to operating leases	(126)	—
Net cash used in investing activities	**(25,483)**	**(180)**
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	93,465	—
Payments for deferred initial public offering costs	(5,411)	—
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	11,919	52,255
Proceeds from term loan, net of issuance costs	—	6,210
Payment of issuance costs related to term loan modification	(50)	—
Proceeds from exercises of stock options	205	34
Net cash provided by financing activities	**100,128**	**58,499**
Increase in cash, cash equivalents, and restricted cash	45,668	32,853
Cash, cash equivalents, and restricted cash at beginning of the period	40,225	7,372
Cash, cash equivalents, and restricted cash at end of the period	**$ 85,893**	**$ 40,225**

CARLSMED, INC.

STATEMENTS OF CASH FLOWS - CONTINUED

(in thousands)

	Year Ended December 31,	
	2025	2024
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$ 1,198	$ 1,115
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Conversion of convertible preferred stock upon initial public offering	$ 108,729	$ —
Reclassification of warrants from liability classified to equity classified	$ 760	$ —
Vesting of early exercised common stock options	$ 42	$ 56
Right-of-use asset obtained in exchange for lease liability	$ 593	$ —
Reclassification of financial commitment asset to debt discount	$ 69	$ —
Unpaid purchases of property and equipment	$ 41	$ —
Capitalized software included in accounts payable and accrued liabilities	$ 127	$ —
Preferred stock warrants issued in connection with term loan modifications	$ —	$ 313
Unpaid deferred offering costs	$ —	$ 423
Cash, Cash Equivalents, and Restricted Cash Information:		
Cash and cash equivalents, beginning of period	$ 40,125	$ 7,222
Restricted cash, beginning of period	100	150
Cash, cash equivalents, and restricted cash, beginning of period	40,225	7,372
Cash and cash equivalents, end of period	85,793	40,125
Restricted cash, end of period	100	100
Cash, cash equivalents, and restricted cash, end of period	$ 85,893	$ 40,225

The accompanying notes are an integral part of these Financial Statements.

CARLSMED, INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization

Description of Business

Carlsmed, Inc. (the "Company") is a medical technology company within the surgical device with enabling technology sector. The Company was incorporated in Delaware in June 2018 and is headquartered in Carlsbad, California. The Company designs, manufactures, and markets *aprevo*®, a comprehensive technology platform for spine fusion surgery procedures that are performed at hospitals and ambulatory surgical centers.

The aprevo platform includes proprietary surgical planning software, using outcomes-based algorithms that are aided with artificial intelligence, and resulting custom-built, anatomically designed vertebral interbody implants. These implants provide each patient with a personalized vertebral fit to address their unique pathology and anatomy.

The U.S. Food and Drug Administration ("FDA") cleared the aprevo lumbar interbody implants through its 510(k) regulatory pathway for the correction of adult lumbar spinal deformity in December 2020 and several degenerative conditions of the lumbar spine in August 2022. The Company commenced its limited clinical release with its first U.S. patient implant in February 2021, and in October 2021, the Company commenced its U.S. commercial launch of aprevo.

In November 2024, the FDA 510(k) cleared the aprevo interbody implants for cervical spine fusion surgery as part of the FDA-cleared aprevo Technology Platform and in December 2025, the Company commenced the U.S. launch of aprevo Technology Platform for cervical fusion surgeries. Also in December 2025, the Company received FDA 510(k) clearance for accompanying personalized cervical plating solutions. We expect to more broadly commercialize the aprevo cervical platform, including with the anticipated commercial launch of our corra Cervical Plating System, in 2026.

Reverse Stock Split

On July 10, 2025, the Company effectuated a 1-for-5.58 reverse stock split of the Company's issued and outstanding shares of common stock, Series A, Series B, and Series C convertible preferred stock, as well as stock option awards to purchase shares of common stock, restricted stock units ("RSUs"), and warrants to purchase shares of common stock, Series B convertible preferred stock, and Series C convertible preferred stock. Consequently, all issued and outstanding shares of stock, stock option awards, RSUs, warrants, and per share data have been retroactively adjusted in these financial statements to reflect the reverse stock split for all periods presented. The par value of the common stock and convertible preferred stock remain unchanged. As the number and issuance price of all outstanding convertible preferred stock were adjusted, the conversion ratios for each series of the Company's convertible preferred stock were unchanged. Stockholders entitled to fractional shares as a result of the reverse stock split received cash payment in lieu of receiving fractional shares.

Initial Public Offering

On July 24, 2025, the Company completed its initial public offering of 6,700,000 shares of its common stock, at a price to the public of $15.00 per share (the "IPO"). The net proceeds received by the Company from the IPO were $93.5 million, after deducting underwriting discounts and commissions and before additional offering expenses of $5.4 million paid by the Company. The underwriters had the option for a period of 30 days from the IPO date to purchase an additional 1,005,000 shares of common stock at the IPO price, less underwriting discounts and commissions, which was not exercised. Immediately prior to the closing of the IPO on July 24, 2025, all shares of the Company's convertible preferred stock converted into shares of the Company's common stock. In connection with this conversion, all warrants to purchase convertible preferred stock are now exercisable into common stock.

Liquidity and Capital Resources

As of December 31, 2025, the Company had $109.9 million of cash, cash equivalents, restricted cash and short-term investments, $15.6 million debt outstanding under its loan and security agreement with Customers Bank (the "Customers Loan Agreement"), and an accumulated deficit of $100.8 million.

The Company expects to continue to generate operating losses for the foreseeable future as it continues to expand commercial operations and develop its product portfolio. The Company believes that its existing cash on hand will be sufficient to meet anticipated capital requirements for its operations for at least 12 months from the date of the issuance of the accompanying Financial Statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying Financial Statements have been prepared by management in accordance with accounting principles generally accepted in the United States ("GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"). In the opinion of the Company's management, the accompanying Financial Statements and notes include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the periods presented.

Use of Estimates

The preparation of the Financial Statements in conformity with GAAP requires management to make informed estimates that require assumptions that affect the reported amounts in the accompanying Financial Statements. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ materially under different assumptions and conditions.

Cash and Cash Equivalents

"Cash and cash equivalents" in the accompanying Balance Sheets consist of bank deposits and highly liquid investments, including money market fund accounts, and certificates of deposit, with original maturities of three months or less from the purchase date. The carrying amounts reported in the accompanying Balance Sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

Restricted Cash

"Restricted cash" in the accompanying Balance Sheets represents cash held as collateral for the Company's facility leases.

Short-Term Investments

"Short-term investments" in the accompanying Balance Sheets represents investments in certificates of deposits which are carried at cost and have original maturities of greater than 90 days but within one year. Accrued interest earned on short-term investments is recorded within "Prepaid expenses and other current assets" on the accompanying Balance Sheets.

Accounts Receivable and Allowance for Credit Losses

"Accounts receivable, net of allowances" in the accompanying Balance Sheets are presented net of allowances for credit losses. The Company maintains an allowance for expected credit losses for accounts receivable, which is recorded as an offset to accounts receivable. Changes in this allowance are recorded as "general and administrative" expense in the Statements of Operations and Comprehensive Loss. Expected credit losses include losses expected based on known credit issues with certain customers as well as a general expected credit loss allowance based on relevant information, including historical loss rates, current conditions, and reasonable economic forecasts that affect collectability. The Company maintained an allowance for credit losses accounts of $1.7 million and $1.2 million as of December 31, 2025 and 2024, respectively. The Company recorded a provision for credit losses of $0.4 million for both the years ended December 31, 2025 and 2024.

Concentrations of Financial Instrument Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that may exceed federally insured limits and certain accounts receivable balances. Risks associated with cash and cash equivalents are mitigated by banking with creditworthy institutions with platforms that administer deposits across multiple banks within federally insured limits. Additionally, cash invested in certificates of deposit ("CDs") are maintained in a Certificate of Deposit Account Registry Service ("CDARS") account. By using a CDARS account, the Company's large deposits are divided into smaller amounts and placed with multiple FDIC ("Federal Deposit Insurance Corporation") insured banks that are members of the CDARS network. Each member bank issues CDs in amounts under $250,000, so that the entire deposit balance is eligible for FDIC insurance.

The Company mitigates potential losses from uncollectible accounts receivable through its credit approval and ongoing collection and customer monitoring activities. To date, the Company has not experienced any losses on its financial instruments and believes that it has adequately recorded allowances for uncollectible accounts receivable in each reported period.

As of December 31, 2025 and 2024, the Company did not have accounts receivable balances from any one customer exceeding 10% of total accounts receivable. The Company did not have revenue from any one customer exceeding 10% of total revenue for the year ended December 31, 2025. There was one customer that accounted for 10% of the Company's revenue for the year ended December 31, 2024.

Fair Value of Financial Instruments

Assets and liabilities are recorded at fair value on a recurring basis in the accompanying Balance Sheets. These accounts are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative accounting guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- *Level 1*: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.
- *Level 2*: Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.
- *Level 3*: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company's financial instruments consisting of cash, cash equivalents, short-term investments, accounts receivables, prepaid expenses, accounts payable, and accrued liabilities approximate fair value due to the short maturities for each.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value hierarchy during the periods presented.

(in thousands)	Total Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2025				
Money market funds [1]	$ 60,738	$ 60,738	$ —	$ —
Certificates of deposit with original maturity of 3 months or less [1]	24,036	—	24,036	—
Certificates of deposit with original maturity greater than 3 months [2]	24,000	—	24,000	—
Total financial assets	$ 108,774	$ 60,738	$ 48,036	$ —
As of December 31, 2024				
Money market funds [1]	$ 37,744	$ 37,744	$ —	$ —
Total financial assets	$ 37,744	$ 37,744	$ —	$ —
Warrant liabilities	$ 457	$ —	$ —	$ 457
Total financial liabilities	$ 457	$ —	$ —	$ 457

(1) Included as a component of "Cash and cash equivalents" on the accompanying Balance Sheets.

(2) Included as a component of "Short-term investments" on the accompanying Balance Sheets.

Inventory

The Company maintains minimal inventories because aprevo is made specific to each patient's anatomy to address their pathology and is not otherwise made-to-stock. Work-in-process inventory consists of titanium alloy implants for spine fusion surgical procedures, pending sterilization and packaging. Finished goods inventory is ready for shipment to the customer for use in a spine fusion surgical procedure.

Inventories are valued at the lower of cost or net realizable value, determined by the specific identification method. At each balance sheet date, the Company evaluates its inventories for obsolescence, based on notification of permanently canceled surgeries and ongoing estimates of permanent cancellations. The Company records the corresponding charge for obsolete inventory through "cost of sales."

The components of reported "inventory" are as follows:

(in thousands)	As of December 31, 2025	As of December 31, 2024
Finished goods	$ 1,788	$ 595
Work in process	57	400
Total	$ 1,845	$ 995

Property and Equipment and Long-Lived Assets

"Property and equipment, net," consist of office equipment, furniture and fixtures, leasehold improvements, and software; each is stated at cost, less accumulated depreciation and amortization.

Internally developed software consists of capitalized costs incurred during the application development stage, which include costs to design the software configuration and interfaces, coding, installation and testing. Costs incurred during the preliminary project stage, along with post-implementation stages of internally developed software, are expensed as incurred.

Property and equipment are depreciated using the straight-line method over the estimated useful life of the corresponding asset commencing with the date when an asset is ready for its intended use, which ranges from three to five years and recorded to the respective Company department associated with its use.

Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be recoverable. If/when an asset is determined to be permanently impaired, the Company will record a charge in that period equal to the amount by which the carrying amount exceeds the fair market value of the asset.

Leases

The Company leases office and laboratory space to conduct business operations. Whether the contract is, or contains a lease, is assessed at contract inception and the classification and initial measurement are assessed at the lease commencement date in line with Financial Accounting Standards Board ("FASB") ASC Topic 842, *Leases* ("ASC 842"). The Company's leases only meet the requirements for operating lease classification in each year presented in the accompanying financial statements.

At the lease commencement date, the Company recognizes a "right-of-use asset" and a "lease liability" for all leases, except short-term leases with an original term of 12 months or less. The right-of-use asset represents the right to use the leased asset for the lease term including any renewal options reasonably certain to be exercised. The lease liability represents the present value of the lease payments under the lease. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any prepayments to the lessor less any lease incentives received. All right-of-use assets are periodically reviewed for impairment in accordance with standards that apply to long-lived assets.

The lease liability is initially measured at the present value of the minimum lease payments, discounted using an estimate of the Company's incremental borrowing rate for a collateralized loan with the same term as the underlying lease. Since the Company's leases do not provide an implicit rate, it utilizes the appropriate incremental borrowing rate for accounting purposes and is determined as the rate of interest that a market participant would have to pay to borrow on a collateralized basis, over a similar term, and in a similar economic environment.

Minimum lease payments included in the measurement of lease liabilities consist of (i) fixed lease payments for the non-cancelable lease term, (ii) fixed lease payments for optional renewal periods where it is reasonably certain the renewal option will be exercised and (iii) variable lease payments that depend on an underlying index or rate, based on the index or rate in effect at lease commencement. Certain leases require payments for non-lease costs such as utilities and common area maintenance. The Company elected an accounting policy to not account for payments of non-lease costs separately from the related lease payments. This policy election results in a higher initial measurement of lease liabilities when such non-lease payments are fixed amounts. Certain leases require variable lease payments that do not depend on an underlying index or rate, such as the Company's proportionate share of actual property taxes and utilities, which are recognized in operating expenses as incurred.

Lease expense reported in the accompanying Statements of Operations and Comprehensive Loss is recognized on a straight-line basis over the operating lease term.

Warrant Liabilities

Prior to the closing of the IPO on July 24, 2025, the Company had issued warrants to purchase convertible preferred stock in conjunction with the Customers Loan Agreement (see *Note 4*). The Company accounted for its issued convertible preferred stock warrants as liabilities in accordance with *ASC 480*. The liability-classified warrants were initially measured at fair value, resulting in an implied discount on the related financing arrangement that was deferred as an asset as it relates to tranches of the Customers Loan Agreement. The deferred asset is recorded within “other assets” on the accompanying Balance Sheets and is amortized into interest expense using the straight-line method over the period in which the Company can draw on the remaining tranches of the credit facility. Changes in fair value of the warrant liabilities are recognized in the Statements of Operations and Comprehensive Loss.

In conjunction with the IPO, all of the outstanding shares of convertible preferred stock were converted into common stock. As a result, the Series B Warrant and Series C Warrant that had previously been exercisable for convertible preferred stock became exercisable for common stock. Upon the closing of the IPO on July 24, 2025, the Series B Warrant that was exercisable into 52,776 shares of common stock and the Series C Warrant that was exercisable into 5,093 shares of common stock met the criteria for equity classification and accordingly were reclassified from liabilities to equity, with the difference between their fair value immediately prior to reclassification and their prior recorded fair value being recognized in the accompanying Statements of Operations and Comprehensive Loss. The fair value of these warrants immediately before reclassification was $0.7 million and are included in additional paid-in capital as of December 31, 2025. On the closing of the IPO on July 24, 2025, the Series B Warrant contained 5,644 shares of common stock and the Series C Warrant contained 15,282 shares of common stock that were exercisable contingent on specified revenue and loan draw milestones (see *Note 4*) and therefore continued to be classified as liabilities because they did not meet the criteria for equity classification.

During the year ended December 31, 2025, the Company achieved a revenue milestone, causing 5,095 additional shares of common stock underlying the Series C Warrant to become exercisable and accordingly were reclassified from liabilities to equity as they met the criteria for equity classification. The difference between the fair value of the warrants immediately prior to reclassification and their prior recorded fair value was recognized in the accompanying Statements of Operations and Comprehensive Loss. The fair value of these warrants at the time of reclassification was $0.1 million, and are included in "additional paid-in capital" as of December 31, 2025.

On October 29, 2025, as a part of the Fifth Amendment to the Customers Loan Agreement, the Series B Warrant and Series C Warrant were amended and restated and the remaining aggregate 15,831 shares of common stock that were exercisable contingent on loan draw milestones were canceled (see *Note 4*). On the effective date of the Fifth Amendment, the Company remeasured the warrants for the final time and recognized the change in fair value within the accompanying Statements of Operations and Comprehensive Loss.

As of December 31, 2025, the Company no longer has any warrants outstanding that are classified as liabilities.

The fair value of the warrant liabilities was determined based on significant inputs not observable in the market, which represents a “Level 3” measurement within the fair value hierarchy. Prior to the IPO, the fair values of the warrant liabilities were measured using the “hybrid method.” The hybrid method is often used when a company is expecting a liquidity event in the near future and is a combination of the option-pricing and probability-weighted expected return methods. Estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying shares of convertible preferred stock, the remaining contractual term of the warrants, and probability of number of shares the warrants will become exercisable into. The most significant assumption in the model impacting the fair value of the warrants was the fair value of the Company’s convertible preferred stock as of each remeasurement date. Subsequent to the IPO, the fair value of the warrant liabilities is measured using the Black-Scholes option pricing model.

A summary of the changes in the total fair value of the warrant liabilities for the years ended December 31, 2025 and 2024, is as follows:

(in thousands)	Warrant Liabilities
Fair value as of December 31, 2023	$ —
Issuance of Series B preferred stock warrants	203
Modification of Series B preferred stock warrants	29
Issuance of Series C preferred stock warrants	81
Change in fair value of warrant liabilities	144
Fair value as of December 31, 2024	457
Change in fair value of warrant liabilities	328
Reclassification of warrants from liability classified to equity classified	(760)
Cancellation of liability classified warrants	(25)
Fair value as of December 31, 2025	$ —

Convertible Preferred Stock

Prior to the closing of the IPO on July 24, 2025, the Company had issued convertible preferred stock. The Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs. The convertible preferred stock was presented as mezzanine equity in the accompanying Balance Sheets due to the stock containing certain redemption features that were not solely within the Company's control. As a result of the IPO, all of the outstanding shares of convertible preferred stock were converted into 15,245,731 shares of common stock. Refer to *Note 7* for more information on the convertible preferred stock.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in "stockholders' equity (deficit)" or the applicable series of convertible preferred stock as a reduction of proceeds generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the Statements of Operations and Comprehensive Loss. As of December 31, 2025 and 2024, there were zero and $0.4 million deferred offering costs, respectively, which are included in "other assets" in the accompanying Balance Sheets.

The Company completed its IPO on July 24, 2025. As a result, the deferred offering costs were offset against the proceeds of the IPO (see *Note 1*).

Revenue Recognition

The Company recognizes revenue from its aprevo sales in accordance with FASB ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 requires the amount and timing of revenue recognition to align with the completed transfer of promised goods or services to customers and the Company's entitled contractual consideration in return.

The following five steps are applied under *ASC 606* for the Company's revenue recognition: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) it satisfies a performance obligation.

The Company's contracts with customers typically include one performance obligation: the delivery of aprevo interbody implant with the accompanying inserter. Revenue from the sales of aprevo is typically recognized by the Company at the time of its use as part of the spine fusion surgical procedure, which represents the point in time when the performance obligation is satisfied in full. The consideration the Company is entitled to for sales of aprevo is fixed based on the stated contractual amount.The Company generally does not have obligations for returns, refunds, and other similar obligations.

The Company utilizes contracted sales agents that cover each surgery and has determined that it is the "principal" in these transactions as it is responsible for product fulfillment and customer acceptability, carries the inventory risk, and has sole discretion in setting the price for the products. The Company therefore recognizes revenue at gross (i.e., reported revenue is not reduced for sales agents' fees that are reported in "sales and marketing" expense in the accompanying Statements of Operations and Comprehensive Loss). Payment terms are typically 30 to 60 days. Payment is generally not received in advance of surgery and therefore, the Company does not typically record contract liabilities or deferred revenue.

Cost of Sales

"Cost of sales" includes the patient-specific design costs and manufacturing costs of the aprevo interbody implants and accompanying inserter that are capitalized within inventories. These include allocations for personnel costs, software license amortization, contract manufacturing, and other third-party services, packaging and shipping costs, overhead cost allocations, and provisions of excess and obsolesce inventory charges.

Research and Development

"Research and development" expenses include personnel costs (including salaries, bonuses, stock-based compensation expense, and benefits), allocated facility costs, product prototype materials, product testing, clinical studies that facilitate the development of new products, allocated software license amortization expenses, and consulting and other service fees. These costs are recognized in the accompanying Statements of Operations and Comprehensive Loss in the period incurred.

Sales and Marketing

"Sales and marketing" expenses consist of selling expenses related to employee related costs, including salaries, commissions, bonuses, stock-based compensation expense, benefits, and travel, as well as independent sales agent fees. Marketing expenses consist of various digital and print initiatives to increase market awareness of the Company's product and technology, conference and trade show fees, and consulting services. The Company may provide ancillary and generic surgical instruments for the convenience of its independent sales agents that cover each surgery. These costs are also recognized in the period incurred and included within "sales and marketing" expenses in the accompanying Statements of Operations and Comprehensive Loss.

General and Administrative

"General and administrative" expenses consist primarily of employee-related costs, including salaries, bonuses, stock-based compensation expense and benefits, for personnel in executive, legal, finance, and human resources. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance and facility-related costs. These costs are recognized in the accompanying Statements of Operations and Comprehensive Loss in the period incurred.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for stock options and restricted stock units granted to employees, consultants, and members of its Board of Directors. Stock option awards are at an exercise price of not less than 100% of the fair market value of common stock on the respective date of grant. The grant date is the date the terms of the award are formally approved by the Company's Board of Directors. The Company uses the Black-Scholes option pricing model to estimate the fair value of stock option awards as of the date of grant. For issuances of restricted stock units with service vesting conditions, the Company determines the fair value of the award based on the closing market value of its common stock on the grant date. For issuances of restricted stock units with market vesting conditions, the Company determines the fair value of the award using a Monte Carlo simulation methodology considering the probability of achievement of the market conditions.

The measurement of the fair value of stock option awards, and recognition of stock-based compensation expense, requires assumptions by management that may involve inherent uncertainties and the application of management's judgment, including (a) the estimated fair value of the Company's common stock on the date of the option grant, (b) the expected term of the stock option until its exercise by the recipient, (c) stock price volatility over the expected term, (d) the prevailing risk-free interest rate over the expected term, and (e) expected dividend payments over the expected term.

Management estimates the expected term of awarded stock options utilizing the "simplified method" for awards since the Company does not yet have sufficient exercise history since its corporate formation and lacks specific historical and implied stock volatility information. Management estimates stock price volatility for option grants by evaluating the average historical volatility of a peer group of companies for the period immediately preceding the option grant for a term that approximates the options' expected term. Estimates for the risk-free interest rate are based upon the U.S. Department of the Treasury yield curve in effect at award grant for the period that corresponds with the expected term of the awarded stock option. The expected dividend yield is zero because the Company has never paid cash dividends and does not expect to for the foreseeable future. The Company has elected to account for share-based award forfeitures as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws expected to be in effect when the asset or liability is expected to be realized or settled. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that is deemed more likely than not to be realized.

In the ordinary course of business, there may be transactions for which the ultimate tax outcome is uncertain. The Company assesses uncertain tax positions in each of the tax jurisdictions in which it has operations and accounts for the related financial statement implications. Unrecognized tax benefits are reported using the "two-step approach" under which tax effects of a position are recognized only if it is more likely than not to be sustained and the amount of the tax benefit recognized is equal to the largest tax benefit that is greater than 50% likely of being realized upon ultimate settlement of the tax position.

Determining the appropriate level of unrecognized tax benefits requires the Company to exercise judgment regarding the uncertain application of tax law. The amount of unrecognized tax benefits is adjusted when information becomes available or when an event occurs indicating a change is appropriate. The Company includes interest and penalties related to its uncertain tax positions as part of income tax expense, if any. The Company did not have any interest or penalties related to its uncertain tax positions for the years ended December 31, 2025 and 2024.

Comprehensive Loss

Comprehensive loss encompasses all changes in equity other than those arising from transactions with stockholders. For the years ended December 31, 2025 and 2024, the Company had no other comprehensive loss items and accordingly, "net loss" equaled "comprehensive loss."

Earnings per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) attributable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted earnings (loss) per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. Since the Company had net loss in the years ended December 31, 2025 and 2024, basic and diluted net loss per common share are the same.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

Income Taxes - In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Tax Disclosures* ("ASU 2023-09"). This ASU expands disclosures in an entity's income tax rate reconciliation table and regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update is effective for fiscal years beginning after December 15, 2024. The Company adopted this guidance retrospectively during the fiscal year ended December 31, 2025 and, as a result, certain disclosures for the year ended December 31, 2024 were reclassified to align with the current year presentation within *Note 11*. The adoption of ASU 2023-09 did not have a material impact on the Company's financial statements.

Recently Issued Accounting Standards Not Yet Effective

Expense Disaggregation Disclosures - In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). This ASU requires new financial statement disclosures disaggregating prescribed expense categories within relevant income statement expense captions. ASU 2024-03 will be effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting the standard.

Financial Instruments - Credit Losses - In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses for Accounts Receivable and Contract Assets* ("ASU 2025-05"). This ASU provides entities with the option to elect a practical expedient that assumes that the current conditions as of the balance sheet date will remain unchanged for the remaining life of the asset when developing a reasonable and supportable forecast as part of estimating expected credit losses on these assets. ASU 2025-05 will be effective for fiscal years beginning after December 15, 2025 and interim periods within those fiscal years. The Company is currently evaluating the impact of adopting the standard.

Internal-Use Software - In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"). This ASU is intended to simplify the capitalization guidance by removing all references to prescriptive and sequential software development stages. This ASU also requires entities to begin capitalizing software costs when management authorizes and commits to funding the software project, and it is probable that the project will be completed and the software will be used for its intended purpose. ASU 2025-06 will be effective for fiscal years beginning after December 15, 2027 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting the standard.

Derivatives and Share-Based Consideration from a Customer - In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). This ASU provides for a new scope exception to the derivatives guidance for underlyings based on the operations or activities specific to one of the parties to the contract, and also clarifies that share-based noncash consideration received from a customer as consideration for the transfer of goods or services in a revenue contract is subject to the revenue guidance and not the financial instruments guidance unless and until the company's right to receive or retain the share-based noncash consideration is unconditional as defined in ASU 2025-07. The amendments are effective for annual reporting periods beginning after December 15, 2026, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting the standard.

3. Balance Sheet Account Detail

The composition of selected captions within the accompanying Balance Sheets are summarized below:

Property and Equipment, Net

The components of "property and equipment, net" as of December 31, 2025 and 2024 are as follows:

(in thousands)	As of December 31, 2025	As of December 31, 2024
Office equipment	$ 671	$ 488
Furniture and fixtures	144	91
Leasehold improvements	355	80
Construction in progress	524	—
Software	319	—
Total	2,013	659
Less: accumulated depreciation	(526)	(399)
Property and equipment, net	$ 1,487	$ 260

Depreciation expense for the years ended December 31, 2025 and 2024 was $0.3 million and $0.1 million, respectively. The Company has not recognized any impairment loss for any long-lived assets for the years ended December 31, 2025 and 2024.

Accrued Liabilities

The components of "accrued liabilities" as of December 31, 2025 and 2024 are as follows:

(in thousands)	As of December 31, 2025	As of December 31, 2024
Accrued sales agent commissions	$ 1,793	$ 1,420
Accrued clinical studies	291	529
Liability associated with stock option exercises prior to vesting	70	112
Accrued professional fees	560	90
Other accrued expenses	573	536
Total accrued liabilities	$ 3,287	$ 2,687

4. Debt

Customers Bank Credit Facility

In December 2022, the Company and Signature Bank, subsequently succeeded by Customers Bank, entered into a loan and security agreement (the "Customers Loan Agreement") with an initial maturity to December 2026 that provided $12.5 million of available principal. The Customers Loan Agreement required the Company to pay a tiered cash-based "Success Fee" upon a defined Liquidity Event that was eliminated in March 2024 in connection with the Third Amendment, as discussed below.

The Customers Loan Agreement bore interest at the *greater of* (a) 1.0% below Prime Rate or (b) 5.25%. The Customers Loan Agreement also included an end of term charge of 4.21% of the aggregate principal amount funded, and such end of term charge remains in effect through the Third Amendment and Fourth Amendment. The end of term charge is recorded within "other long-term liabilities" within the Balance Sheets and is accrued over the term of the loan through interest expense within the Statements of Operations and Comprehensive Loss using the "effective interest method." Debt issuance costs are accounted for as a debt discount and amortized as "interest expense" within the Statements of Operations and Comprehensive Loss over the term of the loan using the "effective interest method."

On March 7, 2024, the Company amended the Customers Loan Agreement (the "Third Amendment") to increase the total principal available under the credit facility from $12.5 million to $18.8 million, subject to the achievement of certain revenue and other milestones, with extended maturity up to December 20, 2027, if certain conditions are met. The applicable per annum interest rate was adjusted to the greater of (a) WSJ Prime Rate + 0.25% or (b) 5.25%.

As part of the Third Amendment, the Success Fee was contractually eliminated and replaced with the issuance of a warrant exercisable for up to 58,420 shares of Series B convertible preferred stock at an exercise price of $6.93 per share (the "Series B Warrant"). Upon issuance, the Series B Warrant was immediately exercisable for 26,881 shares with the remaining 31,539 additional shares becoming exercisable upon the required achievement of certain revenue milestones and/or draws of this expanded credit facility. The Series B Warrant was scheduled to expire 10 years from the issuance date of March 6, 2024, but was amended and restated in connection with the subsequent Fourth Amendment (see below). The fair value of the Series B Warrant at issuance in conjunction with the Third Amendment was $0.2 million.

In May 2024, the Company drew $6.3 million under the Customers Loan Agreement upon the achievement of requisite revenue milestones.

On December 30, 2024, the Company further amended the Customers Loan Agreement (the "Fourth Amendment") to expand the credit facility from $18.8 million to $27.5 million, with the addition of two new debt draw tranches. Upon the Fourth Amendment, the Company had the ability to draw $7.5 million immediately and the remaining $4.4 million was contingent upon the achievement of a requisite revenue milestone. During the year ended December 31, 2025, a requisite revenue milestone was met which resulted in the interest-only period being extended through January 31, 2027, followed by principal repayment over 33 months thereafter. Additionally, as a result of the requisite revenue milestone being met, the remaining $4.4 million became available to draw. Upon achievement of an additional revenue milestone, the interest-only period and repayment terms could be further extended to an interest-only period through July 31, 2027, followed by principal repayment over 27 months thereafter. However, such additional revenue milestones were not met prior to being replaced under the Fifth Amendment discussed below.

As part of the Fourth Amendment, the Company partially modified the aggregate 58,420 Series B Warrant issued with the Third Amendment, reducing the number of shares exercisable subject to remaining future draws of the credit facility as of the date of the Fourth Amendment from 11,289 shares to 5,644, with the remaining 5,644 shares becoming exercisable ratably with subsequent debt draws. Additionally, the expiration date for the Series B Warrant was extended to December 30, 2034. The modification of the Series B Warrant upon the Fourth Amendment resulted in an immaterial increase in the warrant liability.

Additionally, as part of the Fourth Amendment, the Company issued a new warrant that was exercisable into the Company's Series C convertible preferred stock ("Series C Warrant"), subject to certain revenue and debt draw milestones. The Series C Warrant was exercisable for up to 20,375 shares at an exercise price of $10.74 per share and expires on December 30, 2034. Upon issuance, the Series C Warrant was immediately exercisable into 5,093 shares with the remaining 15,282 additional shares becoming exercisable upon the required achievement of certain revenue milestones and/or draws of this expanded credit facility. During the year ended December 31, 2025, the Company achieved the revenue milestone, causing the Series C Warrant to be exercisable into an additional 5,095 shares.

In connection with the close of the Company's IPO on July 24, 2025, all of the outstanding shares of convertible preferred stock were converted into common stock. As a result, the warrants to purchase convertible preferred stock are now exercisable into common stock. Refer to *Note 2* for additional information regarding the reclassification of certain warrants from liability classified to equity classified during the year ended December 31, 2025.

On October, 29, 2025, the Company amended the Customers Loan Agreement (the "Fifth Amendment") to expand their credit facility to include (i) a term loan in the principal amount of up to $50.0 million (the "Term Loan"), $17.5 million of which is contingent upon the achievement of requisite revenue milestones, and (ii) a $10.0 million non-formula revolving line of credit (the "Non-Formula Revolving Line"), provided that at no time shall the aggregate amount advanced under the Term Loan and the Non-Formula Revolving Line exceed $50.0 million.

The maturity date of the Term Loan was extended to October 15, 2030, with an interest-only period through October 15, 2027, followed by principal repayment over 36 months thereafter. Upon achievement of a certain revenue milestone, the interest-only period and repayment terms of the Term Loan may be extended through April 15, 2028 followed by principal repayment over 30 months, and upon achievement of an additional milestone, may be further extended through October 15, 2028, followed by principal repayment over 24 months thereafter. The Non-Formula Revolving Line will mature on October 15, 2028. The applicable per annum interest rate did not change as a result of the Fifth Amendment and remains as the greater of (a) WSJ Prime Rate + 0.25% or (b) 5.25%, and was 7.00% as of December 31, 2025.

In connection with the Fifth Amendment, the Company partially amended the Series B Warrant, reducing the number of shares of common stock exercisable subject to future draws under the Customers Loan Agreement as of the date of the Fifth Amendment from 58,420 to 52,776 (the "Amended Series B Warrant"). In addition, the Company partially amended the Series C Warrant, reducing the number of shares of common stock exercisable subject to future draws under the Customers Loan Agreement as of the date of the Fifth Amendment from 20,375 to 10,188 (the "Amended Series C Warrant" and, together with the Amended Series B Warrant, the "Amended Warrants"). As a result of the Amended Warrants, Customers Bank's contingent rights to exercise the Warrants for an aggregate of 15,831 shares of common stock were canceled. As of December 31, 2025, the Series B and Series C Warrants are exercisable for 52,776 and 10,188 shares of the common stock, respectively.

On December 23, 2025, the Company amended the Customers Loan Agreement (the "Sixth Amendment") to permit the Company to maintain certain limited deposit accounts outside of Customers Bank. No other terms of the Customers Loan Agreement were affected by the Sixth Amendment.

Each of the Third, Fourth, Fifth, and Sixth Amendments were accounted for as debt modifications with no gain or loss recognized. The carrying value of amounts outstanding under the Customers Loan Agreement approximates its fair value as of December 31, 2025. The fair value of the term loan is classified as a Level 2 measurement because interest rates charged are similar to other financial instruments with similar terms and maturities.

As of December 31, 2025, $15.6 million of principal was outstanding under the Term Loan that is set to mature on October 15, 2030 and there were no borrowings outstanding under the Non-Formula Revolving Line. As of December 31, 2025, an aggregate $26.9 million remained available for borrowing under the Term Loan and the Non-Formula Revolving Line, net of amounts outstanding of $15.6 million . The Company was in compliance with all applicable Customers Loan Agreement covenants.

Interest expense on the Customers Loan Agreement was $1.4 million and $1.3 million for the years ended December 31, 2025 and 2024, respectively. Of these amounts, $0.2 million was related to amortization of the debt discount and issuance costs for both the years ended December 31, 2025 and 2024. The effective interest rate was 7.60% as of December 31, 2025.

The following table summarizes contractual principal payments as of December 31, 2025:

Year ending December 31,	*(in thousands)*
2026	—
2027	868
2028	5,208
2029	5,208
2030	4,341
Total future principal payments	15,625
Unamortized issuance costs	(279)
Total term loan, net	**$ 15,346**

5. Common Stock

In accordance with the Company's Amended and Restated Certificate of Incorporation dated July 24, 2025, the Company is authorized to issue two classes of stock—common stock and preferred stock. The Company shall have authority to issue 600,000,000 shares of common stock with par value of $0.00001 per share and 10,000,000 shares of preferred stock with par value of $0.00001 per share. As of December 31, 2025, the Company does not have any issued or outstanding shares of preferred stock.

Common stock reserved for future issuance as of December 31, 2025, consisted of the following:

	As of December 31, 2025
Common stock options outstanding	3,151,787
Restricted stock units outstanding	181,810
Shares available for future issuance under the 2025 Plan	2,573,538
Series B Warrant (1)	52,776
Series C Warrant (1)	10,188
Total common stock reserved for future issuance	**5,970,099**

(1) The Series B Warrant and Series C Warrant are exercisable into common stock (see *Note 2*).

SVB Common Stock Warrant

In April 2021, in connection with its entry into a loan and security agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), the Company issued a warrant to purchase up to an aggregate of 10,338 shares of common stock at an exercise price of $0.34 per share (the "SVB Common Stock Warrant"). In July 2021, pursuant to the terms of the SVB Common Stock Warrant, the SVB Common Stock Warrant became exercisable for an additional 10,349 shares of common stock at an exercise price of $0.34 per share in connection with a principal draw. In February 2022, the Company amended the SVB Loan Agreement to draw additional principal and the SVB Common Stock Warrant became exercisable for an additional 5,176 shares of common stock at an exercise price of $0.40 per share. In December 2022, the Company terminated and repaid in full all amounts outstanding under the SVB Loan Agreement. On August 14, 2025, the Company issued 25,184 shares of common stock in conjunction with a net cashless exercise of the SVB Common Stock Warrant. As a result of the exercise, the SVB Common Stock Warrant is no longer outstanding.

6. Stock-Based Compensation

In September 2019, the Company adopted the Carlsmed, Inc. 2019 Stock Incentive Plan, which was subsequently amended, most recently in January 2025 (the "2019 Plan"). The 2019 Plan is administered by the Company's board of directors (the "Board of Directors"). On July 10, 2025, the Board of Directors adopted, and the Company's stockholders approved, the Carlsmed, Inc. 2025 Equity Incentive Plan (the "2025 Plan"), which became effective on July 21, 2025. The 2025 Plan replaced the 2019 Plan, as the Board of Directors determined to not make additional grants under the 2019 Plan following the closing of the IPO. However, the 2019 Plan will continue to govern outstanding equity awards granted under the 2019 Plan. The 2025 Plan allows the Company to grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other awards. The number of shares initially available for issuance under awards granted pursuant to the 2025 Plan was 3,595,177. As of December 31, 2025, there were 2,573,538 shares available for issuance pursuant to the 2025 Plan.

The exercise price of a share subject to a stock option may not be less than the fair market value of a share of the Company's common stock at the grant date. Stock options granted to employees typically vest over four years, with 25% vesting on the first anniversary of the grant date and the remainder vesting ratably on a quarterly basis thereafter, subject to continued employment, and a contractual term of 10 years; related expense is recognized in the accompanying Statements of Operations and Comprehensive Loss on a straight-line basis over each award's vesting period.

The Company also grants stock option awards to non-employees, including members of the Board of Directors. Options granted under the 2025 Plan and the 2019 Plan may be subject to vesting acceleration in connection with a "Change in Control" or "Corporate Transaction," as defined in the respective plans.

The 2019 Plan allows for the exercise of certain stock option grants prior to vesting ("early exercise"), with such grants approved by the Board of Directors. For these awards, in the event of employee termination, the Company has the right, but not the obligation, to repurchase the portion of unvested stock at the *lower of* the exercise price or the then-current fair value. A liability is recorded within "accrued liabilities" on the accompanying Balance Sheets that is equal to the cash received for these early exercises, and this liability is reduced as vesting occurs. Unvested shares that have been early exercised are reflected in "common shares issued" but excluded from "common shares outstanding" on the accompanying Financial Statements. As of December 31, 2025, 59,738 shares of early exercised stock options were outstanding, representing an early exercise liability of $0.1 million. As of December 31, 2024, 95,579 shares of early exercised stock options were outstanding, representing an early exercise liability of $0.1 million.

RSUs granted typically have three-year vesting schedules and the related expense is recognized in the accompanying Statements of Operations and Comprehensive Loss on a straight-line basis over each award's vesting period.

Stock Options

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	1,785,633	$ 1.01	7.5	$ 5,938
Granted	1,840,346	9.88		
Exercised	(458,530)	0.44		
Forfeited	(15,662)	4.49		
Outstanding at December 31, 2025	3,151,787	$ 6.26	8.3	$ 21,526
Vested and Exercisable at December 31, 2025	1,184,224	$ 2.04	6.5	$ 11,676

The weighted average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $4.77 and $2.57 per share, respectively. The total fair value of options that vested during the years ended December 31, 2025 and 2024 was $1.3 million and $0.2 million, respectively, based on the grant date fair value.

The aggregate intrinsic value in the above table is calculated as the difference between the fair value of the Company's common stock price and the exercise price of the stock options. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $1.9 million and $0.2 million, respectively.

The Company recorded stock-based compensation expense for stock options of $1.6 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, there was $8.5 million of unrecognized compensation for unvested stock options and the weighted-average period over which this remaining compensation cost will be recognized is 3.0 years.

The grant date fair value of the options is determined using an option pricing model. The assumptions that were used in estimating the grant date fair value of stock options under the option pricing method for the years ended December 31, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Expected stock price volatility [1]	44.0%	45.4%
Risk-free interest rate [2]	4.16%	4.32%
Expected annual dividend yield [3]	0.0%	0.0%
Expected term (years) [4]	6.01	5.97

(1) Based on the median stock price volatility for peer public companies over a historic timeframe similar to the expected term, with adjustments for differences in size and capital structure.

(2) Based on the U.S. Treasury yield curve in effect as of the valuation date.

(3) The Company has not paid and does not currently anticipate paying a cash dividend on its common stock.

(4) The expected term of stock options granted to employees represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term, which calculates the expected term as the average time-to-vesting and the contractual life of the options for stock options issued to employees and non-employees.

Restricted Stock Units

The Company did not have any RSUs granted or outstanding during the year ended December 31, 2024.

The following summarizes RSU activity, excluding PSUs (defined below), for the Company for the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested - December 31, 2024	—	$ —
Granted	69,332	15.00
Vested	—	
Forfeited	—	
Non-vested - December 31, 2025	69,332	$ 15.00

The Company recorded stock-based compensation expense for RSUs, excluding PSUs, of $0.2 million for the year ended December 31, 2025. As of December 31, 2025, there was $0.9 million of unrecognized compensation for unvested RSUs, excluding PSUs, and the weighted-average period over which this remaining compensation cost will be recognized is 2.6 years.

Performance Restricted Stock Units

During the year ended December 31, 2025, the Company granted 112,478 RSUs to an employee that have a contractual term of four years and vest upon the satisfaction of performance, market, and service conditions ("PSUs"). The performance conditions require either (1) the completion of an initial public offering where the Company's stock is listed on an established stock exchange or (2) the occurrence of a corporate transaction, such as a merger, acquisition, or similar liquidity event. The market condition is based on the achievement of share price targets following the completion of an initial public offering or on the date of a corporate transaction. The service condition requires the employee to provide continued service through the achievement of both the performance and market conditions. The grant date fair value of such PSUs of $3.14 per PSU was determined using a Monte Carlo simulation methodology, which takes into consideration the probability of achievement of the market conditions.

Expense for the PSUs began on the grant date and is recognized over the derived requisite service period of the award. However, no compensation expense was recognized until the performance-based vesting condition was probable of being achieved. On July 24, 2025, the Company completed its IPO, satisfying the performance condition of the PSUs. Consequently, compensation expense has been recognized proportionally for the completed portion of the requisite service period up to the IPO. The remaining unrecognized expense will be amortized over the remaining derived requisite service period associated with the market condition, regardless of whether the market condition is ultimately satisfied.

The Company recorded stock-based compensation expense for PSUs of $0.1 million for the year ended December 31, 2025. As of December 31, 2025, there was $0.2 million of unrecognized compensation for unvested PSUs and the weighted-average period over which this remaining compensation cost will be recognized is 1.5 years.

Stock-based Compensation Cost

The compensation cost that has been included in the Company's Statements of Operations and Comprehensive Loss for all stock-based compensation arrangements is detailed as follows:

	Year Ended December 31,	
(in thousands)	2025	2024
General and administrative	$ 904	$ 126
Research and development	616	68
Sales and marketing	407	59
Total	$ 1,927	$ 253

7. Convertible Preferred Stock

In March 2024, the Company issued a total of 3,586,091 shares of Series C convertible preferred stock at a price of $10.74 per share for gross cash proceeds of $38.5 million.

In September 2024, the Company issued a total of 1,304,032 shares of Series C convertible preferred stock at a price of $10.74 per share for gross cash proceeds of $14.0 million. In January 2025, the Company issued a total of 1,117,743 shares of Series C convertible preferred stock at a price of $10.74 per share for gross cash proceeds of $12.0 million. The September 2024 and January 2025 issuances of Series C convertible preferred stock were completed below the fair value of the shares as of each respective issuance date. The Company recorded the excess of fair value over the issuance price as a "deemed dividend" within additional paid-in-capital ("APIC") in the amount of $0.6 million as of both issuance dates. The deemed dividends reflect the distribution of value from common stockholders to preferred stockholders due to the implicit discount on these shares issued in September 2024 and January 2025. Since the Company remained in an accumulated deficit position at each respective issuance date, these deemed dividends were recorded directly to APIC rather than retained earnings.

The Company closed the IPO on July 24, 2025 and all of the outstanding shares of convertible preferred stock were converted into 15,245,731 shares of common stock. Prior to the closing of the IPO, and as of December 31, 2024, the Company's convertible preferred stock contained the following rights and privileges.

Dividends

Series A, Series B, and Series C preferred stock had the first right to receive any dividend, only when and if declared by the Company on each outstanding share of preferred stock in an amount equal to a dividend of 6% of the applicable original issue price per annum. Dividends for each series of preferred stock were to be payable pari passu and were non-cumulative. Series A, Series B, and Series C preferred stock had certain preferential dividend rights over common stock as set forth in the Company's Amended and Restated Certification of Incorporation. No dividends on preferred stock or common stock were declared by the Company from its inception through December 31, 2025.

Conversion into Common Shares

Series A, B, and C convertible preferred stock was convertible into common shares at the holders' election. The number of common shares received upon conversion was determined by dividing the original issuance price by the conversion price, then multiplying by the number of preferred shares being converted. The initial conversion price per share for Series A, Series B, and Series C convertible preferred stock was equal to the respective original issuance prices per share and therefore was convertible into common stock on a 1:1 as-converted basis. The respective initial conversion prices per share for all series of convertible preferred stock were subject to adjustment in the event of share splits, combinations, mergers, dividends and distributions, and other capital reconstructions.

Redemption

Series A, Series B, and Series C preferred stock were not redeemable for cash. However, Series A, Series B, and Series C preferred stock included terms whereby certain deemed liquidation events could trigger redemption, at the holders' option, that were outside the control of the Company. Accordingly, Series A, Series B, and Series C preferred stock are classified outside of permanent equity on the accompanying Balance Sheets as of December 31, 2024.

Voting Rights

The holders of Series A, Series B, and Series C preferred stock were entitled to one vote per share held on any matter presented for a vote of the stockholders at any meeting of the stockholders of the Company, subject to the potential adjustments set forth in the Company's Amended and Restated Certificate of Incorporation.

Liquidation Preference

In the event of a liquidation, dissolution or winding up of the Company or a Deemed Liquidation Event, the Series A, Series B, and Series C preferred stockholders had a participating liquidation preference to the common stockholders in the amount per share equal to the original issue price plus any declared but unpaid dividends. As such, the payment of the liquidation preference would be $2.81 per share for Series A preferred stock, $6.93 per share for Series B preferred stock, and $10.74 per share for Series C preferred stock plus any declared but unpaid dividends, after which the shares of Series A, Series B, and Series C preferred stock would participate in any remaining proceeds available for distribution to stockholders with holders of common stock pro rata on an as-converted basis. If upon a liquidation, dissolution or winding up of the Company or a Deemed Liquidation Event the assets of the Company were not sufficient to pay the holders of the Series A, Series B, and Series C preferred stock the amount to which they were entitled, the holders of the Series A, Series B, and Series C preferred stock shall share ratably in any distribution of the assets in proportion to the amounts to which they would otherwise have been entitled in proportion to the respective amounts that would otherwise have been payable in respect of such shares if all amounts payable on or with respect to such shares were paid in full.

8. Net Loss Per Share

Basic net loss per share is calculated by *dividing* net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding, net of the weighted-average unvested restricted stock subject to repurchase by the Company, if any, during the period. Diluted loss per share is calculated by *dividing* the net loss attributable to common stockholders by the weighted-average number of common shares outstanding, adjusted for the effects of potentially dilutive common stock, which are comprised of stock options and stock warrants, using the "treasury-stock method," and convertible preferred stock, using the "if-converted method."

Because the Company reported net losses for the period presented, all potentially dilutive common stock is antidilutive for this period and therefore basic and diluted net loss per common share are the same. The convertible preferred stock are considered participating securities; however, they were excluded from the computation of basic loss per share in the periods of net loss as there is no contractual obligation for the holders to share in the losses of the Company.

The following table presents the number of anti-dilutive shares excluded from the calculation of diluted net loss per share as of December 31, 2025 and 2024:

	As of December 31,	
	2025	2024
Common stock options outstanding [1]	3,151,787	1,785,633
Convertible preferred stock (common stock equivalent) [2]	—	14,127,988
Restricted stock units outstanding [3]	181,810	—
Series B Warrant [4]	52,776	58,420
Series C Warrant [5]	10,188	20,375
SVB Common Stock Warrant [6]	—	25,863
Total	3,396,561	16,018,279

(1) 1,184,224 stock options vested and exercisable as of December 31, 2025.
(2) Convertible preferred stock was eligible to convert to common stock on a 1:1 basis upon the holder's election or upon a Deemed Liquidation Event. Convertible preferred stock was converted into common stock on the IPO (see *Note 7*).
(3) No restricted stock units are vested as of December 31, 2025.
(4) Series B Warrant exercisable into 52,776 shares of common stock as of December 31, 2025.
(5) Series C Warrant exercisable into 10,188 shares of common stock as of December 31, 2025.
(6) On August 14, 2025, the SVB Common Stock Warrant was exercised (see *Note 5*).

9. Commitment and Contingencies

Legal Matters

The Company from time to time is involved in legal matters incidental to the conduct of its business. In the opinion of management, there are no claims outstanding that would have a material adverse effect on the Company's financial position, results of operations, or cash flows.

Operating Lease

In the ordinary course of business, the Company enters into lease agreements with unaffiliated third parties for its facilities and office equipment. As of December 31, 2025, the Company had two active operating leases for a combined 23,000 square feet of administrative, engineering, and research and development space located in Carlsbad, California.

The first lease encompasses 16,000 square feet and commenced on May 1, 2021, and was originally set to expire on April 30, 2024. On December 4, 2023, the Company entered into a first amendment to the original lease agreement which resulted in the lease term extending to June 30, 2028. The Company used its incremental borrowing rate at the lease modification date of 9.08% in determining the discount rate utilized to present value the future minimum lease payments since an implicit interest rate in the lease agreement was not determinable.

On May 15, 2025, the Company entered into a second amendment to its original lease agreement, which modified the lease terms to lease an additional suite comprising an additional 7,000 square feet of space. The lease modification was accounted for as a separate contract. This new lease is set to expire on June 30, 2028. The Company used its incremental borrowing rate at the lease modification date of 7.62% in determining the discount rate utilized to present value the future minimum lease payments since an implicit interest rate in the lease agreement was not determinable.

Total lease expenses for the years ended December 31, 2025 and 2024 were $0.7 million and $0.6 million, respectively.

The Company's real estate taxes, insurance costs, and common area maintenance, are included in monthly rent and not separately itemized. Rent expense is allocated to cost of sales, research and development, sales and marketing, and general and administrative expenses in the accompanying Statements of Operations and Comprehensive Loss.

The weighted-average lease terms and discount rates are as follows:

	As of December 31, 2025	As of December 31, 2024
Weighted-average remaining lease term	2.50	3.50
Weighted-average discount rate	8.63%	9.08%

The aggregate future minimum lease payments under this lease as of December 31, 2025, are as follows:

(in thousands) Year ending December 31,	Payments
2026	895
2027	926
2028	472
Total undiscounted lease payments	$ 2,293
Less: imputed interest	(225)
Present value of future lease payments	$ 2,068
Short-term operating lease liabilities	752
Long-term operating lease liabilities	1,316
Total operating lease liabilities	$ 2,068

The operating cash outflows included in the measurement of the operating lease liabilities was $0.6 million and $0.5 million for the years ended December 31, 2025 and 2024, respectively.

10. Segment Reporting

The Company has one business activity and operates as a single operating and reportable segment: the designing, manufacturing, and marketing of aprevo, a comprehensive technology platform for spine fusion surgical procedures. The Company typically derives its current revenues from selling aprevo to its hospital and ambulatory surgical center customers.

The Company's "Chief Operating Decision Maker" (the "CODM") is its Chief Executive Officer. The CODM uses net loss reported on the Statements of Operations and Comprehensive Loss to assess performance and allocate resources for the reportable segment. This metric helps assess the effectiveness of the Company's product offering and monitor budget versus actual results.

The following table provides the operating financial results of the Company's single reportable segment. It includes the significant expense categories regularly provided to the CODM, computed under GAAP and reconciled to the Company's total "net loss" as presented in the Statements of Operations and Comprehensive Loss:

	Year Ended December 31,	
(in thousands)	2025	2024
Revenue	$ 50,511	$ 27,165
Less:		
Cost of sales	12,471	7,117
Selling expenses	26,426	15,550
Marketing expenses	4,666	4,649
Product and software development costs	8,722	6,640
Clinical, medical, and regulatory expenses	4,486	4,247
Other segment expenses*	24,314	13,084
Interest expense	1,430	1,321
Interest income	(2,698)	(1,330)
Change in fair value of warrant liabilities	328	144
Net loss	$ (29,634)	$ (24,257)

* Other segment expenses primarily include corporate, compliance, and research and development support expenses.

Assets provided to the CODM are consistent with those reported on the accompanying Balance Sheets. All long-lived assets are held in the United States, and net losses are solely attributable to U.S. operations.

11. Income Taxes

The Company had no federal or state income tax expense nor any payments for federal or state income taxes for the years ended December 31, 2025 and 2024. The Company's pretax loss for 2025 and 2024 was solely due to domestic operations.

A reconciliation of income tax expense to the amount computed by applying the statutory federal income tax rate to the loss from operations for the years ended December 31, 2025 and 2024 are summarized as follows:

(in thousands, except for percentages)	For the Year Ended December 31, 2025		For the Year Ended December 31, 2024	
Income tax benefit at federal statutory rate	$ (6,223)	21.0 %	$ (5,094)	21.0 %
State and local income tax benefit, net of federal income tax effect*	(60)	0.2	(50)	0.2
Tax credits:				
Research and development tax credit	(460)	1.6	(338)	1.4
Changes in valuation allowance	6,190	(20.9)	5,245	(21.6)
Nontaxable or nondeductible items:				
Permanent items	189	(0.6)	89	(0.4)
Stock-based compensation	117	(0.4)	25	(0.1)
Officer's compensation	55	(0.2)	—	—
Changes in unrecognized tax benefits	175	(0.6)	137	(0.6)
Other, net	17	(0.1)	(14)	0.1
Provision for income taxes	$ —	0.0 %	$ —	0.0 %

* State taxes in California made up the majority (greater than 50%) of the tax effect in this category for 2025 and 2024.

The Company's "net deferred tax assets" are comprised of the following as of December 31, 2025 and 2024:

(in thousands)

Deferred tax assets:	As of December 31, 2025	As of December 31, 2024
Net operating loss carryforwards	$ 17,902	$ 10,934
Capitalized R&D expenses	4,232	5,143
Lease liability	528	434
Accrued expenses	1,117	406
R&D credits and other tax credits	1,548	1,020
Inventory	849	438
Stock-based compensation	215	46
Other	448	315
Gross deferred tax assets	$ 26,839	$ 18,736
Less: valuation allowance	(26,369)	(18,332)
Net deferred tax assets	$ 470	$ 404
Deferred tax liabilities:		
Right-of-use asset	(466)	(404)
Other	(4)	—
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize existing deferred tax assets. Based on the weight of evidence, including a history of operating losses, management has determined that it is more likely than not that the Company's net deferred tax assets will not be realized. Accordingly, a valuation allowance has been established by the Company to fully offset these net deferred tax assets. The valuation allowance increased by $8.0 million and $6.1 million during the years ended December 31, 2025 and 2024, respectively.

At December 31, 2025, the Company had federal and state net operating loss ("NOL") carryforwards of approximately $69.0 million and $57.5 million, respectively. The federal losses will carry forward indefinitely and can be used to offset up to 80% of future annual taxable income. State loss carryforwards of approximately $10.5 million will carry forward indefinitely. State loss carryforwards of approximately $47.0 million begin expiring in 2032, unless previously utilized. The Company also has federal and state research and development ("R&D") credit carryforwards totaling $1.3 million and $1.0 million, respectively. The federal credits begin to expire in 2039, unless previously utilized, and the state credits do not expire.

The Company's NOL and credit carryforwards may be subject to a substantial annual limitation pursuant to Internal Revenue Code ("IRC") Sections 382 and 383 in connection with future utilization and potential ownership changes of the Company. These ownership changes may limit the amount of NOL and credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by the IRC results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups. As of December 31, 2025, the Company has not completed a study to assess whether an ownership change within the meaning of IRC Section 382 has occurred. If a change in ownership occurred which resulted in a limitation on the amount of NOLs and credits which may be available to offset future taxable income, the related deferred tax asset would be reduced or eliminated with a corresponding reduction in the valuation allowance.

As of December 31, 2025, and 2024, the Company had unrecognized tax benefits of $0.6 million and $0.4 million, respectively. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits would not have any effect on the Company's effective tax rate.

The Company recognizes interest and penalties related to income tax matters in income tax expense. No such costs were recorded during the years ended December 31, 2025 and 2024, and the Company had no accrued interest or penalties recorded as of December 31, 2025 or 2024.

Generally, the Company’s federal and state income tax returns since inception in 2018 are subject to examination by tax authorities. The Company is not under examination by any tax jurisdiction.

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was signed into law, which enacts significant changes to U.S. tax and related laws. Some of the provisions of the new tax law affecting corporations include, but are not limited to, expensing of domestic research expenses, increasing the limit of the deduction of interest expense deduction to thirty percent of EBITDA, and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. The provisions of the OBBBA became effective for the Company during the third quarter 2025. The new tax law did not have a material impact on the Company's current or future effective rate for income taxes or cash taxes paid.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Annual Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosures controls were effective at a reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

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

Changes in Internal Control

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the period covered by this Annual Report that have materially affected, or are likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our management team, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal controls over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, the effectiveness of any internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to completely eliminate all potential for misconduct. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in any cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements

During the fiscal year ended December 31, 2025, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. A current copy of the code is posted on the Investors——Corporate Governance section of our website, which is located at www.carlsmed.com.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Global Select Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, officers, and employees that are designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report as Exhibit 19.1.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

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

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

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

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Carlsmed, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated July 24, 2025 (File No. 001-42756)).
3.2	Amended and Restated Bylaws of Carlsmed, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated July 24, 2025 (File No. 001-42756)).
4.1	Specimen common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
4.2+	Second Amended and Restated Warrant to Purchase Stock by and between Customers Bank and the Registrant, dated as of October 29, 2025 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K dated October 30, 2025 (File No. 001-42756)).
4.3+	Second Amended and Restated Second Warrant to Purchase Stock by and between Customers Bank and the Registrant, dated as of October 29, 2025 (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K dated October 30, 2025 (File No. 001-42756)).
4.4+	Amended and Restated Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated March 12, 2024 (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
4.5*	Description of Capital Stock.
10.1#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.2#	2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.3#	Form of Stock Option Agreement and Exercise Notice under the 2019 Stock Incentive Plan (early exercise) (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.4#	Form of Stock Option Agreement and Exercise Notice under the 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.5#	Restricted Stock Unit Agreement, by and between Michael Cordonnier and the Registrant, dated as of March 5, 2025, under the 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.6#	2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed on August 28, 2025 (File No. 001-42756).
10.7#	2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q filed on August 28, 2025 (File No. 001-42756).
10.8#	Form of Option Award Agreement under the 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A dated July 15, 2025 (File No. 333-288339)).
10.9#	Form of RSU Award Agreement under the 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1/A dated July 15, 2025 (File No. 333-288339)).
10.10#+	Employment Agreement, by and between the Registrant and Michael Cordonnier, dated as of June 24, 2025 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.11#+	Employment Agreement, by and between the Registrant and Leonard Greenstein, dated as of June 24, 2025 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).

10.12#+	Employment Agreement, by and between the Registrant and William Durall, dated as of June 24, 2025 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.13#+	Employment Agreement, by and between the Registrant and Niall Casey, dated as of June 24, 2025 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.14*#	Non-Employee Director Compensation Policy.
10.15+	Loan and Security Agreement, dated as of December 20, 2022, by and between Signature Bank and the Registrant (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.16	First Amendment to the Loan and Security Agreement, dated as of March 21, 2023, by and between Signature Bridge Bank, N.A. and the Registrant (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.17	Second Amendment to the Loan and Security Agreement, dated as of October 2, 2023, by and between Customers Bank and the Registrant (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.18	Third Amendment to the Loan and Security Agreement, dated as of March 7, 2024, by and between Customers Bank and the Registrant (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.19	Fourth Amendment to the Loan and Security Agreement, dated as of December 30, 2024, by and between Customers Bank and the Registrant (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1 dated June 26, 2025 (File No. 333-288339)).
10.20	Fifth Amendment to the Loan and Security Agreement, dated as of October 29, 2025, by and between Customers Bank and the Registrant (incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K dated October 30, 2025 (File No. 001-42756)).
10.21*	Sixth Amendment to the Loan and Security Agreement, dated as of October 29, 2025, by and between Customers Bank and the Registrant.
10.22*#	Form of PSU Award Agreement.
19.1*	Insider Trading Policy.
23.1*	Consent of Independent Registered Accounting Firm.
24.1*	Power of Attorney (included on signature page to this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Clawback Policy.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover page formatted as Inline XBRL and contained in Exhibit 101

* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan.

+ Certain of the schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5). The Registrant hereby undertakes to provide further information regarding such omitted materials to the SEC upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

CARLSMED, INC.

Date: February 25, 2026

By: /s/Michael Cordonnier
Michael Cordonnier
Chief Executive Officer, President and Chairman of the Board of Directors
(Principal Executive Officer)

Date: February 25, 2026

By: /s/ Leonard Greenstein
Leonard Greenstein
Chief Financial Officer
(Principal Financial and Accounting Officer)

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Michael Cordonnier and Leonard Greenstein and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and any other documents in connection therewith, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Michael Cordonnier **Michael Cordonnier**	Chairman, Chief Executive Officer, and President *(Principal Executive Officer)*	February 25, 2026
/s/ Leonard Greenstein **Leonard Greenstein**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 25, 2026
/s/ Kevin O'Boyle **Kevin O'Boyle**	Director	February 25, 2026
/s/ Niall Casey **Niall Casey**	Director	February 25, 2026
/s/ Robert Mittendorff **Robert Mittendorff**	Director	February 25, 2026
/s/ Jonathan Root **Jonathan Root**	Director	February 25, 2026
/s/ Kevin Sidow **Kevin Sidow**	Director	February 25, 2026
/s/ Philip Young **Philip Young**	Director	February 25, 2026