UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ **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: 001-38593

Establishment Labs Holdings Inc.

(Exact name of Registrant as specified in its charter)

British Virgin Islands	**98-1436377**
State or Other Jurisdiction of Incorporation or Organization	I.R.S. Employer Identification No.
11401 Century Oaks Terrace Suite 400 Austin, Texas	**78758**
Address of Principal Executive Offices	Zip Code

+ 1 800 924-5072

Registrant's Telephone Number, Including Area Code

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Shares, No Par Value	ESTA	The Nasdaq Capital Market

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one)

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. Yes ☒ No ☐

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 Exchange Act Rule 12b-2). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $975,097,617. Shares of the registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose. The registrant has no non-voting equity.

As of February 26, 2026, the number of the registrant's common shares outstanding was 29,320,846.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 annual meeting of shareholders (the "2026 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2026 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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EXPLANATORY NOTE

In this report, unless the context indicates otherwise, the terms “Establishment Labs,” “Company,” “we”, “us” and “our” refer to Establishment Labs Holdings Inc., a British Virgin Islands entity, and its consolidated subsidiaries.

We own, or have rights to use, trademarks and trade names that we use in connection with the operation of our business, including Establishment Labs and our logo as well as other brands such as Motiva Implants, SilkSurface/SmoothSilk, ProgressiveGel, TrueMonobloc, BluSeal, Divina, Ergonomix, Ergomonix2, Ergonomix2 Diamond, Mia Femtech, MotivaImagine, GEM, Zen and Preservé, among others. Other trademarks and trade names appearing in this report are the property of their respective owners. Solely for your convenience, some of the trademarks and trade names referred to in this report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names.

WEBSITE REFERENCES

In this Annual Report on Form 10-K, we make references to our website at establishmentlabs.com. References to our website throughout this Form 10-K are provided for convenience only, and the content on our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. You can find many (but not all) of these statements by looking for words such as “approximates,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “would,” “may” or other similar expressions in this report. Any statements that refer to projections of our future financial or operating performance, our liquidity and anticipated cash plans, anticipated trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about our future operating results, clinical trials, or products, are forward-looking statements.

We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. We caution investors that any forward-looking statements presented in this report, or that we may make orally or in writing from time to time, are expressions of our beliefs and expectations based on currently available information at the time such statements are made. Such statements are based on assumptions, and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond our control. Although we believe that our assumptions are reasonable, they are not guarantees of future performance. As a result, our actual future results may differ from our expectations, and those differences may be material.

Factors that could cause or contribute to these differences include, among others, those risks and uncertainties discussed below under “Summary of Risk Factors” and under Part I, Item 1A. “Risk Factors,” as such risk factors may be amended, updated or superseded from time to time by our subsequent filings with the Securities and Exchange Commission. The risks and uncertainties included herein are not exhaustive, and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for us to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

We are not undertaking any obligation to update any forward-looking statements. Accordingly, investors should use caution in relying on past forward-looking statements, which speak only as of the date they are made.

SUMMARY OF RISK FACTORS

The following is a summary of certain key risk factors for investors in our securities. You should read this summary together with the more detailed description of risks and uncertainties discussed below under Item 1A. “Risk Factors” before investing in the Company.

- Unfavorable global economic and political conditions, including slower growth or recession, inflation, decreases in consumer spending power or confidence or trade wars, have in the past, and could in the future, adversely affect our business, financial condition or results of operations.
- We have incurred losses to date, and our ability to achieve and maintain profitability depends on the commercial success of our Motiva Implants.
- If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing.
- We have a limited operating history in the United States and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.
- Our business depends on maintaining our brand and ongoing customer demand for our products and services, and a significant reduction in sentiment or demand could affect our results of operations.
- If we fail to compete effectively against our competitors, many of whom have greater resources than we have, our revenues and results of operations may be negatively affected.
- Any disruption at our existing facilities could adversely affect our business and operating results.
- In certain markets, we engage or anticipate engaging in direct sales efforts. We may fail to maintain and develop our direct sales force, and our revenues and financial outcomes could suffer as a result. Furthermore, our direct sales personnel may not effectively sell our products.
- If we are unable to educate clinicians on the safe, effective and appropriate use of our products and designed surgeries, we may experience unsatisfactory patient outcomes, negative publicity and increased claims of product liability and may be unable to achieve our expected growth.
- Our success depends, in part, on our ability to continue to enhance our existing products and services and develop or commercialize new products and services that respond to customer needs and preferences, which we expect will require us to incur significant expenses.
- Delays or failure to obtain necessary clearances or approvals would adversely affect our ability to grow our business.
- Compliance with ongoing regulatory obligations and continued regulatory review may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.
- The medical technology industry is complex and intensely regulated at the federal, state, and local levels, and government authorities may determine that we have failed to comply with applicable laws or regulations.
- We rely on a single-source, third-party supplier for medical-grade long-term implantable silicone, which is the primary raw material used in our Motiva Implants. As has occurred in the past, if this supplier were to increase prices for this raw material or experience interruptions in its ability to supply us with this raw material, our business, financial condition and results of operations could be adversely affected.
- We have significant exposure to the economic and political situations in emerging market countries, and developments in these countries could materially impact our financial results or our business more generally.

- Pandemics, epidemics, or other public health crises may adversely affect our business and financial results in the future.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our liquidity and financial performance.
- Our results of operations have been in the past, and could be in the future, adversely affected by fluctuations in currency rates.
- Negative publicity concerning our products or our competitors' products, including due to product defects or recalls and any resulting litigation, or long-term safety impacts, could harm our reputation and reduce demand for silicone breast implants, either of which could adversely impact our financial results and/or share price.
- News coverage in recent years has called into question the long-term safety of breast implants, including through reports of breast implant-associated anaplastic large cell lymphoma linked to our competitors' products which have led to regulatory actions regarding macrotextured devices in several countries and the worldwide recall of one of our competitor's macrotextured implants and tissue expanders. These events and reports of other forms of cancer, including squamous cell carcinoma and various lymphomas, from breast implant products may lead to a reduction in the demand for silicone breast implants and could adversely affect our business.
- The medical device industry is characterized by patent litigation, and we could become subject to litigation or other proceedings to protect or enforce our intellectual property rights that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

PART I

ITEM 1. BUSINESS

Overview

We are a global medical technology company focused on improving patient safety and aesthetic outcomes, initially in the breast aesthetics and reconstruction market. We initially incorporated in Costa Rica in 2004 and subsequently reorganized in 2013 under a parent holding company in the British Virgin Islands.

Our line of silicone gel-filled breast implants, branded as Motiva Implants, is the centerpiece of our medical technology platform. Our 5-year results from our Motiva U.S. IDE study as well as our patient and practitioner reported post-market surveillance data indicate that Motiva Implants have low rates of adverse events (including rupture, capsular contracture, and implant-related reoperations) that compare favorably with those of our competitors. We believe these proprietary technologies that differentiate our Motiva Implants result in improved safety and aesthetic outcomes and thus drive our revenue growth.

Since launching Motiva Implants in October 2010, the majority of our revenue has been generated from sales of our Motiva Implants. To date, our Motiva Implants are registered to be sold in over 100 countries, including our line of SmoothSilk Round and SmoothSilk Ergonomix Round Implants recently approved in the United States. Our portfolio of products are commercially available via exclusive distributors or our direct sales force and includes five product families of Motiva Implants: (i) Round and Ergonomix Round, (ii) Ergonomix Oval, (iii) Anatomical TrueFixation, (iv) Ergonomix2 Round and Ergonomix2 Diamond and (v) Flora Tissue Expander.

Our products incorporate first of-its-kind safety features, including: (i) SmoothSilk / SilkSurface (an optimized biocompatible advanced smooth surface that is designed to reduce capsular contracture), (ii) Qid RFID technology and ZEN (a non-invasive, electronically readable serial number that enables product identification and enhances safety and patient peace of mind), (iii) BluSeal visual barrier layer (a proprietary indicator that allows for verification of complete barrier layer presence) and (iv) TrueMonobloc gel-shell-patch configuration (a highly durable, easy-to-insert performance shell, gel and patch system that allows for smaller incisions and smaller scars).

Recent Developments

Regulatory and Operational Updates

On October 14, 2025, we announced the publication of “The 3-Year Results of a 100-Patient Prospective Study of Safety and Effectiveness of Mia Femtech” in the *Aesthetic Surgery Journal*. The study showed a very low rate of complications, with no reports of capsular contracture (Baker Grade III/IV), implant rupture, nipple or breast sensitivity loss, incision-related complications, infection, seroma, rippling, hematoma, or BIA-ALCL; the reoperation rate at 3 years was 1%. Patient and surgeon satisfaction was high, with patients reporting an 87% increase in breast satisfaction at 3 years and 90% of surgeons “very satisfied” with their overall experience and none “dissatisfied”. See “Our Clinical Data—Mia Femtech Clinical Study” below for additional information.

On May 7, 2025, we announced the appointment of Peter Caldini as Chief Executive Officer following the retirement of Juan José Chacón-Quirós as CEO, effective March 1, 2025. Mr. Caldini served as Interim CEO from March 1, 2025 until May 7, 2025. Mr. Chacón-Quirós continued as a member of the Board and as an advisor with the Company.

On March 6, 2025, we partnered with GRAMMY winner Meghan Trainor, generating over 9 billion media impressions and supporting our U.S. market launch.

In February 2025, we launched Preservé, a minimally invasive breast tissue-preserving technology for breast augmentation, revision augmentation and mastopexy augmentation. The initial commercial launch took place in Brazil, with further launches in other countries occurring throughout 2025, including an early experience group in the United States. Launches in additional countries, including a full launch in the United States, are expected in 2026.

Financing Activities

We signed an Inventory Funding Agreement, or Funding Agreement, on May 23, 2025, with RTW Master Fund, LTD., RTW Innovation Master Fund, LTD., and RTW Biotech Opportunities Operating LTD, collectively referred to as the Funding Providers, and RTW Investments, LP, as the funding representative, to finance purchases of silicone raw material to support the manufacture of Motiva Implants in an aggregate amount not to exceed $10 million in a funding period. Under the Funding Agreement, the Funding Providers will finance, upon request, eligible invoices at a 12% annual interest rate for an initial four-month term, or a later date if agreed by the Funding Providers in writing in their sole discretion. We drew $5 million at each of June 20, 2025 and September 26, 2025, and recorded this liability in “Other Liabilities, Short-Term”. On September 25, 2025, the Funding Agreement was amended to extend the due date for the amount received in June 2025 to May 15, 2026.

On September 29, 2025, we entered into a Fourth Amendment to the Credit Agreement, or the Fourth Amendment, which provided for the availability of the Tranche D Term Loans to commence as of the effective date of the amendment, notwithstanding the revenue milestone originally set forth in the Agreement, and (ii) increased, effective September 28, 2025, the minimum liquidity that the Company and its subsidiaries that are guarantors under the Agreement are required to maintain from $25 million to $30 million. The fourth tranche, or the Tranche D Term Loan, of $25 million was advanced in September 2025.

During fiscal 2025, we also entered into short-term insurance premium financing arrangements to fund the payment of business insurance premiums. The aggregate financing provided under these arrangements totaled approximately $3.4 million and bears interest at rates ranging from approximately 7.7% to 8.3% per annum. The borrowings are short-term in nature and mature within ten months of issuance.

Our Market

Breast Augmentation

Breast augmentation surgery is one of the leading aesthetic surgical procedures by number of procedures globally. Approximately 1.7 million breast augmentations were performed worldwide in 2024, according to the International Society of Aesthetic Plastic Surgery, or ISAPS.

Breast Reconstruction

The American Society of Plastic Surgeons noted in their *Procedural Statistics Release* that 162,579 breast reconstruction surgeries were performed in 2024 in the United States. According to Grand View Research, the global breast reconstruction market is expected to grow at a CAGR of 6.7% from 2025 to 2030. The market, valued at $2.16 billion in 2024, is projected to exceed $3.15 billion by 2030. This growth is expected to be driven by factors like technological advancements, increased awareness, higher disposable income of women, growing medical tourism and a rising number of breast cancer cases worldwide.

Traditional Breast Implants and Their Limitations

Despite the global demand for breast augmentation procedures, there has been relatively little innovation since the 1990s. In 1992, due to emerging safety concerns, the FDA placed a moratorium on sales of silicone breast implants in the United States, which was lifted in 2006. This, combined with the ongoing FDA requirement for a PMA approval of all marketed breast implants, has discouraged breast implant innovation over the past 30 years. Many of the legacy breast implant options have relatively high complication rates, and we believe many do not mimic natural breast tissue.

10-year Competitor CORE Study Date, Primary Augmentations

The table below reports key adverse event information from published data from 10-year prospective Core clinical trials conducted by the only three competitor companies currently approved to market silicone breast implants in the United States.

	Sientra 10-Year	Allergan 10-Year	Mentor 10-Year
Number of Patients	N=1,116 Patients	N=455 Patients	N=552 Patients
Rupture[1]	8.5%	9.3%	24.2%
Capsular Contracture	12.9%	18.9%	12.1%
Reoperation	24.0%	36.1%	25.5%

Kaplan-Meier risk rates were the primary method of analysis for the above data. This table represents the final data from the primary augmentation cohort of the same study referenced in the above five- and six-year PMA studies conducted by our competitors. This 10-year data for Sientra, Allergan and Mentor was released in 2018, 2018, and 2015, respectively.

(1) The rupture rates represent the MRI cohort only for each respective study, which consisted of 571 patients for Sientra, 158 patients for Allergan and 202 patients for Mentor.

We believe that the improved appearance, more natural feel and patient safety profile of our Motiva Implants provide a strong competitive advantage that will help us to both capture market share and achieve higher patient conversion rates by addressing the primary concerns described by patients who choose not to pursue breast augmentation surgery.

Our Growth Strategy

Our goal is to be the global leader in aesthetic surgical implant technology, including breast implants, while improving patient safety through product innovation. The key elements of our strategy include:

- ***Expand revenues in the U.S. market.*** We received 510(k) clearance for the Motiva Flora SmoothSilk Tissue Expander in October 2023 and PMA approval for our Motiva Implants from the FDA in September 2024, and we began commercial sales in the United States in October 2024. The U.S. is one of the largest breast implant market in the world, and Motiva Implants are the first new breast implant PMA-approved by the FDA since 2013.
- ***Expand revenues in existing markets.*** We anticipate continued growth in our existing markets, driven by our Motiva Implants and expanding our portfolio of minimally invasive products, including Preservé and Mia Femtech.
- ***Optimize patient conversion through sales and marketing programs.*** We employ a multi-faceted marketing strategy that includes social media engagement, influencers, conference presence, online advertising and patient and physician education programs.
- ***Pursue strategic acquisitions.*** From time to time, we may seek out other innovative products, services and procedures that complement our existing product portfolio We have acquired distributor networks in strategic markets and may pursue additional acquisitions in the future.
- ***Continue a high level of engagement with key opinion leaders.*** We promote Motiva Implants, in part, through physician education events led by key opinion leaders. In 2025 and 2024, we conducted 607 and 239 events, respectively, through our medical educational platform.

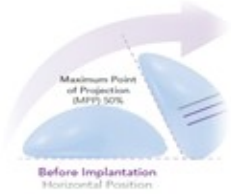
Seasonality

Our business is subject to predictable seasonal fluctuations that affect demand for our products and contribute to variability in quarterly results. In the United States, procedural volumes for breast augmentation typically peak in the spring ahead of the summer season and again from October to December and decline in January and February when surgeons attend professional meetings and in late June through early August when patients and surgeons take vacations. These industry-wide seasonal patterns can lead to U.S. market volume declines of approximately 20% to 30% in certain periods, affecting demand for Motiva Implants.

These seasonal trends contribute to variability in our quarter-over-quarter performance and should be considered when evaluating our operating results. Although the degree of seasonality may vary by geography and product line, these patterns are characteristic of the broader breast aesthetics industry and influence both distributor purchasing behavior and direct sales volume.

Our Products and Technologies

The key characteristics of our primary products are described in the table below:

Product	Motiva Round	Motiva Ergonomix	Motiva Ergonomix2	Motiva Flora Tissue Expander
				
Description	Round soft silicone-gel filled breast implants	Gravity sensitive round soft silicone-gel-filled breast implants	Gravity sensitive soft silicone-gel-filled breast implants with improved mechanical properties	Breast tissue expander, used to gradually expand a patient's breast tissue prior to the placement of a long-term breast implant
Product Catalog	Available in 160 round catalogs, including four projection heights	Available in 160 round catalogs, including four projection heights	Available in more than 160 round catalogs, including four projection heights; Available in 60 catalogs for Diamond implants	Available in 15 catalogs, with three different heights
Key Features	• SilkSurface/SmoothSilk shell surface • ProgressiveGel PLUS Silicone gel fill • TrueMonobloc construction • BluSeal shell barrier layer • Qid Safety Technology RFID microtransponder	▪ SilkSurface/SmoothSilk shell surface ▪ ProgressiveGel Ultima, Silicone gel fill ▪ TrueMonobloc construction ▪ BluSeal shell barrier ▪ Qid Safety Technology RFID microtransponder ▪ Ergonomy and more natural look	▪ SilkSurface/SmoothSilk shell surface • ProgressiveGel Ultima, Silicone gel fill ▪ TrueMonobloc+ construction ▪ BluSeal+ shell barrier • ZEN RFID microtransponder ▪ Motiva SuperSilicones	▪ SilkSurface/SmoothSilk shell surface ▪ Anatomical design ▪ Compatible with MRI and CT scans ▪ Injection site located with RF technology, using the Motiva Port Locator ▪ Orientation line observable on X-Ray ▪ Fixation suture tabs
Sales Territories	Over 100 countries			

Motiva Implants

The Motiva breast implants are a Class III Medical Device (based on the designations in the U.S. and the E.U.) indicated for breast augmentation and breast reconstruction, including revision surgeries to correct or improve the result of a previous breast implant surgery. We launched Motiva Implants commercially in October 2010. Motiva Implants incorporate several proprietary features that we believe contribute to their favorable safety profile, natural appearance and feel. Our latest generation of Motiva Implants utilizes our proprietary Gravity Sensitive Ergonomix design, with a round base implant that responds to gravity by shifting its maximum point of projection, offering the more "natural" projection of a shaped implant without the malposition and rotation issues frequently associated with shaped implants. Furthermore, our fill material with the ProgressiveGel platform of silicone gel rheologies consists of highly purified biocompatible gels with specific viscoelastic properties that we believe enables Motiva Implants to respond to the patient's motion in ways that more closely mimic the appearance, feel and movement of natural breast tissue. Our catalog includes over 1,000 product variations with round, oval and anatomical

shapes and volumes ranging from 95cc to 1060cc, resulting in a wider range of options than those offered by our major competitors.

Ergonomix2 incorporates the latest innovations, including our most advanced ultra-high purity chemistries designed for enhanced device safety mechanical properties and improved patient ergonomics. Ergonomix2 also features our patented SmoothSilk surface technology, which is the basis of Motiva Implants' low inflammatory characteristics that have contributed to the lowest capsular contracture rates in the industry. Ergonomix2 was CE marked in December 2020 and labeled for use in both aesthetic and reconstruction procedures.

A study published in February 2023 by the British Association of Plastic, Reconstructive and Aesthetic Surgeons of breast reconstruction procedures using Ergonomix from January 2017 to January 2022 for 156 patients concluded that Ergonomix implants showcase a unique set of technologies that provide good results with a low complication rate.

Shell Surface: SmoothSilk

The surface topography of the breast implant shell surface varies between commercially available breast implants. Our SmoothSilk surface on all Motiva Implants was designed to reduce the inflammatory process caused by the immune response, enhancing product biocompatibility. The controlled manufacturing process provides the same surface topography around the entire implant for the benefit of patients.

Our retrospective implant data shows that Motiva Implants have a lower rate of capsular contracture and seromas when compared to published data from competitors. We believe that these results are due in large part to the proprietary surface of our Motiva Implants. Our proprietary shell surfaces have an average roughness of 4 microns and have more uniform surface features than those of our primary competitors based on several studies using methods such as scanning electron microscopy, profilometry testing and statistical parameters comparisons.

An abstract presented in 2017 by researchers at Montana State University showed less accumulation of both bacteria and biofilm on SmoothSilk surface in vitro when compared to smoother and textured implant surfaces. Biofilm formed on implant surfaces increases the risk of bacteria accumulation and capsule formation.

In December 2018, we commissioned an independent report from the French reference laboratory Laboratoire National de Metrologie et d'Essais, or LNE, on the surface characteristics of our Motiva Implants. Based upon its testing, LNE concluded that the SmoothSilk shell surface in the Motiva Implants is a smooth surface as defined by ISO 14607:2018 categorization.

A 2021 published study with a high impact factor in Nature Biomedical Engineering led by Professor Robert Langer, Institute Professor at the Massachusetts Institute of Technology (MIT) at David H. Koch Institute for Integrative Cancer Research, concluded that the SmoothSilk surface can largely suppress the foreign body response and fibrosis provoking the least amount of inflammation in comparison with the other commercially available surfaces. A larger percentage of macrophages in the cell mix indicates an inflammatory response, which is an early stage in capsule formation. We believe the more moderate inflammatory response observed on SmoothSilk is responsible for improved biocompatibility and lower complication profile.

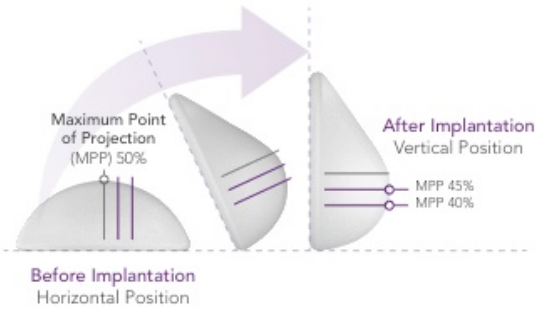
In November 2022, another publication related to the SmoothSilk surface was published in the Journal of Engineering Tribology by researchers from the College of Engineering at University of California, Santa Barbara. The extent of the surface roughness as examined for the silicone implant shells for SmoothSilk resulted in the lowest friction coefficient and fewest wear debris particles in the size range favored by the macrophages. This highlights the optimal ranges of the SmoothSilk design to reduce frictional shared stress and wear debris during the tribological interactions.

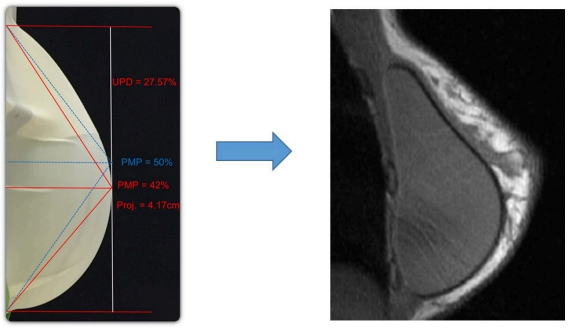
ProgressiveGel Family

The proprietary silicone chemistries that comprise our ProgressiveGel family allow for a high degree of viscoelasticity and strength while adding characteristics such as softness and high ductility that enable movement dynamics more like that of natural breast tissue. We believe that the cohesive properties reduce the likelihood of silicone gel leakage in the event of a rupture in the shell. The strength of the gel is believed to contribute to a reduced frequency of gel fracture, a condition which leads to deformed implant shape and stress on the implant's shell. While other manufacturers have claimed a "high strength" gel, ours combines a notably high elasticity (the ability to stretch without permanent deformation) with low viscosity, both of which are designed to reduce the susceptibility of the implants to rupture while improving their tactile feel and movement dynamics. Additionally, the

improved adhesion of the gel to the shell structure avoids the appearance of separation spots, an aesthetic defect commonly seen in competitor products.

In addition to the anticipated safety advantages, our ProgressiveGel family provides for movement characteristics that resemble natural breast tissue. Our later generation Ergonomix products further mimic natural tissue, with a maximum point of projection that shifts lower to create a natural human breast shape when a patient is standing. This allows our Motiva Implants to provide the more natural aesthetics of “shaped” or “teardrop” implants without the risk of associated drawbacks such as breast deformation from rotation and unnaturally hard tactile feel. The images below illustrate the implants’ ability to change shape depending on the patient’s positioning.





TrueMonobloc

Our TrueMonobloc technology, which is incorporated into all generations of Motiva Implants currently sold, combines proprietary chemistry with our proprietary manufacturing techniques to create a shell, gel and other components that are tightly bound to one another. This results in an implant that is more homogeneously elastic and resistant to separation of the gel from the shell, addressing one type of implant failure that can lead to shell ruptures and silicone leaks. This also enables Motiva Implants to be stretched and squeezed to a more significant degree, which we believe currently enables breast augmentation through incision sizes smaller than one inch, compared with the published industry norm of approximately two inches. A surgical technique that we have developed, which we call Minimally Invasive Aesthetics, or Mia Femtech, utilizes our next-generation Ergonomix2 Diamond implant to take advantage of these physical properties to enable a less-invasive procedure for the patient. The following image shows that TrueMonobloc enables significant manipulation of a Motiva Implant without separation of gel from shell.

Radio-Frequency Identification Platform (RFID) Technology

We offer a Radio-Frequency Identification Device microtransponder (also referred to as Qid, or the latest generation, ZEN) that is placed in the filling gel as an optional feature for all implant styles. This microtransponder provides each device with a unique electronic serial number for traceability purposes.

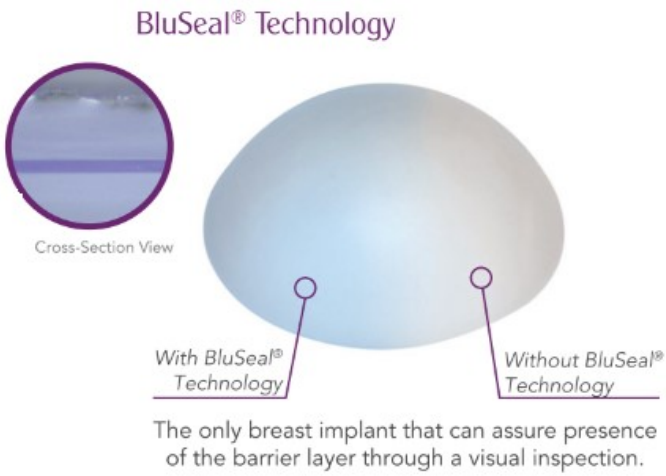
The microtransponder contains only a unique 15-digit code that identifies the product and does not contain any patient information. This microtransponder can be read with a simple pass from our non-invasive and inexpensive reading device, the Qid Safety Technology Reader, and the serial number corresponds with related information in our MotivaImagine database such as implant type, size and other characteristics. Patients can create a secure account, register the products and include applicable patient information either through the MotivaImagine application or our website, to access their implant information. The MotivaImagine application and Motiva Implants website also allow the patient to access the implant warranty information. This traceability is intended to give patients comfort that any future recalls can be positively identified as applying, or not applying, to that patient's particular implant. This addresses a key concern that often discourages women who are otherwise interested in implants from making the choice to move forward with the surgery. Motiva Implants are currently the only breast implants on the international market with Qid Safety Technology; however, we believe there is an opportunity to sell these microtransponders to other medical device companies in the space.

Each implant's unique electronic serial number is encoded into the RFID circuitry as part of a three-point authentication system: the microtransponder, the reader and the database. This authentication system prevents unauthorized access to any personal information of the patient and is compliant with FDA regulations.

In October 2023, we announced Zen, which is part of our next generation Zensor RFID platform. The new Zen technology has all the previous benefits of Qid, but is now entirely non-ferromagnetic. In 2023, the Motiva Ergonomix2 Diamond implants used in the Mia Femtech system feature Zen and are available in select geographies with Motiva Ergonomix2 Round Implants in programs like the JOY program. We believe the Zensor platform has the potential to add additional capabilities in future generations, such as the measurement of temperature and other parameters. Zen with temperature sensing is currently in human trials as part of an IRB-approved study.

BluSeal

The Motiva Implant shell is constructed of successive layers of silicone elastomer and a low diffusion barrier layer. The key function of the low diffusion barrier layer is to prevent diffusion of low molecular weight siloxane species from the implant to the tissues. This barrier layer embeds our BluSeal indicator technology, which is a key feature used during the manufacturing process to verify that the barrier is present in a uniform way around the entire shell. It is also used as a visual quality control and safety measure to minimize potential gel diffusion. This patented manufacturing innovation is intended to highlight any imperfections in the barrier layer coverage with a distinct color. Our BluSeal indicator technology also provides the plastic surgeon with the ability to verify whether the barrier layer has coverage defects or other imperfections before implantation that might lead to post-implantation shell rupture or gel bleed. We believe this is another safety innovation that contributes to our substantially lower reported implant rupture rates as compared to reports for our primary competitors.



Motiva Flora Tissue Expander

The Motiva Flora Tissue Expander is used in breast reconstruction surgery for temporary implantation (less than six months) to gradually expand the breast tissue prior to the placement of a long-term breast implant. After implantation, the device is periodically filled with saline solution via an injection port to increase its volume to stretch the skin and create a pocket for breast implant placement. The injection port is dome-shaped and includes an RFID coil, which can be accurately located utilizing the port locator. The Motiva Flora Tissue Expander is the first MRI Conditional expander and is the only tissue expander in the market with an integrated RFID port with no magnets, allowing for use of the expander safely alongside MRI (1.5 and 3 Tesla) scanning. The Motiva Flora received CE mark in June 2020 and 510(k) clearance from the FDA in October 2023 and has been registered in 79 countries. The Motiva Flora also includes the SmoothSilk surface, which provides biocompatibility benefits described above. Our catalog includes 15 variations, including three different heights, and a range of volumes from 260 to 995 cc.

Minimally Invasive Aesthetics: Preservé and Mia Femtech

In February 2025, we introduced Preservé in targeted markets, a minimally invasive breast tissue-preserving technology designed for breast augmentation, revision augmentation, and mastopexy augmentation. This innovative solution aims to maintain the structural anatomy and function of the breast during aesthetic surgery, resulting in more stable and natural outcomes compared to traditional methods. Preservé utilizes our proprietary minimally invasive surgical tools along with Ergonomix2 implants, which feature the patented SmoothSilk surface for improved biocompatibility and softness. These implants are unique in the industry, adapting their shape as the body changes position. Preservé is suitable for primary augmentations of up to four cups, hybrid augmentations, and mastopexy augmentations. The initial commercial launch occurred in Brazil, with further launches in other countries occurring throughout 2025, including an early experience group in the United States. Launches in additional countries, including a full launch in the United States, are expected in 2026.

In April 2023, we launched Mia Femtech — a patient-centric procedure designed to allow breast augmentation to be performed under local anesthesia rather than general anesthesia, through smaller incisions, with faster recovery times and a resulting reduction in surgical complications. The Mia Femtech system includes the specially-designed Ergonomix2 Diamond implant, which received CE mark in December 2020, and its proprietary tools, including the Motiva Inflatable Balloon and the Motiva Injector.

In December 2020, we received a CE mark for our Motiva Ergonomix2 Diamond breast implant, the implant used in the Mia Femtech procedure. In early 2021, we completed enrollment in our one hundred patient Mia® Femtech case series in Costa Rica. In October 2025, we published the three-year results of the Motiva Femtech Clinical Study. The study, which had a three-year follow-up compliance rate of 93%, found no reports of capsular contracture (Baker Grade III/IV), ruptures (suspected or confirmed), bleeding, hematoma, or seroma requiring intervention in the study. Based on our market research, we believe Mia Femtech will continue to attract new consumers and expand the market for breast aesthetic procedures.

We currently offer Mia Femtech in multiple countries across the world with plastic surgeons fully certified to provide the Mia experience.

Our Clinical Data

Investigational Device Exemption (IDE) Study to Support PMA

We are conducting a prospective IDE clinical trial in the United States on our Motiva Round and Motiva Ergonomix Round product families. Our IDE submission was approved by the FDA on March 20, 2018 to perform

a single open-label, prospective, multi-center trial, with follow-up visit data reported annually and at the time of filing. We will continue to monitor patients for ten years post-implantation. The primary endpoints of the trial are safety, effectiveness and patient satisfaction. In general, our trial design and patient enrollment are consistent with prior PMA studies conducted by Allergan, Mentor, and Sientra. In August 2019, we announced that we were implementing a bifurcated regulatory strategy in the United States, which is designed to allow us to initiate the rolling submission of data to the FDA from the primary augmentation and revision augmentation cohorts, and then subsequently supplement our PMA with data from the reconstruction cohorts. All the enrollment procedures and the three-year study subject follow-up have been completed in the aesthetics cohort, which includes primary augmentation and revision augmentation, with total enrollment of 451 and 265 subjects, respectively. In the fourth quarter of 2021, we initiated a modular PMA submission process with the FDA and submitted the first of four expected modules. In April 2022, we released preliminary results of the two-year patient follow-up data for the primary augmentation cohort of our IDE clinical trial. The second module was submitted in May 2022. In June 2022, full enrollment of the IDE clinical trial was complete, and all surgeries in the primary reconstruction cohort were performed. In August 2022, the third module was submitted to the FDA. The final fourth module was submitted to the FDA in February 2023.

We received FDA PMA approval for the augmentation cohort in September 2024. The IDE Study reconstruction cohort is ongoing with all reconstruction patients having recently completed 3-years of study follow-up.

In March 2025, the results of the Motiva US IDE Study were published, including the five-year data for 451 primary augmentation patients enrolled in the study based on a follow-up compliance rate of 89%. The five-year, by-patient, Kaplan-Meier risk rates of first occurrence of complications for patients (95% confidence interval) in the primary augmentation cohort were as follows:

Primary Augmentation	5-year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5%
Rupture, suspected or confirmed; MRI cohort[1]	0.6%
Breast pain	1.2%
Infection	0.9%
Implant removal, with or without replacement	3.1%
Any reoperation[2]	8.8%
Any complication[3]	12.0%

Kaplan-Meier risk rates were the primary method of analysis for the above data. This table represents preliminary data available as of September 2024 and does not necessarily reflect final clinical results nor demonstrate the investigational device's safety and effectiveness for the U.S. trial.

(1) MRI cohort N=176
(2) Any surgery on the breast or chest area, device or non-device related, including size change
(3) Any device or non-device related event, including reoperation

Mia Femtech Clinical Study

We are conducting an Institutional Review Board, or IRB, approved prospective study that enrolled 100 subjects between December 2020 and April 2021. In October 2025, we published the three-year results of the Motiva Femtech Clinical Study of data based on a follow-up compliance rate of 93%. The three-year risk rates of first occurrence of complications for patients (95% confidence interval) in the Mia Femtech cohort were as follows:

Primary Augmentation	3-year (N=100), 95% CI
Capsular contracture (Baker Grade III/IV)	0.0%
Rupture, suspected or confirmed[1]	0.0%
Infection	0.0%
Seroma	0.0%
Hematoma	0.0%
Changes in Nipple Sensation	0.0%
Changes in Breast Sensation	0.0%
Malposition/Displacement[2]	1.0%
Inferior malposition	0.0%
Any reoperation	1.0%

This table represents preliminary follow-up data available as of October 2025 and does not necessarily reflect final clinical results nor demonstrate the ultimate safety or effectiveness of the Mia Femtech procedure.

(1) Includes overall and MRI cohort (33 subjects/ 66 implants) combined
(2) One patient had an implant malposition and underwent implant reposition; no implant exchange

Patient and Practitioner-Reported 15-Year Safety Post-Market Surveillance Data

Dating from the commercial launch of Motiva Implants in October 2010 through December 2025, we have sold over 4.8 million breast implants in various countries. We maintain a Quality Management System database to track and report complaints received from patients or physicians. From October 2010 through December 2025, a total of 7,400 complaints have been reported, investigated and processed, representing approximately 0.1% of the total Motiva Implants sold through December 2025. There were no reported cases of double capsule formation or primary cases of breast-implant associated anaplastic large-cell lymphoma, or BIA-ALCL, in this data set. There were 82 cases of early seroma and 28 cases of late seroma reported. The table below shows the rates of rupture, capsular contracture and reoperation for adverse events of our Motiva Implants from the data gathered through December 2025. In contrast to the above 10-year competitor CORE Study data required for FDA PMA reporting, our PMS data is collected to monitor product safety and effectiveness in the commercial setting.

	Motiva Implants
Number of Implants Sold	N= 4,841,575 Implants[1]
Rupture	< 0.1%
Capsular Contracture	< 0.1%
Reoperation for Adverse Events	< 0.1%
Reoperation (All Causes)	N/A[2]

(1) Data is internally tracked on an individual implant basis rather than by patient.

(2) Complaint database does not capture reoperations for reasons not related to safety.

Sales and Marketing

We primarily derive revenue from sales of our Motiva Implants from two types of customers: (1) medical device distributors and (2) direct sales to physicians, hospitals, and clinics. Our products are commercially available in over 100 countries through exclusive distributors, except in the United States, Brazil, Argentina and several European countries where we sell through our direct sales force. As of December 31, 2025, our sales organization included 278 employees and contractors. All of these sales personnel are supported through a suite of tools, including marketing and training materials, mobile smartphone applications, and access to a robust schedule of physician education events. We also pay significant attention to helping our distributors maintain positive

relationships with surgeons and clinics in their respective regions, and to positioning our product in the marketplace as a premium product with consequent premium pricing.

We demonstrate our confidence in Motiva Implants with the Motiva Always Confident Warranty, which offers patients a free replacement for any Motiva Implant that ruptures, for the life of the product. We also replace any implant which is replaced due to capsular contracture of Baker Grade III or IV severity at any time in the first 10 years of post-implantation. In addition, we offer an extended warranty at additional cost outside the JOY program, which provides financial assistance to cover surgical costs resulting from rupture or capsular contracture. In the United States, the Motiva Health Program also covers implant replacement for late forming seroma and double capsule complication within 10 years post-implantation and provides financial assistance for surgical costs related to BIA-ALCL. An extended warranty is available for an additional cost, covering up to $15,000 for surgical expenses based on specific circumstances.

We employ a multi-faceted marketing strategy that includes social media engagement, influencers, conferences, advertisements and education.

Intellectual Property

Our success depends at least in part upon our ability to protect our core technology and intellectual property. To accomplish this, we rely on a combination of intellectual property rights, including patents, trade secrets and trademarks, as well as customary contractual protections.

We have assembled a broad portfolio of intellectual property related to our medical device and aesthetics products. We believe this intellectual property, combined with proprietary manufacturing processes and the regulatory approvals we have successfully obtained outside of the United States, provide us with a strong market position. As of December 31, 2025, we own or have rights to 36 issued, 1 allowed and 12 pending patents in the United States related to various aspects of our Motiva Implants (such as implant barrier layers, surface texture technology, minimally invasive implant delivery systems, minimally invasive and tissue preservation procedures and systems and our Qid Safety Technology or ZEN radio frequency identification devices). In addition, we own or have rights to 178 issued, 1 allowed and 48 pending foreign applications and 1 pending Patent Cooperation Treaty, or PCT, application. Our owned and licensed patents are expected to expire at various times between March 2032 and February 2040. Our owned and licensed pending applications, if granted, likely would expire between September 2033 and October 2045.

In addition to pursuing patents on our products, we have taken steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners, and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. In addition, we intend to expand our international operations, and effective patent, copyright, trademark and trade secret protection may not be available or may be limited in foreign countries.

In general, the medical device industry is characterized by the existence of a large number of patents and frequent allegations and related litigation regarding patent and other intellectual property rights. Third parties, including our competitor companies, may assert patent, copyright, trademark and other intellectual property rights against us, our partners or our customers. Our standard license and other agreements may obligate us to indemnify our partners and customers against such claims. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any such claims. Successful claims of infringement by a third party could prevent us from selling or distributing certain products or performing certain services, require us to expend time and resources to develop non-infringing products, or force us to pay substantial damages, including treble damages if we are found to have willfully infringed patents-royalties or other fees. We cannot assure you that we do not currently infringe, or that we will not in the future infringe, upon any third-party patents or other proprietary rights.

Research and Development

Our goal is to continue to improve our existing products, as well as develop new products and new surgical techniques. We have a highly experienced team and deep customer and key opinion leader relationships. We also have sophisticated internal prototyping and testing equipment.

We have and will continue to work with several institutions in our effort to advance implant technology and generate additional scientific data to support the improved safety outcomes associated with our products, including:

- Massachusetts Institute of Technology
- Medical University of Innsbruck
- Department of Bioengineering at Rice University
- University of Cape Town Faculty of Health Sciences
- University of California, Santa Barbara
- University Hospital Ghent Department of Plastic Surgery
- The Chair of Plastic Surgery at the School of Medicine and Psychology of Sapienza University of Rome

We have incurred, and expect to continue to incur, significant R&D expenses. We incurred R&D expenses of $20.2 million for the year ended December 31, 2025, compared to $19.7 million for the year ended December 31, 2024. Our R&D expenses consist of costs associated with our clinical and post-approval studies, regulatory activity and product development, including the development of Motiva Implants and other current and future aesthetic and reconstruction surgical devices on our product platform.

Implantable RFID Microtransponder Platform

The RFID technology platform that we use in the Qid feature of our Motiva Implants is independently cleared as a system via the FDA's 510(k) pathway. We are developing more sophisticated functionality using this technology platform. We believe our RFID technology will be an attractive platform for a variety of other applications, including unique device identification for other types of implantable medical devices, functional implantable biosensors, and diagnostic monitoring. Future specific indications include detection of device life cycles (e.g., flexion/contraction cycles for artificial hip and knee joints) and monitoring of analytes such as circulating tumor cells and blood chemistry components. Some of these applications we may choose to develop and commercialize internally, while others may be more appropriately commercialized via partnerships with other medical device companies. In October 2023, we launched Zen, a non-ferromagnetic, next- generation passive RFID technology available in Motiva Ergonomix2 Diamond implants used in the Mia Femtech system and select geographies with Motiva Ergonomix2 Round Implants in the JOY program.

We control all the activities of the development and manufacturing of our Qid Safety Technology RFID transponders. This allows us to adapt to specific needs or new developments in our field.

Manufacturing and Suppliers

Facilities

We manufacture our products in ISO-13485-certified manufacturing facilities located in the Coyol Free Zone office park in Alajuela, Costa Rica, a park populated by a number of international medical device companies and granted tax-advantaged status by the government of Costa Rica.

Our two manufacturing facilities include our original manufacturing facility opened at the end of 2016 and the newly-constructed corporate office and manufacturing facility we finalized in 2024. The original facility has approximately 28,000 square feet of office space and production areas which are capable of producing over 400,000 implants a year, with state-of-the-art support systems for sustaining production, including an ice-bank system for cooling the controlled air in the clean room and support areas, water-lubricated air compressors for eliminating the presence of particulates, heat recovery systems for energy saving, and an energy micro-grid comprised of solar panels and energy-storage batteries. These energy efficient systems generate up to 80% of the total energy consumption of the building, which received LEED Gold Certification by the U.S. Green Building Council in August 2017.

In June 2024, we finalized the construction of our Sulàyöm Innovation Campus including 100,000 square feet of manufacturing, medical, research, and office space allowing us to increase our manufacturing capacity by approximately 730,000 units per year. The facility has space to further expand manufacturing capacity, as needed. The facility obtained necessary regulatory approvals and commenced manufacturing by the end of fiscal 2024. The Sulàyöm Innovation Campus is certified as LEED Platinum and EDGE Advanced, reflecting adherence to the

highest international standards of sustainable construction and energy efficiency. See Note 3 “Balance Sheet Accounts” for additional information regarding this construction project.

Both of our facilities in the Coyol Free Zone are Carbon Neutral certified by the Costa Rican Ministry of Environment, Energy, and Telecommunications, based on the implementation of efficiency-aimed actions such as the reduction of energy consumption through the acquisition of more efficient equipment; the combined use of solar panels, ice banks, and battery storage units; and the avoidance of fossil fuels for our operations.

In 2025, the U.S. FDA authorized our Costa Rican facilities to manufacture all Motiva USA PMA-approved products, including our Round and Round Ergonomix Breast Implants. This approval expands our U.S.-bound production capacity and supports long-term operational efficiency.

All of our manufacturing facilities have received the MDSAP regulatory certification. MDSAP was established by a coalition of international medical device regulatory authorities, including Australia’s TGA, Brazil’s ANVISA, Health Canada, Japan’s MHLW and PMDA and the U.S. FDA. The goal of MDSAP is to allow a single regulatory audit of a medical device manufacturer’s Quality Management System to satisfy the needs of the participating regulatory jurisdictions. This program enables manufacturers to contract with an authorized third-party auditing organization, in our case the British Standards Institute, to conduct a single audit to satisfy the relevant regulatory requirements of the participating regulatory authorities including the FDA, which recognizes MDSAP audit reports as a substitute for FDA Establishment Inspection Reports.

We are also subject to periodic inspections and audits by various international regulatory and notified bodies, and we believe our past performance in these audits reflects the strength of our Quality Management System and manufacturing controls. We consider this to be a key element of our risk management and business continuity strategies and a competitive advantage as we have full control of the product lifecycle. Our in-house manufacturing team undergoes well defined training programs throughout their period of employment. We believe our manufacturing experience, know-how, and process-related trade secrets are also a competitive advantage.

Process

We produce our shell surfaces using a novel 3D negative imprinting molding technique that allows much more precise control over feature size, a uniform distribution of features on the surface, no particles creation, and less unit-to-unit variation. Our primary competitors utilize the “salt-loss” technique or “polyurethane foam imprint” technique. The “salt-loss” technique blows crystals of salt or sugar onto the uncured silicone shell in order to produce surface texture and the “polyurethane foam imprint” technique uses a foreign material to press against the last uncured silicone layer to produce surface features. We believe our 3D negative imprinting technique is more efficient and consistent than the techniques used by our competitors because the application of our advanced smooth surface is integrated with the molding process, rather than requiring a separate, subsequent process step.

Suppliers

We source manufacturing inputs from a number of outside suppliers. In particular, we obtain NuSil brand medical-grade silicone from Avantor, Inc. (formerly NuSil Technology LLC), or Avantor, which is a sole-source supplier of such products to the majority of the silicone breast implant industry. In May 2022, we entered into a master supply agreement with Avantor, which provides for specified prices per unit of each relevant component, has an initial term ending on December 31, 2026 and automatically renews for successive terms of one year each for up to five successive renewal terms. Avantor has recently informed us that it does not intend to allow the agreement to renew automatically and plans to enter into negotiations regarding future supply terms.

Other critical materials are the silicone patches and other silicone components used for the assembly of our breast implants. All of these components are also made with NuSil medical-grade silicone and manufactured by specialized silicone contract manufacturing suppliers. All component suppliers undergo strict quality inspections to ensure these can meet our quality standard. Other important components are the primary packaging polycarbonate trays, the Tyvek sealing lids and packaging. All these components are also critical to maintain the integrity of the product throughout its shelf-life, and all of these suppliers must be qualified, and all materials must be validated prior to being approved for manufacturing activities. We conduct annual evaluations for most of our suppliers and engage in second-source supplier initiatives to ensure the continuity of business operations, enhance quality, and reduce costs.

Competition

The U.S. market for silicone breast implants is relatively concentrated, within Allergan Aesthetics, a division of AbbVie, Mentor Worldwide LLC, a division of Johnson & Johnson, and Sientra Inc., which was acquired by Tiger Aesthetics Medical. Internationally, the market is more fragmented, with the primary producers being GC Aesthetics plc, Silimed, Inc., Groupe Sebbin SAS, Hans Biomed Crop., Polytech Health & Aesthetics, and Arion Laboratories.

Our major competitors in the silicone breast implant marketplace are either publicly traded companies or divisions or subsidiaries of publicly traded companies with significantly more market share and resources than we have. These companies have greater financial resources for sales, marketing and product development, broader established relationships with healthcare providers and third-party payers, and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer in all geographies. Our competitors also have regulatory approval to market and sell their products in countries where we currently do not. In addition, our competitors may offer pricing programs with discounts across their non-breast aesthetic product portfolios.

We also face potential future competition from a number of companies, medical researchers and existing medical device companies that may be pursuing new implant technologies. These include non-implant breast augmentation through injections of autologous adipose tissue, new material technologies such as synthetic fillers, and new methods of enhancing and reconstructing the breast.

We believe the primary competitive factors in our current and future markets include:

- safety and outcomes data generated in clinical studies;
- regulatory approvals;
- technological characteristics of products;
- complementary platforms of non-implant products, such as facial fillers and fat grafting technologies;
- product price;
- customer service; and
- support by key opinion leaders.

Notwithstanding the competitive advantages that may be held by our larger competitors across many of the above factors, we believe our competitive strengths include our patient safety profile; proprietary implant technologies; a complementary suite of products and designed surgical procedures (including MotivaHybrid, Motiva MinimalScar, Mia Femtech, and Preservé); vertically integrated manufacturing capabilities in Costa Rica utilizing proprietary 3D imprinted molding methods; a global sales platform combining exclusive distributor arrangements with direct sales in key markets such as Brazil and Europe; and a management team with significant experience in the medical aesthetics industry.

Federal Food, Drug, and Cosmetic Act

Breast implants are regulated as medical devices in the United States, and are subject to the Federal Food, Drug, and Cosmetic Act, or FDC Act, as implemented and enforced by the FDA. The FDA administers requirements covering the design, development, testing (non-clinical and clinical research), safety, effectiveness, manufacturing, labeling, packaging, promotion, advertising, distribution, recordkeeping, import/export and post-market surveillance of medical devices in order to ensure that devices distributed in the United States are safe and effective for their intended uses and otherwise meet the requirements of the FDC Act. The FDA also collects user fees for certain medical device submissions and annual fees for medical device establishments.

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, authorization of a de novo application, or approval of a PMA. Under the FDC Act, medical devices are classified as Class I (lowest risk), II (moderate risk), or III (highest risk), with each successive class reflecting a greater extent of manufacturer and regulatory control needed to ensure device safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the 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 and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. Class III devices are those deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting, or some implantable devices, or devices that have a new intended use or employ advanced technology that is not substantially equivalent to that of a legally marketed device. These must comply with all requirements under the FDC Act, including specific requirements and limitations pursuant to the order issued by FDA subsequent to PMA approval. While our instruments are cleared as Class II devices, breast implants are currently classified as Class III devices requiring an approved PMA for commercial distribution.

510(k) Clearance Pathway

Manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDC Act requesting permission to commercially distribute the device (generally known as 510(k) clearance). To obtain 510(k) clearance, the submitted 510(k) notice must demonstrate that the proposed device is "substantially equivalent" to a predicate device (i.e., a legally marketed device that is not subject to PMA approval) already on the market. The FDA's 510(k) clearance process usually takes from three to twelve months, but it can take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products.

If the FDA agrees that the device is substantially equivalent to a legally marketed predicate device, it will grant 510(k) clearance to commercially market the device. 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.

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. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If that happens, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

In February 2019, we received 510(k) clearance for the Motiva Single-use Sterile Sizers.

In October 2023, the FDA granted 510(k) clearance for the Motiva Flora SmoothSilk Tissue Expander.

Premarket Approval Application Pathway

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

The FDA will approve the new Class III device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). A PMA may include post-approval conditions intended to ensure the

safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported the PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Related to our devices specifically, the FDA's guidance document "Saline, Silicone Gel, and Alternative Breast Implants" currently recommends that a core study, which can be a single, open label, multi-center study, be conducted with ten years or more of prospective patient follow-up. To date, PMAs for silicone breast implants have been submitted for approval to the FDA with a minimum of three years of premarket core study data. Additionally, the FDA will not approve the PMA until it conducts a pre-approval inspection of our manufacturing facility and determines that it is in compliance with good manufacturing practices, as set forth in the FDA's QMSR. The PMA review and approval process generally takes from one to three years but may take longer. The FDA's guidance document "Saline, Silicone Gel, and Alternative Breast Implants" also states that manufacturers seeking approval of breast implants will be subject to post-approval requirements, which may include, but are not limited to, long-term follow-up of the core clinical study patients, conduction of new enrollment post-approval studies, participation in a patient registry or other studies, training programs for physicians and surgeons, and periodic reporting requirements.

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

In September 2024, we received PMA approval from the FDA for our Motiva Implants including our Post Approval Study. Beginning in October 2024 we submitted a PMA Supplement for our Post Approval Study protocol, and we began selling Motiva Implants for use in breast augmentation for patients in the United States.

In November 2024, we received PMA Approval for our Post Approval Study (PAS), which is currently enrolling patients.

In November 2025, we submitted a PMA Supplement requesting approval of an additional manufacturing site (B23) for the manufacture of PMA approved products. FDA approval was received in December 2025.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations, including regulations related to informed consent, Institutional Review Board, or IRB, review and approval, Good Clinical Practices, or GCPs, and labeling of investigational devices. Our clinical study sites are additionally subject to possible inspection by the FDA.

If the device presents a "significant risk" to human health, as defined by the FDA, the device sponsor must submit an IDE application to the FDA, which must be approved prior to commencing human clinical 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 subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which modification is required, it may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical 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. Acceptance of an IDE application for review does not guarantee that the FDA will allow the study to begin and, if it does, 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. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan, or the rights, safety or welfare of human subjects.

During a 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 are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate it at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-Market Regulation

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

- establishment registration and device listing with the FDA;
- QMSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of “off-label” uses of cleared or approved products, as well as other requirements related to promotional activities;
- clearance or approval of product modifications to cleared or approved devices, where warranted;
- 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 FDC Act that may present a risk to health;
- 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;
- 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; and
- any post-market restrictions or conditions imposed by the FDA on a specific device.

Our manufacturing facilities, as well as those of certain of our suppliers, will be subject to periodic and for-cause inspections by the FDA to verify compliance with the QMSR and other regulatory requirements. The QMSR, which covers 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 medical device master file and complaint files. These requirements impose procedural and documentation requirements upon us and our third-

party manufacturers related to the methods used in and the facilities and controls used for designing, manufacturing, packaging, labeling and storing medical devices. As a manufacturer, we are subject to periodic inspections by the FDA. Following these inspections, the FDA may assert noncompliance with QMSR requirements on a Form 483, which is a report of observations from an inspection, or by way of “untitled letters” or “warning letters” that could cause us or any third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated QMSR or other FDA requirements. Our failure to maintain compliance with the QMSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products could result in restrictions, including the removal of the device from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in sanctions including (but not limited to) Warning Letters, fines, injunctions, consent decrees and civil penalties, customer notifications or repair, replacement, refunds, recall, detention or seizure of our products, operating restrictions, partial suspension or total shutdown of production, refusal to grant export approval, or criminal prosecution.

The FDA and comparable foreign regulatory authorities closely regulate the post-approval marketing and promotion of medical devices, including standards and regulations for direct-to-consumer advertising, communications about unapproved uses, industry- sponsored scientific and educational activities and promotional activities involving the internet. Devices may be marketed only for the approved or cleared indications and in accordance with the provisions of the approved or cleared label.

HIPAA and Other Privacy Laws

We are subject to various laws governing the privacy and security of health information and other personally identifiable information. The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, or HIPAA, established comprehensive U.S. federal protection for the privacy and security of protected health information. HIPAA applies to “Covered Entities,” which are health plans, healthcare clearing houses, and certain healthcare providers which conduct certain healthcare transactions electronically, and to “Business Associates,” persons or entities that perform a function or provide specified services on behalf of a Covered Entity that involves the creation, use, maintenance or transmission of protected health information. Both Covered Entities and Business Associates must have in place administrative, physical, and technical standards to guard against the misuse of protected health information. Some of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We may perform future activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity. There are also additional federal and state privacy laws that impose restrictions on the access, use, and disclosure of personal information, including data that is not protected health information, or are otherwise more stringent than HIPAA.

Our activities must also comply with other applicable privacy laws, including the EU General Data Protection Regulation, or EU GDPR, and the UK General Data Protection Regulation, or UK GDPR, or collectively, EU/UK GDPR. There are also privacy laws in other jurisdictions that impose restrictions on the access, use, and disclosure of personal information. All of these laws may impact our business. If we fail to comply with these privacy laws, or if significant changes in the laws restrict our ability to obtain tissue samples and associated patient information, this could significantly impact our business and our future business plans.

Fraud and Abuse Laws

As participants in the healthcare industry, we are subject to anti-fraud and abuse laws in various countries. Many of these anti-fraud laws are broad in scope and impose significant penalties for violation. Prohibitions under some of these laws include:

- the submission of false claims or false information to government programs;
- deceptive or fraudulent conduct;

- excessive or unnecessary services, services that do not meet medical necessity, or services at excessive prices; and
- defrauding private sector health insurers.

Numerous national and state agencies enforce the anti-fraud and abuse laws. In addition, actions under the False Claims Act can be brought by private whistleblowers on behalf of themselves and the government and are entitled to receive a portion of any final recovery. In addition, we, and our partners, may be subject to foreign laws and regulations and other compliance requirements, including, without limitation, anti-kickback laws, false claims laws and other fraud and abuse laws.

In particular, if our products become eligible for reimbursement by federal healthcare programs (directly or indirectly) in the United States, our business activities could be subject to scrutiny and enforcement under one or more U.S. federal or state healthcare fraud and abuse laws and regulations, including:

- The federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, for the referral of an individual for the furnishing of an item or service, or to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid.
- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government.
- The fraud provisions of HIPAA, which impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services.
- Analogous state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require medical technology companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws and local ordinances that require identification or licensing of sales representatives.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government healthcare programs, additional reporting and government oversight, or the curtailment or restructuring of our operations. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance program. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable global privacy, security and fraud laws may prove costly.

Transparency Laws

We are subject to transparency requirements (also known as "sunshine laws") in France, including obligations to report payments or transfers of value to, and the nature of the agreements we sign with, a broad class of French healthcare professionals and organizations. If our products that are approved in the United States become eligible for direct or indirect reimbursement by federal healthcare programs like Medicare or Medicaid, we will also become subject to the Physician Payment Sunshine Act and its amendments and implementing regulations, which require annual reporting of payments and transfers of value to physicians, certain advance practice professionals,

and teaching hospitals, along with ownership interests held by physicians or their immediate family. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

Coverage and Reimbursement

Significant uncertainty exists regarding the coverage and reimbursement status of products approved or cleared by the FDA and, in foreign countries, other government authorities.

In the United States, sales of any products for which we may receive regulatory approval or clearance for commercial sale will depend in significant part on the availability and adequacy of coverage and reimbursement from third-party payors. Third-party payors include federal and state government authorities, managed care providers, private health insurers and other organizations. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a product does not ensure that other payors will also provide coverage for the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list which might not include all of the FDA approved or cleared products for a particular indication. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so-called health technology assessments) in order to obtain reimbursement. The Health Technology Assessment, or HTA, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic, impact and the economic and societal impact related to the use of a health technology. The outcome of the HTA will often influence the pricing and reimbursement status granted to the product under review by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on HTA, or HTA Regulation. The HTA Regulation aims to boost cooperation among EU Member States in assessing health technologies and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation entered into force on January 11, 2022, and started to apply from January 12, 2025, with phased implementation. Under the HTA Regulation, EU Member States are required to use common HTA tools, methodologies, and procedures across the EU. Among other things, the HTA Regulation establishes an HTA coordination group, composed of national HTA bodies, which jointly conduct Joint Clinical Assessments, or JCAs, of new medicines and certain high-risk medical devices (Class III implantable devices and Class III active devices that administer or remove medicinal products) and introduces a single EU-level submission file for JCAs. However, the HTA Regulation focuses on the clinical aspects of HTA, i.e. the relative clinical effectiveness and relative clinical safety of a new health technology as compared with existing technologies, and, as such, individual EU Member States remain responsible for determining the overall value of a new health technology within their healthcare systems, as well as making pricing and reimbursement decisions.

Third-party payors are increasingly challenging the prices charged for, examining the medical necessity of, and assessing the cost-effectiveness of medical products and services, in addition to their safety and efficacy. If third-party payors do not consider a product to be cost-effective compared to other available products, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce physician ordering and patient demand for the product.

The marketability of any products for which we receive market authorization for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status are attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health Reform

In the United States and some foreign jurisdictions, there has been significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls and

restrictions on reimbursement. Because private payers often follow Medicare and Medicaid coverage policy and payment limitations in setting their own reimbursement rates, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative and regulatory measures.

Such legislative changes in the United States include the Patient Protection and Affordable Care Act (PPACA), which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, and impose additional health policy reforms.

More recently, on July 4, 2025, the “One Big Beautiful Bill Act,” or OBBBA, was signed into law. The OBBBA is projected to decrease federal healthcare spending by approximately $1 trillion by reducing Medicaid spending and enrollment and making changes to federal Medicare spending. The law also made changes to ACA marketplace enrollment that are projected to decrease the number of individuals with marketplace coverage. It is unclear if these changes will impact demand for our products.

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

International Medical Device Regulations

International marketing of medical devices is subject to foreign government regulations, which vary substantially from country to country.

In the EU, the Medical Devices Regulation (EU) 2017/745, or EU MDR, applicable since May 26, 2021, establishes comprehensive requirements for the safety, performance, and market access of medical devices in the EU. This legislation applies to all countries within the European Economic Area, or the EEA, including EU Member States, Iceland, Liechtenstein and Norway. On December 16, 2025, the European Commission published a legislative proposal to amend the EU MDR. Adoption of the proposed amendments to the MDR could occur in 2027. However, the timing remains subject to negotiation and approval by the European Parliament and the Council.

Medical devices must comply with the General Safety and Performance Requirements, or the GSPR, laid down in Annex I to the EU MDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark on products, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR of the EU MDR and obtain the right to affix the CE mark, our medical devices must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function, which are not sterile and are not reusable surgical instruments), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPR, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EU Member State to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would audit and examine the technical documentation and the quality system for the manufacturer, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPR. This Certificate and the related conformity assessment process allows the manufacturer to affix the CE mark to the medical devices after having prepared and signed a related EC Declaration of Conformity. Breast implants intended for aesthetic purposes are specifically regulated under Annex XVI to the EU MDR. They must meet the same stringent safety, performance, and clinical evaluation requirements as medical devices, including conformity assessment by a Notified Body.

On January 31, 2020, the United Kingdom withdrew from the EU. Since January 1, 2021, the Medical Devices (EU Exit) Regulations 2020 have introduced several changes to the process of placing medical devices on the Great Britain market. The CE mark will continue to be recognized in Great Britain until June 30, 2030, depending on the device type and classification. Additionally, CE Certificates of Conformity issued by Notified Bodies designated in the EU will remain valid in Great Britain during this period.

Following the end of mutual recognition between the EU and Switzerland on May 26, 2021, CE-marked medical devices can still be legally placed on the Swiss market. However, medical devices manufacturers must now appoint a Swiss Authorized Representative (CH-REP) and comply with additional requirements, including Swissmedic registration, to continue to place medical devices on the Swiss market.

Outside of the EU, the UK and Switzerland, regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of medical devices prior to granting marketing approval. For example, in China, approval by the National Medical Products Administration, or NMPA, must be obtained prior to marketing a medical device. In Brazil, the inspections and approvals of products and facilities carried out by the ANVISA and InMetro agencies are required prior to marketing a Class 3a medical device like our Motiva Implants. We received regulatory clearance in Brazil in March 2017 and launched our Motiva Implants commercially in July 2017. In November 2022, Motiva Implants and the Motiva Flora tissue expander have been approved for use in Japan by the Pharmaceuticals and Medical Devices Agency (PMDA). These products have also received reimbursement for post-mastectomy reconstruction under the Japanese National Health System. In November 2023, Motiva Implants received National Medical Products Administration (NMPA) approval in China. The process in such countries may be lengthy and require the expenditure of significant resources, including the conduct of clinical trials. In other countries, the regulatory pathway may be shorter or less costly. The timeline for the introduction of new medical devices is heavily impacted by these various regulations on a country-by-country basis, which may become longer and more costly over time.

Anti-Corruption Laws

We are subject to applicable anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the UK Bribery Act, and similar anti-corruption laws in the countries in which we distribute our products. Anti-corruption laws generally prohibit offering, promising, giving, or authorizing others to provide anything of value, either directly or indirectly, to a government official or private party in order to influence official action or otherwise gain an unfair business advantage, such as to obtain or retain business. The Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, prohibits any U.S. individual or U.S.-controlled business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. We have implemented policies, procedures, and internal controls that are designed to comply with these laws and regulations.

Human Capital

As of December 31, 2025, we had 1,004 employees. None of our employees are represented by a labor union or covered by collective bargaining agreements except for certain employees in Brazil and Argentina.

The human capital measures and objectives we focus on in managing our business include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of share-based and cash-based compensation awards, in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

We believe that our future success largely depends upon our continued ability to attract and retain highly qualified management and technical personnel. Talent management is critical to our ability to execute on our long-term growth strategy. To facilitate talent attraction and retention, we strive to make our company a safe and rewarding workplace with opportunities for our employees to grow and develop in their careers, supported by strong compensation and benefits and by programs that build connections among our employees. We continue to be committed to an inclusive culture which values equity, opportunity, and respect. In support of our inclusive culture, we offer competitive compensation and benefits, including stock awards and strive to recruit a robust talent pool across all levels of the organization.

Environment and Corporate Sustainability

Our manufacturing processes currently require the controlled use of potentially harmful chemicals, including highly flammable solvents, and we are subject to inspections and other regulatory requirements, including Costa Rican regulations regarding environmental protection and hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure we are in compliance with these laws and regulations. We would be subject to significant penalties for failure to comply with these laws and regulations. For more information, please refer to Section 1A “Risk Factors”.

Working toward a more sustainable future by reducing our environmental footprint is important to us. Our manufacturing facilities are certified as Carbon Neutral by the Costa Rican Ministry of Environment, Energy, and Telecommunications, or MINAE. Additional information on our environmental efforts can be found in our 2023 Annual Review, which is available at https://establishmentlabs.com/wp-content/uploads/2024/07/Sustainability-Annual-Review-2023.pdf.

We are defined by our commitment to women’s health and well-being. We believe offering innovative options that empower women in their breast health and wellness journey is the right path to building a new industry. Sustainability is key to our existence and future. As a global medical technology company, we seek to create positive and long-term social, environmental, and economic impact with our products, experiences, activities, and corporate efforts. Accordingly, our global sustainability commitment leads us to increase our contribution toward long-term sustainability. Our sustainability framework lays the foundation to ensure this commitment is present in everything we do. It describes our pillars, statements, priorities, and guidelines that enable our journey toward sustainability. All these efforts are founded on our four material categories: women’s health and well-being, environment, people, and governance.

Additional information on our governance, women’s empowerment initiatives and sustainability efforts can be found at establishmentlabs.com/our-impact/esg-documents/.

Available Information

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information with the SEC. The SEC maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

We maintain an Internet site at www.establishmentlabs.com. We will, as soon as reasonably practicable after we electronically file or furnish our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to those reports, if applicable, make available such reports free of charge on our website. Our website also contains other items of interest to our investors, including, but not limited to, investor events, press and earnings releases and sustainability initiatives.

ITEM 1A. RISK FACTORS

Investing in our common shares involves a high degree of risk. We operate in a rapidly changing economic and competitive environment that presents numerous risks, many of which are driven by factors that we cannot control or predict. The following risk factors describe circumstances or events that could have a negative effect on our business, financial condition or operating results. You should consider the following risks carefully, together with all the other information in this Annual Report on Form 10-K, including our consolidated financial statements and notes thereto, before you invest in our common shares. If any of the following risks occur, our business, financial condition, or operating results, could be adversely affected. As a result, the trading price of our common shares could decline, and you could lose part or all of your investment. Additional risks and uncertainties not currently known to us or that we currently believe are not material could also impair our business, financial condition or operating results.

Risks Related to the Development and Commercialization of Our Products

We have a limited operating history in the United States and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We marketed our products solely in countries outside of the United States from October 2010 until 510(k) clearance for the Motiva Flora SmoothSilk Tissue Expander in October 2023 and FDA approval of our Motiva

Implants in September 2024, and as such, we have a limited operating history in the United States upon which to evaluate our business and forecast our future net sales and operating results.

Due to our limited operating history in the United States, we may not have the institutional knowledge or experience to be able to implement and execute our business strategy and effectively address the risks that we may face. In addition, we may fail to identify or respond effectively to emerging trends that could negatively affect our business. As a result of this or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Our success depends, in part, on our ability to continue to enhance our existing products and services and develop or commercialize new products and services that respond to customer needs and preferences, which we expect will require us to incur significant expenses.

In recent years, we have incurred significant costs in connection with the research and development of Motiva Implants, the Mia Femtech technology, and our other product candidates, products and services.

We may not be able to compete effectively with our competitors and ultimately satisfy the needs and preferences of our customers, unless we can continue to enhance existing products and develop or acquire new innovative products and services. Product development requires the investment of significant financial, technological and other resources. Product improvements and new product introductions also require significant planning, design, development and testing at the product and manufacturing process levels. We may not be able to timely or effectively develop product improvements or new products and services. Likewise, we may not be able to acquire new products on terms that are acceptable to us, or at all. Furthermore, in most countries, we need to obtain regulatory approval in order to market and sell our products, which may limit our ability to act quickly in scaling commercialization in those countries. Our competitors' new products may beat our products to market, be more effective or safer or have new features, obtain better market acceptance or render our products and services obsolete. Any new or modified products and services that we develop may not receive regulatory clearance or approval, or achieve market acceptance or otherwise generate any meaningful sales or profits for us.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages could prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel, the ability to accept the payment of user fees, statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. The Trump Administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of applications. Further, government funding of the FDA and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Additionally, the FDA is transitioning from the Quality System Regulation (QSR) to the Quality Management System Regulation (QMSR), with the transition period concluding in February 2026. This transition requires us to align our quality management systems with the new requirements, which may require significant resources and operational adjustments. Failure to comply with QMSR requirements by the applicable deadline could result in enforcement actions, delays in product approvals, or other adverse regulatory consequences.

Disruptions at the FDA and other agencies, including staffing reductions, funding limitations, or policy changes under the current or future administrations, may also slow the time necessary for new drugs and devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Any reduction in FDA resources or changes in regulatory priorities could delay approval of our products or modifications to existing products, extend the timeline for compliance activities, or otherwise adversely affect our business. For example, during various times in the past, the U.S. government has shut down and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. A prolonged government shutdown occurs, or other events, including uncertainty regarding the FDA's funding, operations or policy goals, that prevents the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future federal government shutdowns, delays in annual

appropriations or budget freezes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Any future distribution or commercialization agreements we may enter into with respect to our current or planned products may place the development of these products outside our control or may otherwise be on terms unfavorable to us.

We may enter into additional distribution or commercialization agreements with third parties with respect to our current or planned products, for commercialization in or outside the United States. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size medical device and diagnostic companies, regional and national medical device and diagnostic companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our planned products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable planned products. Collaborators may own or co-own intellectual property covering our products that results from our collaboration with them. In such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of planned products, increases in our costs to develop the planned products or the termination of development of a planned product.

If we are unable to educate clinicians on the safe, effective and appropriate use of our products and designed surgeries, we may experience unsatisfactory patient outcomes, negative publicity and increased claims of product liability and may be unable to achieve our expected growth.

We make extensive physician medical education resources available to clinicians in an effort to ensure that they have access to current treatment methodologies, are aware of the advantages and risks of our Motiva Implants and other products and are educated regarding the safe and appropriate use of our products. It is critical to the success of our business to broadly educate clinicians who use or desire to use our products to provide them with adequate instructions in the appropriate use of our products and designed surgeries. Certain of our products require the use of specialized techniques which may not be covered in medical school curricula and/or product-specific knowledge. For example, metal implants such as screws or artificial joints produce an artifact when magnetic resonance imaging, or MRI, is used to image the area in which the object resides. Our Qid Safety Technology microtransponder embedded in certain Motiva Implants contains metal and causes an artifact that can affect breast cancer screening using MRI, and this artifact is not present in other imaging modalities such as breast ultrasound and film or digital mammography. It is important that we educate physicians and patients on the risks associated with MRI artifacts and how to mitigate them if they choose to utilize Motiva Implants that contain a Qid microtransponder. Failure to provide adequate training and education could result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or increased product liability claims or lawsuits against the company, any of which could have a material and adverse effect on our business and reputation. Claims against the company may occur even if such claims are without merit and/or no product defect is present, due to improper surgical technique, inappropriate use of our products, or other lack of awareness regarding the safe and effective use of our products. If we fail to educate physicians and patients about any of these factors, they may make decisions or conclusions regarding Motiva Implants without full knowledge of the risks and benefits or may view our Motiva Implants negatively.

As part of our effort to educate and train plastic surgeons through our medical educational platform, we completed 607 and 239 medical training sessions worldwide during 2025 and 2024, respectively. If we are unable to offer, or if we experience a delay in offering, medical training sessions, we may experience reduced or slower than expected adoption of our products. Although we offer virtual training sessions through our medical educational platform, any limited ability to provide in-person programs to surgeons may reduce the effectiveness of, and interest in, our medical education efforts.

Commercial success of Motiva Implants in the United States or elsewhere depends on our ability to accurately forecast customer demand, manufacture sufficient quantities of product in the implant sizes that patients and physicians request, and manage inventory effectively, and the failure to do so could

have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Manufacturing silicone breast implants requires costly capital equipment and a highly skilled workforce. There is a significant lead time to build and certify a new manufacturing facility. Although we believe our current facilities give us adequate manufacturing capacity to meet current demand, we have, in the past, been unable to fill all incoming orders. If demand increases faster than we expect, or if we are unable to produce the quantity of goods that we expect with our current facilities, we may not be able to grow revenue at an optimal rate. There may be other negative effects from supply shortages, including loss of our reputation in the marketplace and a negative impact on our relationships with our distributors.

On the other hand, if demand for our products declines, or if market supply surpasses demand, we may not be able to reduce manufacturing expenses or overhead costs proportionately. We have invested significantly in our manufacturing capacity in order to vertically integrate our business. If an increase in supply outpaces the increase in market demand, or if demand decreases, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, higher inventory carrying costs and associated working capital, changes in revenue mix, and/or price erosion, any of which would lower our margins and adversely impact our financial results.

Risks Related to Our Business, Industry and Operations

We have incurred losses to date, and our ability to achieve and maintain profitability depends on the commercial success of our Motiva Implants.

We have incurred losses to date and expect to continue to incur losses for the foreseeable future. Sales of our Motiva Implants accounted for approximately 99% and 96% of our revenues for each of the years ended December 31, 2025 and 2024, respectively, and we expect our revenues to continue to be driven primarily by sales of these products. We also continue to incur significant research and development and general and administrative expenses related to our operations. We do not expect to be profitable in 2026, and in future years we expect to incur significant research and development expenses related to, among other things, the IDE and the post-approval clinical studies of Motiva Implants in the United States. Investment in medical device product development, particularly clinical studies, is highly speculative. It entails substantial upfront capital expenditures and significant risk that any potential planned product will fail to demonstrate adequate accuracy or clinical utility. We may not be profitable for some time. As of December 31, 2025, we had an accumulated deficit of $495.8 million.

In order to achieve and sustain profitability, our revenues from our products will need to grow beyond the levels we have achieved in the past. If physicians and/or patients do not perceive our products to be competitive in features and safety when compared to other products in the market, or if demand for our Motiva Implants or for breast implants in general decreases, we may fail to achieve sales levels that provide for future profitability.

If we are unable to continue to commercialize Motiva Implants and our other products, or if we are unable to obtain a partner to commercialize them, we may not be able to produce any incremental revenues related to Motiva Implants and our other products. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects. Even if we are able to reach profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and planned products, or continue our operations.

Unfavorable global economic and political conditions, including slower growth or recession, inflation, decreases in consumer spending power or confidence or trade wars, have in the past, and could in the future, adversely affect our business, financial condition or results of operations.

Our results of operations have been in the past, and could be in the future, adversely affected by general conditions in the global economy and in the global financial markets, such as trade wars, slower growth or recession, adverse impacts on currency exchange rates, continued inflation or decreases in consumer spending or confidence, as well as changing political conditions. A severe or prolonged economic downturn could result in a variety of risks to our business, including general economic pressure on our customers' patients. Elective aesthetic procedures, including breast augmentation, are typically not covered by insurance and are less of a priority than other items for patients that have lost their jobs, are furloughed, have reduced work hours or have to allocate their cash to other priorities. As a result, adverse changes in the global economy, including as a result of

inflationary pressures, elevated interest rates, geopolitical conflicts, including the Russia-Ukraine war and the Hamas-Israel conflict, political instability or macroeconomic fallout from significant U.S. policy changes and government spending cuts, may cause consumers to reassess their spending choices and reduce demand for elective aesthetic procedures, as well as may disrupt global supply chains, increase costs for raw materials and logistics, and create broader macroeconomic instability, which could have an adverse effect on our net sales and profitability. In addition, the growing availability and adoption of glucagon-like peptide-1 (GLP-1) drugs and related pharmaceutical therapies for obesity and metabolic conditions could reduce discretionary consumer spending on elective aesthetic procedures and/or reduce underlying demand for certain procedures if these therapies directly or indirectly address patient concerns that might otherwise by treated with our products.

Additionally, there is significant uncertainty about the future relationship between the United States and other countries with respect to trade policies, taxes, government regulations, and tariffs. The Trump Administration has imposed additional tariffs on imports from various countries as well as imposed baseline reciprocal tariffs on imports from certain trading partners. These tariffs, and any additional tariffs that may be imposed, could increase our costs for raw materials, components, and finished goods and may adversely affect our supply chain and manufacturing operations in Costa Rica. In response to U.S. trade actions, certain countries have imposed or threatened to impose retaliatory actions against the United States, including retaliatory tariffs on U.S. goods, which could affect demand for our products in those markets or otherwise disrupt global trade. The ultimate impact of tariffs will depend on various factors, including the scope, timing, amount, nature, implementation, and duration of such tariffs, as well as any retaliatory measures by other countries, but could materially increase our operating costs, reduce demand for our products, and adversely affect our financial condition and results of operations.

These policies may also lead to supply chain constraints and additional inflation, further increasing operational costs and may result in reductions in discretionary spending in our markets and demand for our products. A weak or declining global economy or disruptions caused by geopolitical uncertainty or regional political stability could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers or distributors to delay making payments for our products. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business.

If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing.

We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our planned development and commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our products and technologies.

Our operations have consumed substantial amounts of cash since our inception, and we expect to incur significant expenses in connection with our planned research, development and product commercialization efforts. We believe that our available cash and cash from operations will be sufficient to satisfy our liquidity requirements for at least the next 12 months. If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. However, we are subject to restrictive covenants under the Credit Agreement which restrict our ability to incur additional debt. Any failure to raise the funds necessary to support our operations or liquidity requirements may force us to delay, reduce or suspend our planned clinical trials, research and development programs, or other commercialization efforts.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to do so at an earlier stage than would otherwise be ideal and/or may have to limit valuable rights to our intellectual property, technologies, products, or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional

fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our products.

Our business depends on maintaining our brand and ongoing customer demand for our products and services, and a significant reduction in sentiment or demand could affect our results of operations.

Our success depends on the reputation of our brands, which depends on factors such as the safety and quality of our products, our communication activities, including marketing and education efforts, and our management of our customer experience. Maintaining, promoting and positioning our brands is important to expanding our customer base. This will depend largely on the success of our education and marketing efforts and our ability to provide a consistent, high-quality customer experience.

We utilize social media and may engage high-profile influencers to increase brand awareness and educate consumers, which increases the risk that promotional content is alleged to be false, misleading, or otherwise non-compliant with FDA and other advertising and promotion requirements. Even with contractual controls and monitoring, influencer content may deviate from our guidelines or include off-label or otherwise problematic claims, creating heightened compliance and enforcement risk due to the speed and reach of social platforms.

We may need to make substantial investments in the areas of education and marketing in order to maintain and enhance our brands. Ineffective marketing, negative publicity, significant discounts by our competitors, product defects and related liability litigation, failure to obtain regulatory clearance for our products, counterfeit products, unfair labor practices and failure to protect the intellectual property rights in our brands are some of the potential threats to the strength of our business. To protect our brands' status, we may need to make substantial expenditures to mitigate the impact of such threats.

We believe that maintaining and enhancing our brands in the countries in which we currently sell our products, and in new countries where we have limited brand recognition, is important to expanding our customer base. If we are unable to maintain or enhance the strength of our brands in the countries in which we currently sell our products and in new countries, then our growth strategy could be adversely affected.

If we fail to compete effectively against our competitors, many of whom have greater resources than we have, our revenues and results of operations may be negatively affected.

Alternatives exist for Motiva Implants and for our other products, and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market silicone breast implants. We also face competition from manufacturers of saline-filled breast implants, and we see emerging competition from non-implant breast augmentation techniques such as hyaluronic acid injection and novel fat grafting methodologies. Any of these may present competitive barriers to Motiva Implants.

Our leading competitors are large, multi-national companies with significant resources and capabilities. Sientra, Inc. (acquired by Tiger Aesthetics Medical), Mentor Worldwide LLC (a division of Johnson & Johnson) and Allergan plc (acquired by AbbVie Inc.) have conducted large prospective clinical studies that started in the United States in 2002, 2000 and 1998, respectively, and they use this data extensively to promote their products. This can put us at a disadvantage when promoting our products to physicians and patients, even outside of the United States. In addition, the significant financial and staff resources and brand recognition that our competitors possess mean they may be able to compete with us regardless of the differentiating features of our products. If we are not successful in capturing market share, even outside the United States, or if physicians or patients do not perceive our products to be safer or more favorable, our revenues and/or our operating margins may be significantly impaired.

In addition, manufacturers of competitive products may reduce prices for their competing products in an effort to gain or retain market share and undermine the value proposition that Motiva Implants might otherwise be able to offer to customers. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. These competitors may develop new technologies that are superior to our products or replace silicone.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and

retaining qualified technical and management personnel, establishing clinical study sites and patient registrations for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Pricing pressure from customers and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies and future expansion.

The industry environment for silicone implants and complementary products in certain markets is price sensitive. In these markets, including the United States, our competitors may adopt aggressive pricing strategies to intensify the competitive pricing pressure for breast implants. If we are not successful in educating customers or third-party payers on the differentiation of our Motiva Implants as compared to our competitors' products, customers may choose our competitors' products. Additionally, as more competitors introduce products that compete with ours, we may face additional pricing pressure that would adversely impact our future results.

We expect to increase the size of our organization in certain jurisdictions and functions; as a result, we may encounter difficulties in managing our growth, which could disrupt our operations and/or increase our net losses.

As of December 31, 2025, we had 1,004 employees. Unless it is necessary for us to make reductions to our workforce as a cost management strategy, over the next several years, we expect to experience growth in the number of our employees and the scope of our operations, principally in the areas of manufacturing and sales and marketing, and particularly as we continue to expand our operations in the wake of obtaining approval from the FDA to commercialize our Motiva Implants in the United States. We also intend to continue to improve our operational, financial and management controls, reporting systems and procedures, which may require additional personnel. Such growth could place a strain on our administrative and operational infrastructure, and/or our managerial abilities, and we may not be able to make improvements to our management information and control systems in an efficient or timely manner. We may discover deficiencies in existing systems and controls.

Many of these employees will be in countries outside of our corporate headquarters, which adds additional complexity. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage these activities. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require, in multiple countries;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various distributors, suppliers, and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from growing successfully. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may also be exposed or subject to additional unforeseen or undisclosed liabilities as well as increased levels of indebtedness.

In certain markets, we engage or anticipate engaging in direct sales efforts. We may fail to maintain and develop our direct sales force, and our revenues and financial outcomes could suffer as a result. Furthermore, our direct sales personnel may not effectively sell our products.

We have established a direct sales force for our business in Brazil and the United States, and we have implemented a direct sales strategy in several European countries. We have hired and will need to retain and motivate a significant number of sales and marketing personnel in order to support our anticipated growth in these countries. There is significant competition for quality personnel experienced in such activities, including from companies with greater financial resources than ours. If we are not successful in our efforts to continue recruiting, retaining, and motivating such personnel, we may not be able to increase our revenues, or we may increase our expenses in greater measure than our revenues, negatively impacting our operating results.

We may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may adversely affect our business, financial condition and operating results.

We face an inherent risk of product liability exposure related to the sale of Motiva Implants and our other products. The marketing, sale and use of Motiva Implants and our other products could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed or caused significant adverse events in patients. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products or any planned products we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to plaintiffs;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $25 million in product liability insurance coverage, which may not be adequate to cover all liabilities we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Counterfeit products may be represented as ours, which could compete with our genuine products and may also expose us to risks associated with adverse events and product liability.

We routinely see counterfeit versions of our major competitor's branded products in the marketplace, and we are aware of potential counterfeiting of our Motiva Implants. This is particularly common in emerging markets, where sensitivity to price is higher and regulatory enforcement is under-resourced. These counterfeit products are typically manufactured with significantly lower quality than the products they are claimed to be, and in some cases may be manufactured with silicones that are not medical grade. They may expose patients to significant adverse event risks, and there is a risk that certain adverse events with counterfeit products may be attributed to our genuine products. This could reduce demand for our products, result in negative publicity, or otherwise impact our business and the price of our shares.

Negative publicity concerning our products or our competitors' products, including due to product defects or recalls and any resulting litigation, or long-term safety impacts, could harm our reputation and reduce demand for silicone breast implants, either of which could adversely impact our financial results and/or share price.

The silicone breast implant industry has been the focus of significant regulatory and media scrutiny. Silicone breast implants were removed from the U.S. marketplace for a period in the 1990s and 2000s related to safety concerns. Certain patient advocacy groups exist to publicize real and perceived health risks associated with silicone breast implants and plastic surgery generally. Recently, some breast implant patients have begun to self-identify and report various symptoms that they believe are related to their breast implants; they refer to these symptoms as Breast Implant Illness, or BII, but BII is not an official medical diagnosis. Additionally, the activities of legislative bodies, regulatory agencies, physician organizations, and other groups may lead to publicity around the real and perceived risks to patients from silicone implants. The responses of potential patients, physicians, the news media, legislative and regulatory bodies and others to information about complications or alleged complications of our products or our competitors' products, or products liability litigation against us or our competitors, could materially reduce market acceptance and patient demand for our products, or could, even in the absence of a change in demand, negatively impact our business and reputation and negatively impact our financial condition, results of operations or the market price of our common shares. In addition, activity of this type could result in an increase in the number or size of product liability claims, which would adversely affect our business, financial results, and/or the price of our shares.

News coverage in recent years has called into question the long-term safety of breast implants, including through reports of breast implant-associated anaplastic large cell lymphoma linked to our competitors' products which have led to regulatory actions regarding macrotextured devices in several countries and the worldwide recall of one of our competitor's macrotextured implants and tissue expanders. These events and reports of other forms of cancer, including squamous cell carcinoma and various lymphomas, from breast implant products may lead to a reduction in the demand for silicone breast implants and could adversely affect our business.

Women with breast implants have reported higher rates, as compared to the general population, of breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL, an uncommon type of cancer affecting cells of the immune system. In January 2011, the FDA indicated that there was a possible association between certain saline and silicone gel-filled breast implants and higher rates of BIA-ALCL, with the causal links neither yet understood nor confirmed. In March 2015, France's National Cancer Institute, or NCI, noted that there is a clearly established link between anaplastic large cell lymphoma and certain breast implants, which is referred to as breast implant-associated ALCL, or BIA-ALCL. The NCI noted in that report that most of the reported cases occurred in women with textured implants.

In August 2017, the FDA updated its advisory on BIA-ALCL and subsequently requested all breast implant manufacturers to revise their physician and patient labeling with the most current information. The August 2017 update described BIA-ALCL as "rare" and stated "we have strengthened our understanding of this condition and concur with the World Health Organization designation of BIA-ALCL as a rare T-cell lymphoma that can develop following breast implants". The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and the lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces. The FDA noted it does not recommend prophylactic breast implant removal in a patient without symptoms or other abnormalities.

In March 2018, the FDA further updated its advisory on BIA-ALCL stating "we are reporting that we are aware of 414 total cases of BIA-ALCL. Additionally, studies reported in medical literature estimate that the lifetime risk of developing BIA-ALCL for patients with textured breast implants ranges from 1 in 3,817 to 1 in 30,000." The FDA noted that the update did not change the agency's recommendation and that choosing to obtain a breast implant is a personal decision that patients and providers should make with the most complete information available. In the fourth quarter of 2018, following the non-renewal of its textured breast implant CE Certificates of Conformity in Europe, Allergan plc suspended sales of textured breast implants in Europe and withdrew its remaining textured breast implants on the market within Europe.

On February 6, 2019, the FDA further reported that as of September 2018, the agency had received a total of 660 medical device reports regarding BIA-ALCL cases since 2010. Of the 660 reports, the FDA's analysis suggested that there were 457 unique cases of BIA-ALCL, including nine patient deaths. Additionally, on February 12, 2019, Health Canada confirmed that as of January 1, 2019, it had received reports of 22 confirmed and 22 suspected Canadian cases of BIA-ALCL and that it would be updating its safety review of BIA-ALCL in Spring 2019. In April 2019, the Agence Nationale de Securite du Medicament et des Produits de Sante, or ANSM, the regulatory authority in France, announced that 59 cases of BIA-ALCL had been reported in France since 2011 and banned several types of macrotextured and polyurethane implants linked to BIA-ALCL. Between February and September 2019, authorities from Australia, Colombia, Canada, South Korea and Singapore announced similar bans.

In July 2019, the FDA requested that Allergan plc recall its Biocell® textured implants in the U.S. market and Allergan subsequently announced the global recall of its Biocell® textured breast implants and tissue expanders. In the announcement, the FDA noted that it had reviewed 573 unique cases globally of BIA-ALCL, including 33 patient deaths, of which 12 of the 13 known deaths were attributed to Biocell® implants. The FDA further noted that it will continue to monitor the incidence of BIA-ALCL across other textured and smooth breast implants and tissue expanders as well as other devices intended for use in the breast. The FDA subsequently identified the recall as a Class I recall in September 2019 and stated that use of the recalled devices may cause serious injuries and death. As the BIA-ALCL risk continues to become more highly publicized, this could have a significant negative impact on demand for breast implants globally, including our Motiva Implants.

In August 2020, the FDA updated its analysis of medical device reports of breast implant illness and breast implant associated lymphoma. In this update, the FDA updated the table on the agency's BIA-ALCL webpage to include a total of 733 unique cases and 36 patient deaths globally as of January 5, 2020, which reflect an increase of 160 new cases and 3 deaths since the early-July 2019 update.

In September 2020, the FDA released finalized guidance on breast implant labeling recommendations, including the addition of a boxed warning, a patient decision checklist, material and device descriptions, implant rupture screening recommendations and a patient device card. In October 2021, the FDA took several additional actions to strengthen breast implant risk communication, including restricting the sale and distribution of breast implants to only healthcare providers and facilities that provide information to patients using the patient decision checklist. The FDA also approved new labeling for all legally marketed breast implants that includes a boxed warning, a patient decision checklist, updated silicone gel-filled breast implant rupture screening recommendations, a device description with a list of specific materials, and a patient device card.

In September 2022, the FDA informed the public about reports of cancers, including squamous cell carcinoma, or SCC, and various lymphomas, in the scar tissue (capsule) that forms around breast implants different from the lymphomas described in previous FDA communications as BIA-ALCL. In March 2023, the FDA provided updated information about SCC, noting it has received 24 reports of SCC related to breast implants, but that this this does not necessarily represent cancer incidence because of potential underreporting or duplicated reports. The FDA noted that, while the agency believes the occurrences of SCC or various lymphomas in the capsule around the breast implant to be rare, healthcare providers and people who have or are considering breast implants should be aware that cases have been reported to the FDA and in the literature.

We do not produce the types of rough textured implants that have been involved in these reports. To date, no cases of BIA-ALCL or SCC have been reported in patients who have only had Motiva Implants. Furthermore, there have been no reported cases of BIA-ALCL in patients with smooth implants with no history of previously having a textured device. Future clinical studies or clinical experience may indicate that breast implants expose potentially genetically predisposed patients to greater risks of BIA-ALCL, which may reduce demand for silicone implants generally and expose us to product liability claims, as well as to class actions and other lawsuits. These impacts may occur even without any specific linkage with our products. Moreover, if cases of BIA-ALCL, SCC, or other complications are discovered in the future and/or are reported in patients with Motiva Implants, we could be subject to mandatory product recalls, suspension or withdrawal of our regulatory licensure for sale in one or more countries, and significant legal liability. Any of these may have an adverse effect on our business or operating results, or a negative impact on our share price.

The loss of members of our executive management team or other employees, or other turnover in our management team, could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of members of our executive management team and other key employees. The collective efforts of each of these persons, the majority of whom reside in the United States, are critical as we continue to develop our tests and technologies and pursue our research and development and sales programs. In addition, we have experienced significant changes in our executive leadership in recent years, including in our Chief Executive Officer, Chief Operating Officer and General Counsel positions. As a result of the difficulty in locating qualified new management and other key employees, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. In addition, changes to strategic or operating goals, which can often times occur with the appointment of new executives and directors, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. Executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. We do not have “key person” life insurance on our senior executives, and the loss of any of the key team members would have a negative impact to our business and financial results. In addition, the job market in Costa Rica and other locations in which we operate has recently become more competitive and we are competing for talent with major multinational corporations which have significantly more resources than us, and we may find new difficulties in retaining our most talented employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

We have made multiple acquisitions in the past, and in the future, we may acquire other businesses, form joint ventures or make investments in other companies or technologies. If we are not successful in

integrating these businesses, as well as identifying and controlling risks associated with the past operations of these businesses, we may incur significant costs, receive penalties or other sanctions from various regulatory agencies and/or incur significant diversions of management time and attention.

We believe our business growth will be enhanced if we continually seek opportunities to enhance and broaden our product offerings. As part of our business strategy, we may pursue acquisitions or licenses of assets, or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. We have acquired companies and/or assets and licensed assets in a variety of countries, including Brazil and several European countries.

We may do more of these types of transactions in the future and may also form strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have an adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company may also disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue common shares as consideration, which would dilute the ownership of our shareholders. If the price of our common shares is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our shares as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Integrating any business, product or technology we acquire could be expensive and time-consuming, disrupt our ongoing business, impact our liquidity, and/or distract our management and its success may also depend on our ability to retain any key employees related to the acquired business. If we are unable to integrate any acquired businesses, products or technologies effectively, our business may suffer. Whether as a result of unsuccessful integration, unanticipated costs, including those associated with assumed liabilities and indemnification obligations, negative accounting impact, or other factors, we may not realize the economic benefits we anticipate from acquisitions. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

We have significant exposure to the economic and political situations in emerging market countries, and developments in these countries could materially impact our financial results or our business more generally.

Many of the countries in which our products are sold are emerging markets. Our global growth strategy contemplates the expansion of our existing sales activities in Latin America, Europe, the Middle East, and Asia-Pacific region as well as North America. Our exposure to emerging markets has increased in recent years, as have the number and importance of our distributor arrangements. Economic and political developments in Brazil and other emerging markets, including economic crises, currency inflation, or political instability, have had in the past, and may have in the future, a material adverse effect on our financial condition and results of operations. Moreover, as these markets continue to grow, competitors may seek to enter these markets and existing market participants will likely try to aggressively protect or increase their market shares. Increased competition may result in price reductions, reduced margins and our inability to gain or hold market share, which could have an adverse effect on our financial condition and results of operations.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our liquidity and financial performance.

Bank failures, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023,

Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each swept into receivership. We do not maintain balances with and are not a borrower under or party to any credit agreement, material letter of credit or any other such instruments, with any financial institution currently in receivership. However, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC standard insurance limit, with balances concentrated at a small number of financial institutions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or which we do business with, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the United States or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. In addition, if any of our partners or parties with whom we conduct business are unable to access funds due to the status of their financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Our results of operations have been in the past, and could be in the future, adversely affected by fluctuations in currency rates.

We present our results of operations in U.S. dollars, which is our reporting currency. However, as of December 31, 2025, the majority of our revenues are denominated in currencies other than the U.S. dollar - primarily the euro, the Brazilian real, and the British pound. As of December 31, 2025, the majority of our expenses are denominated in U.S. dollars or in Costa Rican colones, the latter of which is closely linked to the U.S. dollar. In the future, we expect to have significant revenues and expenses denominated in these non-U.S. currencies. As such, unfavorable fluctuations in currency exchange rates have had, and in the future could continue to have, an adverse effect on our results of operations.

Because our consolidated financial statements are presented in U.S. dollars, we must translate revenues, expenses and income, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the U.S. dollar in relation to the British pound, the euro, the Brazilian real and, to a lesser degree, the Costa Rican colones will affect our revenue, cost of goods, and operating expenses as well as the value of balance sheet items originally denominated in other currencies. These changes in exchange rates may cause our growth in consolidated earnings stated in U.S. dollars to be higher or lower than our growth in local currency when compared against other periods. We do not currently engage in currency hedging arrangements to protect us from fluctuations in the exchange rates of the euro and other currencies in relation to the U.S. dollar (and/or from inflation of such currencies), and we are exposed to material adverse effects from such movements. We cannot predict any future trends in rates of inflation or exchange rates of other currencies against the U.S. dollar, and there can be no assurance that any contractual provisions will offset their impact, or that any future currency hedging activities will be successful.

Continued international expansion of our business will expose us to business, regulatory, political, operational, financial, economic and environmental risks associated with doing business internationally.

Our products are commercially available in over 100 countries, and we operate subsidiaries in the United States, Costa Rica, Brazil, and several European countries. Our business strategy contemplates continued international expansion, including partnering with medical device distributors, and introducing Motiva Implants and other planned products outside of the United States. The sale and shipment of our products internationally, as well as the purchase of components from international sources, subjects us to potential trade, import and export, and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export or import privileges, seizure of shipments, restrictions on certain business activities

and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, marketing and sales activities.

In addition, several of the countries in which we sell our products or conduct our operations are, to some degree, subject to political, economic, social or environmental instability. Doing business in Costa Rica and other countries outside the United States involves a number of other risks, including:

- multiple, conflicting and changing laws and regulations such as tariffs and tax laws, export and import restrictions, employment laws, environmental laws, regulatory requirements, price controls, reimbursement schemes and other governmental approvals, permits and licenses;
- difficulties in managing global operations;
- logistics and regulations associated with shipping products, including interruptions resulting from natural or other disasters including earthquakes, volcanic activity, hurricanes, floods and fires, and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- economic weakness, currency fluctuations, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities;
- failure to comply with restrictions on the ability of companies to do business in foreign countries, including restrictions on foreign ownership of telecommunications providers imposed by the U.S. Office of Foreign Assets Control;
- failure to comply with evolving reporting expectations on environmental, social and governance issues;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Any of these risks, if encountered, could harm our future international expansion and operations and, consequently, have an adverse effect on our financial condition, results of operations and cash flows.

Environment, social and governance (ESG) matters may create additional risks and costs.

Increased focus by investors, customers, employees, and other stakeholders on ESG matters, as well as evolving regulatory requirements related to ESG disclosures, may result in increased costs and require additional resources. We may face increasing pressure to make commitments relating to sustainability matters, including greenhouse gas emissions reductions and responsible supply chain practices, among others. Regulatory bodies in various jurisdictions, including the EU through the Corporate Sustainability Reporting Directive and state regulators in the United States, have adopted or proposed ESG disclosure requirements that may apply to our operations.

At the same time, there has been increasing scrutiny of, and in some cases opposition to, ESG initiatives from certain stakeholders and legislators. Certain U.S. states have enacted or proposed "Anti-ESG" legislation that may limit the consideration of ESG factors in certain contexts or impose requirements contrary to voluntary ESG commitments we may make. Navigating these conflicting expectations and requirements may be challenging and could expose us to reputational harm, litigation, or regulatory action regardless of the approach we adopt. Our failure to meet ESG expectations or comply with evolving ESG regulations could adversely affect our reputation, ability to attract and retain employees, access to capital, and relationships with customers and business partners.

Any disruption at our existing facilities could adversely affect our business and operating results.

Our manufacturing headquarters are located in Costa Rica, and all of our main manufacturing activities are conducted in ISO-13485 and GMP compliant manufacturing facilities in Costa Rica through Establishment Labs, S.A. The newest facility in Costa Rica was completed in June 2024 and commenced manufacturing in the second half of fiscal 2024. Despite our efforts to maintain and safeguard our manufacturing facilities, including acquiring insurance and adopting maintenance and health and safety protocols, vandalism, terrorism or a natural or other climate-related disaster, such as earthquake, volcanic activity, fire or flood, could damage or destroy our inventory of finished goods, cause substantial delays in our operations and manufacturing, result in the loss of key information and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have an adverse effect on our business, financial condition and results of operations.

We may be required to record a significant charge to earnings if our goodwill or other intangible assets become impaired.

We have recorded goodwill and intangible assets in connection with our acquisitions, including acquisitions in Brazil and European countries. Under applicable accounting standards, we are required to test goodwill for impairment at least annually (absent any impairment indicators). Our goodwill may become impaired due to factors such as a decline in our stock price and market capitalization, slower growth rates in our industry, changes in competitive conditions, the introduction of newer technology or competing products, or other materially adverse events that have implications on the profitability of our business. Any finding that the value of our goodwill or other intangible assets has been impaired would require us to record an impairment charge, which could materially reduce the value of our assets, reduce our net income or increase our net loss for the year in which the impairment charge occurs, and increase our accumulated deficit. Any such impairment charges could have a material adverse effect on our business, financial condition, and results of operations.

Fluctuations in insurance costs, availability and future insurance requirements could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which would adversely affect our results of operations or financial condition.

Risks Related to Manufacturing and Other Third-Party Relationships

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business and could expose us to liability if our use of such hazardous materials causes injury.

Our manufacturing processes currently require the controlled use of potentially harmful chemicals, including highly flammable solvents. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. These are particularly stringent in California, where Avantor, one of our key suppliers, is located. The cost of compliance with these laws and regulations may become significant and could have an adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

We rely on third parties to conduct certain components of our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, which could interfere with or delay our ability to obtain regulatory approval or commercialize our products.

We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform various functions for our clinical trials. These service providers may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We are required to collect and provide financial disclosure notifications or certifications for our clinical investigators to the FDA. If the FDA concludes that a financial relationship between us and a clinical investigator has created a conflict of interest or otherwise affected interpretation of the trial, the FDA may question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the International Council for Harmonization, or ICH, and the FDA require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products.

We rely on a single-source, third-party supplier for medical-grade long-term implantable silicone, which is the primary raw material used in our Motiva Implants. As has occurred in the past, if this supplier were to increase prices for this raw material or experience interruptions in its ability to supply us with this raw material, our business, financial condition and results of operations could be adversely affected.

We rely on Avantor as the sole supplier of medical-grade silicone used in our Motiva Implants as well as other products that we manufacture under contract to other customers. To our knowledge, Avantor is the only supplier of such raw materials with the appropriate filings with the FDA and other regulatory bodies to enable the manufacturing of products with our requirements. Avantor supplies our major competitors with raw material as well, and at least two of these are larger-volume customers of Avantor than we are.

If Avantor becomes unable or unwilling to supply sufficient quantities of medical-grade silicone of the specifications required for our products, or if Avantor increases prices further in the future, we may not be able to replace this supply source quickly, or at all. Similarly, it may become unable or unwilling to manufacture our needed raw materials in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements. Any replacement supplier would have to be qualified with the relevant regulatory authorities, which is an expensive and time-consuming process during which we may experience an interruption in our manufacturing operations. We may also be unsuccessful in negotiating favorable terms with such a supplier. Any of these contingencies would likely affect the financial results of our operations and may have a negative impact on our share price. In particular, if we are not able to establish a replacement vendor for our medical-grade silicone, we would be unable to manufacture our Motiva Implants as well as other products that we manufacture under contract to other customers until such time as a replacement vendor is identified, which would likely significantly affect the financial results of our operations and have a significantly negative impact on our share price.

In addition, our relationship with Avantor involves other risks, including but not limited to the following:

- it may not be able, or willing, to manufacture silicone raw materials with our agreed-upon specifications;
- it may not be able, or willing, to manufacture our needed raw materials in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements;
- it may not be able to supply sufficient quantities of each raw material quickly enough for us to respond to rapid increases in demand;

- it may unintentionally convey information to our competitors that is helpful in understanding our proprietary compositions and other trade secrets of our manufacturing processes;
- we may be subject to price fluctuations if we fail to meet certain minimum order requirements, or if our existing contract expires or is renegotiated;
- it may lose access to critical services and components, resulting in interruption in manufacture or shipment of medical-grade silicone;
- its facilities may be affected by earthquakes, wildfires, mud slides or other natural disasters, which could delay or impede production of our raw materials;
- we may be required to obtain regulatory approvals related to any change in our supply chain;
- Avantor may wish to discontinue supply of products to us due to its existing relationships with our competitors;
- Avantor may stop supply and claim ownership of intellectual property on materials associated with future products;
- Avantor or its parent entity may encounter financial or other hardships unrelated to our demand for products, which could negatively impact their ability to fulfill our orders and support our regulatory approvals; and
- disputes may arise over the terms of the Master Supply Agreement, by and between the Company and Avantor, dated May 13, 2022.

Various factors outside our direct control, including the reliance on single-source suppliers, may adversely affect manufacturing and supply of our Motiva Implants and other products.

We currently manufacture Motiva Implants at our facilities in the Coyol Free Zone, Alajuela, Costa Rica, under the multi-country MDSAP protocol. Our Qid Safety Technology microtransponders are manufactured by contract manufacturers with final testing and packaging at a manufacturing supplier facility in Regensburg, Germany, with additional inspection of the units at our facilities in Costa Rica, prior to approval for inclusion in Motiva Implants. If demand for our current products and our planned products increases more rapidly than we anticipate, or if we secure regulatory approval to commercialize our products in additional geographies, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. The manufacture of these products in compliance with ISO standards and the FDA's regulations require significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to manufacture and deliver products in a timely manner and as a result, our business, financial condition and results of operations could be adversely affected.

We currently purchase components for the Qid Safety Technology microtransponders under purchase orders and do not have long-term contracts with most of the suppliers of the materials included in these products. We rely on Avantor as the sole supplier of medical-grade silicone used in our Motiva Implants as well as other products that we manufacture under contract to other customers. See the risk factor above titled "We rely on a single-source, third-party supplier for medical-grade long-term implantable silicone, which is the primary raw material used in our Motiva Implants. As has occurred in the past, if this supplier were to increase prices for this raw material or experience interruptions in its ability to supply us with this raw material, our business, financial condition and results of operations could be adversely affected." In addition, the suppliers of certain packaging components and the surgical tools that we sell with Motiva Implants, including the cannulas, retractors, and insertion sleeves, are all purchased by us from single-source suppliers.

If our single-source and other suppliers were to delay or stop producing our components, if the prices they charge us were to increase significantly, or if they elected not to sell to us at all or on commercially reasonable terms, we would need to identify and initiate relationships with alternative suppliers, if possible. We could experience delays in manufacturing our products or the interruption of the availability of Motiva Implants or our other products for sale, while finding another acceptable supplier, which would impact our business, financial condition and results of operations.

Even if such alternative suppliers are available on commercially reasonable terms, the inclusion of substitute components or products must meet our specifications and could require us to obtain regulatory qualification for the new supplier with the appropriate regulatory authorities. The added time and cost to arrange for alternative suppliers could have a material adverse effect on our business. New manufacturers of any current or planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the design and method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

The manufacturing, sterilization and distribution of our Motiva Implants and other products are technically challenging. Changes that our suppliers may make, or additional requirements from regulatory agencies, are outside of our direct control and can have an impact on our processes, on quality, and on the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include:

- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk, particularly given the global nature of our supply and distribution chains;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural or other disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers;
- latent defects that may become apparent after products have been released and that may result in a recall of such products;
- contamination of our raw materials or manufactured products; and
- inclusion of vendors of raw materials not in compliance with ISO-13485 requirements.

We rely on third-party facilities for the sterilization of certain of our products, including facilities that use ethylene oxide (EtO) as a sterilant. Regulatory agencies, including the U.S. Environmental Protection Agency (EPA), have increased scrutiny of EtO emissions, and certain sterilization facilities have voluntarily closed or have been subject to mandated closures or operational restrictions due to environmental concerns. If our sterilization service providers experience closures, capacity constraints, or increased regulatory requirements, we may face interruptions in our ability to sterilize and release products, which could disrupt our supply chain and adversely affect our business, financial condition, and results of operations.

A substantial proportion of our sales are through exclusive distributors, and we do not have direct control over the efforts these distributors may use to sell our products. If our relationships with these third-party distributors deteriorate, or if these third-party distributors fail to sell our products or engage in activities that harm our reputation, or fail to adhere to medical device regulations, our financial results may be negatively affected.

Historically, our sales model has been to sell primarily through distributors rather than through our own sales force, with the notable exception of Brazil, the United States and several European countries where we are selling directly, but, in the future, we may utilize a hybrid sales model that includes both distributors and a direct sales effort. We believe that our reliance on distributors improves the economics of our business, as we do not carry the high fixed costs of a direct sales force in many of the countries in which our Motiva Implants are sold. If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries. Furthermore, distributors can choose the level of effort that they apply to selling our products relative to others in their portfolio. The selection, training, and compensation of a distributors' sales personnel are within their control rather than our own and may vary significantly in quality from distributor to distributor.

In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including anti-competition, anti-money laundering, and sanctions laws, we may not be able to

ensure proper compliance. If our distributors fail to effectively market and sell our products in full compliance with applicable laws, our results of operations and business may suffer.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate inventory supply across our broad range of implant sizes, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Managing our inventory levels is important to our cash position and results of operations and is challenging in the current economic environment. As we grow and expand our product offerings, managing our inventory levels becomes more difficult.

Inventory levels in excess of customer demand may result in inventory write-down or write-offs, which could cause our gross margin to be adversely affected and could impair the strength of our brand. Silicone gel breast implants have shelf life limitations, and we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Conversely, if we underestimate customer demand for our products, we may not be able to deliver products to meet customer requirements, and this could result in damage to our reputations and customer relationships.

Risks Related to Public Health Crises

Pandemics, epidemics, or other public health crises may adversely affect our business and financial results in the future.

As was the case with the COVID-19 pandemic, which resulted in a material disruption of our operations in fiscal 2020 and to a lesser degree in fiscal 2021, we are subject to risks associated with pandemics, epidemics or other public health crises. The full extent to which any pandemic, epidemic, or public health crisis may, directly or indirectly, impact our business, results of operations and financial condition, including our sales, expenses, supply chain integrity, manufacturing capability, research and development activities, and employee-related compensation, is highly uncertain and will depend on future developments that are also highly uncertain and cannot be predicted with reasonable accuracy at this time, including, without limitation:

- the contagiousness or virulence of the virus, disease or other condition giving rise to the pandemic, epidemic or public health crisis;
- the scope and length of any governmental or other restrictions implemented to reduce the spread of virus, disease or other condition giving rise to the pandemic, epidemic or public health crisis or other actions required or recommended to contain or treat infected individuals;
- the deferral of procedures using our products or other adverse impact on patients' willingness to undergo procedures in which our products could be used during or following any pandemic, epidemic or other public health crisis;
- volatility in the global capital markets, impacting access to and cost of capital;
- disruptions in the manufacture and distribution of our products and in our supply chain;
- delays in clinical trials;
- disruptions or restrictions on the ability of many of our employees, and of third parties on which we rely, to work effectively, including "stay-at-home" orders and similar government actions;
- temporary closures of our facilities and of the facilities of our customers and suppliers; and
- other direct and indirect economic impacts, both domestically and abroad, of a pandemic, epidemic, or public health crisis as a result of any or all of the foregoing, including actions taken by local, state, national and international governmental agencies, whether such impact affects customers, suppliers, or markets generally.

Risks Related to Intellectual Property and Data Security

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

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the United States. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have an adverse effect on our business.

If we are not able to obtain and maintain intellectual property protection for our products and technologies, or if the scope of our patents is not sufficiently broad, we may not be able to effectively maintain our market leading technology position.

Our success depends significantly on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries.

The patent position of medical device is highly uncertain and involves complex legal and factual questions with unresolved legal principles. The issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 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 our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of other countries may not protect our rights to the same extent as the laws of the United States. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of

new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

Further, filing, prosecuting and defending patents on all of our planned products throughout the world may be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The medical device industry is characterized by patent litigation, and we could become subject to litigation or other proceedings to protect or enforce our intellectual property rights that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Our competitors or other third parties may also assert infringement claims against us based on existing or future intellectual property rights. In an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. Interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, or any other patent authority may also be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings, inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse result in any litigation or other legal proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any

future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

If we fail to comply with our obligations in our intellectual property agreements, we could lose intellectual property rights that are important to our business.

We are a party, and expect to become party in the future, to certain intellectual property agreements that impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements. Termination of such agreements, or reduction or elimination of our rights under such agreements, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could harm our business and financial condition.

The risks described elsewhere in this Annual Report on Form 10-K pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

Our information systems, or those used by third parties which we rely on, may fail, be impacted by cybersecurity incidents, suffer other security incidents or be vulnerable to other forms of attack or damage.

The operation of our business depends on our information systems and, in some cases, the information systems used by third parties. We rely on our information systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Despite the implementation of security measures, our information systems, or those used by third parties which we rely on, are vulnerable to a variety of cybersecurity incidents and cybersecurity threats, as well as other forms of attack or damage, including damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security incidents, data corruption, and cyberattacks. Cybersecurity incidents can include, but are not limited to, computer viruses, computer denial-of-service attacks, phishing attacks, ransomware attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, social engineering or impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. Further, we rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, enterprise cloud solutions, encryption and authentication technology, employee email, and other similar functions. Although we prefer third parties that are SOC 1 compliant or adhere to other related regulations, our ability to monitor their information security practices is limited, and they may not have adequate security measures in place. They may also experience unexpected power losses, computer system failures, or data network disruptions, negatively impacting the systems or solutions we depend on. If our third-party providers face a security incident or other interruptions, or if there is a flaw or failed software update in the third-party software used in our systems, our information systems may become disabled or inaccessible. This could limit access to our data and business information, potentially causing significant disruptions to our operations.

Attacks upon information 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, information systems change frequently, including from emerging technologies, such as advanced forms of AI and quantum computing, 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 cybersecurity incidents or other incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents or threats due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

While we have not experienced any material cybersecurity incident or other system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, leading to increased costs, product shortages or lost revenues. To the extent that any cybersecurity incident, security breach or other attack or damage to our information systems were to result in a loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, we could incur liability and the further development and commercialization of our current and future products could be delayed. In addition, any such cybersecurity incident, security breach, or other attack or damage could harm our reputation, erode customer confidence in the effectiveness of our security measures, and negatively impact our ability to attract new customers.

The use of artificial intelligence technology by our employees or business partners could result in misuse or loss of proprietary information, violation of laws and regulations, or damage to our reputation and credibility.

Our employees and business partners may use AI technology, including generative AI tools, to perform their work. Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with the use of AI technology. AI algorithms are based on machine learning and predictive analytics, which can create accuracy issues, unintended biases, and discriminatory outcomes that could harm our brand, reputation, business, or customers. Additionally, dependence on AI without adequate safeguards to make certain business decisions may introduce additional operational vulnerabilities by producing inaccurate outcomes, recommendations, or other suggestions based on flaws in the underlying data or other unintended results. The use and disclosure of personal data in AI technology is subject to various data privacy laws and other data privacy obligations. Governments, including the EU through the EU AI Act and various U.S. states, have passed and are likely to pass additional laws regulating AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. Implementing the use of AI successfully, ethically and as intended, will require significant resources. Our competitors or other third parties may incorporate AI into their business,

Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business.

In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, credit card information and personally identifiable information. We collect this kind of information on our customers for purposes of servicing potential warranty claims and for post-marketing safety vigilance. Data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, HIPAA imposes limitations on the use and disclosure of an individual's protected health information by certain healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as Covered Entities, and their business associates, persons or entities that perform a function or provide specified services on behalf of a Covered Entity that involve the creation, use, maintenance or transmission of protected health information. HIPAA also imposes breach notification obligations for breaches of protected health information, including notification requirements to federal regulators and in some cases, notification to relevant media outlets. Most states also have breach notification requirements to affected individuals and in some cases to state regulators in the event of a breach of personal information, which is a broader class of information than the protected health information protected by HIPAA. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner

that is not authorized or permitted by HIPAA, and subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security consumer protection laws

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC sets expectations for taking appropriate steps to safeguard consumers' personal information and providing a level of privacy or security commensurate to promises made to individuals. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Failure to meet these standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Health information is considered sensitive data that merits stronger safeguards. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions.

At the state level, several U.S. states have proposed and passed consumer privacy laws. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act, ("CCPA") includes certain transparency and other requirements to protect personal data and grants California consumers with certain rights regarding their personal data. In addition, California consumers have the right to bring a private right of action in connection with data security incidents involving certain elements of personal data. Additionally, other jurisdictions, such as Virginia, Colorado, Utah, and Connecticut, have enacted similar legislation and/or regulations. Health-specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. These laws and regulations are constantly evolving and may impose limitations on our business activities.

Moreover, as a result of the broad scale release and availability of AI technologies such as generative AI, there is a global trend towards more regulation (e.g., the EU AI Act and AI laws passed in the United States to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.

Many foreign countries and governmental bodies, including the EU, UK, Canada, Australia and other relevant jurisdictions, have laws and regulations concerning the collection and use of personal or sensitive data obtained from their residents or by businesses operating within their jurisdiction. For example, the EU/UK GDPR imposes stringent data protection requirements. It regulates the processing of personal data and places certain obligations on the processing of such personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data collected, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area/UK to third countries including the United States, contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data and security breach/incident notifications. Non-compliance with the EU/UK GDPR can trigger steep fines for the most serious breaches of up to €20 million or 4% of total worldwide annual revenues, whichever is higher. Given the breadth and depth of changes in data protection obligations, meeting the EU/UK GDPR's requirements requires time, resources and a review of the technology and systems currently in use against the EU/UK GDPR's requirements.

We may be at risk of enforcement actions taken by certain EU data protection authorities, the UK Information Commissioner's Office, or ICO, or the Swiss Federal Data Protection and Information Commissioner, or FDPIC, while we continue to build our business practices to ensure that all transfers of personal data to us from the European Economic Area, United Kingdom and Switzerland, are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities and evolving best practices. We may find it necessary to establish systems to maintain personal data originating from the EU in the European Economic Area, which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may adversely affect our business.

Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data

and personal information, within the European Union, the United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products.

The landscape of federal and state laws regulating personal data is constantly evolving, and compliance with these laws requires a flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future. There is the risk that the limits we obtained for our cyber liability insurance may not cover the total loss experienced in the event of a data security incident, including the financial loss, legal costs, and business and reputational harm, particularly if there is an interruption to our systems. Additionally, there is the risk of a data privacy or security incident by an employee, which may expose us to liability. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents. There can be no assurance that the systems we have designed to prevent or limit the effects of cyber incidents or attacks will be sufficient to prevent or detect material consequences arising from such incidents or attacks, or will be sufficient to avoid material adverse impact on our systems after such incidents or attacks do occur.

We rely on third party vendors and service providers to support various aspects of our business operations. However, these third parties may pose risks related to data security, compliance, and contractual obligations. A breach or failure by a third party to adequately protect our data could have adverse consequences for our business and reputation.

Risks Related to Regulatory and Political Environment

The regulatory approval process is expensive, time consuming and uncertain. Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA or similar foreign regulatory authority will authorize the commercialization of our planned products on a timely basis, if at all. Delays or failure to obtain necessary clearances or approvals would adversely affect our ability to grow our business.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations differ from country to country. Our products are commercially available in over 100 countries, including the United States. See Item 1 “Business” in our Annual Report on Form 10-K for additional information about the regulatory process.

Prior to receiving approval to commercialize any of our planned products in the United States or abroad, we may be required to demonstrate with substantial evidence from preclinical and well-controlled clinical studies, and to the satisfaction of the FDA or other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. We may not successfully complete required clinical trials, or they may yield results which are different than anticipated or that can be interpreted in different ways. Additionally, even if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

Regulatory clearance or approval from the FDA or foreign regulatory authorities is not guaranteed, and the approval process is expensive and may take several years. The PMA approval process in the United States generally takes from one to three years and the 510(k) clearance process in the United States usually takes from three to twelve months, although each could take longer. For example, we initiated a modular PMA submission process with the FDA for approval of our Motiva Implants in the United States in 2021 and received FDA approval for our Motiva Implants in the United States in September 2024. The FDA and other regulatory authorities also have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at

any stage, and we could encounter problems that cause us to abandon or repeat clinical studies or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for approval varies depending on the jurisdiction, the planned product, the indication that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following:

- a planned product or one or more of its features may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our manufacturing or our third-party supplier's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

In addition, the FDA or other regulatory authority may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. In the United States, the FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission and approval of a PMA for us to market and sell those products. Any change in the approval policies or new or amended regulations governing the clearance and approval processes could increase the costs of obtaining approval/clearance of a product or result in delays in, or failure to receive or maintain clearance or approval for our products.

Moreover, clearance or approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more international regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. An international regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain international regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and, even if we file, we may not receive necessary approvals to commercialize our products in any market. If our products, fail to demonstrate safety and efficacy in further clinical studies that may be required for U.S. approval, or do not gain regulatory approval, our business and results of operations will be harmed.

If Motiva Implants or any planned products fail to demonstrate safety and effectiveness in preclinical and clinical studies, if there is a change in the approval policies or new or amended regulations governing the clearance and approval process for our products, or if our products do not gain regulatory approval or clearance, our business and results of operations will be harmed.

Once commercialized, modifications to our marketed products may require new 510(k) clearances or approval of PMA supplements, or equivalent steps in other countries, or may require us to cease marketing or recall the modified products until certification, clearances or regulatory approvals are obtained.

Modifications to any of our products once they are commercialized from time to time require new regulatory approvals or clearances, including 510(k) clearances or approval of PMA supplements, or may require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not affect safety or efficacy and does not represent a major change in its intended use, so that no new clearance or approval is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval of a PMA supplement is required. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and/or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

Where we determine that modifications to our products require a new PMA approval or approval of a PMA supplement, we may not be able to obtain those additional approvals for the modifications or additional indications in a timely manner, or at all. Obtaining new approvals can be a time-consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

For those products sold in the EEA, we must notify our EU Notified Body if significant changes are made to the products or if there are substantial changes to our quality management systems affecting those products. Obtaining CE Certificates of Conformity for medical devices can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Even if we receive regulatory approval for a planned product, we will be subject to ongoing regulatory obligations and continued regulatory review. Compliance with ongoing regulatory obligations and continued regulatory review may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

When a regulatory approval is obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Our regulatory approval for Motiva Implants, as well as any regulatory approval that we receive for future modifications to Motiva Implants or for any planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product in real-world post-market use. For example, in connection with FDA approval of our Motiva Implants, we are required to monitor the clinical trial patients for our IDE clinical trial for up to ten years, create a patient registry or large post approval study, and/or other studies, and implement training programs for physicians. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event quarterly reporting, device tracking, device retrieval studies, storage, advertising, promotion and recordkeeping for our products. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

We are also required to comply with regulations regarding the manufacture of Motiva Implants, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect these manufacturing facilities and determine that they are in compliance with FDA good manufacturing practice requirements as set forth in the Quality Management System Regulation, or QMSR, before the products can be approved. These facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the QMSR and associated regulations.

Failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- Warning Letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new devices or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are 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 and results of operations. The discovery of

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

Our products are subject to medical device reporting regulations, which require us to report to the FDA any information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or contribute to a death or serious injury. Our obligation to report under the medical device reporting regulations is triggered on the date on which we become aware of information that reasonably suggests a reportable adverse event occurred. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event, it is an adverse event that is unexpected or if the product characteristic that caused the adverse event is removed in time from our products. If we fail to comply with our medical device reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, demand or initiate a product recall, seize our products, or delay the clearance of our future products.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals 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, which may harm our reputation and have a material adverse effect on our business.

We are subject to extensive and dynamic medical device regulation, and oversight in the United States and other countries. If we fail to obtain or maintain necessary regulatory approvals for our products, or if approvals or clearances for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by various regulatory agencies and governing bodies. Under the U.S. Food, Drug and Cosmetic Act (FDC Act), medical devices must receive FDA clearance or approval or an exemption from such clearance or approval before they can be commercially marketed in the United States. Additionally, such devices are subject to wide-ranging regulations including, among other things: product design, development, manufacture and release; laboratory and clinical testing, labeling, packaging, storage, and distribution; product safety and effectiveness; record-keeping; product promotion and advertising; post-marketing surveillance; post-market approval studies, where applicable; and import and export rules. In the EU, we are required to comply with the EU MDR and obtain CE Certificates of Conformity in order to affix CE mark on our medical devices and place them on the EU market. Breast implants intended for aesthetic purposes fall under Annex XVI (List of groups of products without an intended medical purpose) to the EU MDR and we are also required to obtain CE Certificates of Conformity for these products under the EU MDR in order to place them on the EU market. In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported.

The FDA or other regulators could delay, limit, or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our devices and any accessories are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses;
- disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- insufficiency of the data from preclinical studies or clinical trials to support clearance or approval;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- failure of our manufacturing process or facilities to meet applicable requirements; and

- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Many countries require that product approvals be renewed or recertified on a regular basis, generally every four to five years. The renewal or recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where renewal or recertification applications are required, they may need to be renewed and/or approved in order to continue selling our products in those countries. There can be no assurance that we will receive the required approvals for new products or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

The EU MDR imposes requirements regarding, among others, device design and development, preclinical and clinical requirements, premarket conformity assessment and post-market surveillance, vigilance, and market surveillance. We, along with the Notified Bodies, may face uncertainties as the EU MDR continues to be rolled out and enforced by the European Commission and EEA Competent Authorities. The time required to obtain a CE Certificate of Conformity from a Notified Body in the EU is lengthy and may be unpredictable. On average, the time-to-certification under the EU MDR for all device categories ranges between 13 and 18 months.

Additionally, the U.K.'s withdrawal from the EU and the end of the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland in May 2021 have added certain costs and complexities to the shipment and sales of our products in those countries.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change. On December 16, 2025, the European Commission published a proposal to amend the EU MDR. The primary goal of the proposal is to reduce administrative burden and certification delays, improve predictability and innovation, and help prevent device shortages. However, we cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, operating restrictions and/or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval or clearance by regulatory authorities could have a material adverse effect on our business, financial condition or results of operations.

Our products, such as Motiva Implants, may in the future be subject to product recalls that could harm our reputation, business and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the agency within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving Motiva Implants or other planned devices in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

The medical technology industry is complex and intensely regulated at the federal, state, and local levels, and government authorities may determine that we have failed to comply with applicable laws or regulations.

As a company which manufactures and distributes medical devices and technologies, we are subject to numerous regional, national and local laws and regulations. There are significant costs involved in complying with these laws and regulations. Moreover, if we are found to have violated any applicable laws or regulations, we could be subject to civil and/or criminal damages, fines, sanctions or penalties, including exclusion from participation in governmental healthcare programs. We may also be required to change our method of operations. These

consequences could be the result of current conduct or even conduct that occurred a number of years ago. We also could incur significant costs merely if we become the subject of an investigation or legal proceeding alleging a violation of these laws and regulations. We cannot predict whether any government authority will determine that we are not operating in accordance with law, or whether the laws will change in the future and impact our business.

Under some circumstances, government investigations can also be initiated by private individuals under whistleblower provisions which may be incentivized by the possibility for private recoveries. Responding to inquiries and enforcement activities can be costly and disruptive to our business operations, even when the allegations are without merit. We also may be subject to other financial sanctions or be required to modify our operations. Any of these actions could have a material adverse effect on our business, financial condition and results of operations.

Our relationship with customers, patients and third party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, damages, reputational harm and diminished profits and future earnings.

Our arrangements with third-party payors, patients and healthcare providers may expose us to fraud and abuse laws and other healthcare laws and regulations that may limit the business relationships we establish to market, sell, promote and distribute our products in the United States. Efforts to ensure that our business arrangements with these third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. The requirements and restrictions under these broadly applicable laws and regulations are described in the section on Fraud and Abuse Laws in Item 1, “Business” of this Annual Report on Form 10-K.

Healthcare reform measures could hinder or prevent our planned products’ commercial success.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

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 impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. Actions by the FDA or other governmental agencies applicable to our business may be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024, including most notably, Loper Bright Enterprises v. Raimondo, which overruled the Supreme Court’s previous ruling that courts defer to reasonable agency interpretations of statutes that are silent or ambiguous on a particular topic. The ruling requires courts to exercise their independent judgment when deciding whether an agency has acted within its statutory authority, and that courts may not defer to an agency interpretation solely because a statute is ambiguous. This decision and other administrative law cases may result in additional legal challenges to regulations and guidance issued by federal regulatory agencies, including the FDA, that we have relied on and intend to rely on in the future. Any such challenges, if successful, could have a material impact on our business. In addition to potential changes to regulations and agency guidance as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays in and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations.

Further, in the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and future profitability and the future revenue and future profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The OBBBA, for example, is projected to decrease federal healthcare spending by approximately $1 trillion by reducing Medicaid spending and enrollment and making changes to federal Medicare spending. There is substantial uncertainty as to how the current administration will further seek to modify or revise laws impacting the healthcare system or the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our products in the United States. The impending uncertainty could present new challenges or potential opportunities as we navigate the continued commercialization of Motiva Implants in the United States.

We cannot predict the impact that ongoing healthcare reform will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, and as to the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for our Motiva Implants or other current or planned products in the United States or reduce medical procedure volumes could adversely affect our business plan.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers 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.

The coverage and reimbursement status of newly-approved products is uncertain. Failure *to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.*

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which products they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our products or product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

The pricing, coverage and reimbursement of our product candidates must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. However, sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, we do not have assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products and product candidates. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit or delay sales of any of our future products. A decision by a third-party payor not to cover a product could reduce patient demand for any of our products.

Risks Related to Taxation

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

We have subsidiaries in multiple countries. From time to time, tax authorities disagree with tax positions that we have taken. If we are unable to successfully resolve such disagreements, we could experience increased tax liabilities. For example, the U.S. Internal Revenue Service or another foreign tax authority could challenge the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. A tax authority may, as has occurred recently in Brazil, take the position that certain tax liabilities, interest and penalties are payable by us, in which case, we expect that we might, as we have in Brazil, contest such assessment. Contesting such an assessment can be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could materially increase our anticipated effective tax rate, where applicable. In addition, we may be subject to additional tax liabilities, which could materially and adversely affect our business, financial condition and results of operations. The application, interpretation and enforcement of value-added tax, or VAT, and other taxes and related regulations applicable to medical device companies is complex and evolving.

We are a multinational organization faced with increasingly complex tax issues in many jurisdictions, and changes in tax laws or their application to the operation of our business could adversely impact our operating results and our business.

We conduct operations in multiple jurisdictions, and we are subject to certain taxes, including income, sales and use, employment, value added and other taxes, in the United States and other jurisdictions in which we do business. A change in the tax laws in the jurisdictions in which we do business, including an increase in tax rates or an adverse change in the treatment of an item of income or expense, possibly with retroactive effect, could result in a material increase in the amount of taxes we incur.

Our determination of our tax liability is subject to review by applicable U.S. and foreign tax authorities. Any adverse outcome of such a review could harm our operating results and financial condition. The determination of our worldwide provision for income taxes and other tax liabilities requires significant judgment and, in the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is complex and uncertain. Moreover, as a multinational business, we have subsidiaries that engage in many intercompany transactions in a variety of tax jurisdictions where the ultimate tax determination is complex and uncertain. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies, which could impact our financial position and operating results. Historically, we have allocated some of our employees' and contractors' time across multiple business entities in the international jurisdictions in which we operate. If it were determined that we had misclassified our employees' or contractors' employment status or certain of our expenditures under local laws, we may be subjected to penalties or be required to pay withholding taxes, extend employee benefits, provide compensation for unpaid overtime, or otherwise incur substantially greater expenses with respect to such employees and contractors. Any of the foregoing circumstances could have a material adverse impact on our operating results and financial condition.

In addition, the European Union Economic and Financial Affairs Council has in recent years released a list of non-cooperative jurisdictions for tax purposes. The stated aim of the list is to promote good governance worldwide in order to maximize efforts to promote fair tax competition and address harmful tax practices. In February 2023, Costa Rica was added to this list, which now includes 16 jurisdictions. According to the European Union Economic and Financial Affairs Council, Costa Rica was added to the list because it has not fulfilled a commitment to abolish or amend harmful aspects of its foreign source income exemption regime. Shortly after this, in October 2023, the EU Council announced that three jurisdictions had been removed from the list of non-cooperative tax jurisdiction, one of which was Costa Rica. This follows the reforms made to Costa Rica's Income Tax Law, amending aspects of the foreign-source income exemption regime. The reforms include a clarification to the scope of the territoriality principle and introduction of a new taxation regime for foreign-source passive income.

We are periodically reviewed and audited by tax authorities with respect to income and non-income taxes. Tax authorities may disagree with certain positions we have taken, and we may have exposure to additional income and non-income tax liabilities which could have an adverse effect on our operating results and financial condition. Such authorities could impose additional taxes, interest and penalties, claim that various withholding requirements apply to us or our subsidiaries or assert that benefits of tax treaties are not available to us or our subsidiaries. In addition, our future effective tax rates could be favorably or unfavorably affected by changes in tax rates, changes

in the valuation of our deferred tax assets or liabilities, the effectiveness of our tax planning strategies, or changes in tax laws or their interpretation. Such changes could have an adverse impact on our financial condition.

As a result of these and other factors, the ultimate amount of tax obligations owed may differ from the amounts recorded in our financial statements and any such difference may harm our operating results in future periods in which we change our estimates of our tax obligations or in which the ultimate tax outcome is determined.

Our ability to use net operating losses to offset future taxable income and certain other tax attributes may be subject to certain limitations.

Federal and California laws impose restrictions on the utilization of net operating loss carryforwards and research and development credit carryforwards in the event of a change in ownership of the Company, which constitutes an “ownership change” as defined by Internal Revenue Code Sections 382 and 383. Generally, an ownership change occurs if the percentage of the value of the shares that are owned by one or more direct or indirect “five percent shareholders” increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period. If we have experienced an “ownership change” at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes. We have not experienced an ownership change in the past that would materially impact the availability of its net operating losses and tax credits. Nevertheless, future changes in our share ownership, which may be outside of our control, may trigger an “ownership change” and, consequently, Section 382 and 383 limitations. We have not completed a Section 382 and 383 analysis to determine if an ownership change has occurred. Until such analysis is completed, we cannot be sure that the full amount of the existing net operating loss carryforwards will be available to us, even if we do generate taxable income before their expiration. In addition, under the newly enacted U.S. federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited.

U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, in any taxable year in which either (1) at least 75% of its gross income is passive income; or (2) at least 50% of the average quarterly value of its total gross assets is attributable to assets that produce “passive income” or are held for the production of passive income. Based on the project composition of our income and valuation of our assets, we do not believe we were a PFIC in 2025 and 2024, and we do not expect to become one in the future. However, because our PFIC status is subject to a number of uncertainties, neither we nor our tax advisors can provide any assurances regarding our PFIC status. If we are a PFIC for any taxable year during which a U.S. holder holds our common shares, the U.S. holder may be subject to adverse tax consequences. U.S. investors should consult their advisors regarding the application of these rules and the availability of any potential elections.

If a United States person is treated as owning at least 10% of our common shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly, or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). We may become a controlled foreign corporation. In addition, because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether or not we are treated as a controlled foreign corporation). A U.S. shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income,” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a U.S. shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder’s U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether we or any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether any investor is treated as a U.S. shareholder with respect to any such controlled foreign corporation or furnish to any U.S. shareholders information that may be necessary to comply with the

aforementioned reporting and tax paying obligations. A U.S. investor should consult its advisors regarding the potential application of these rules to an investment in our common shares.

Discontinuation of preferential tax treatments we currently enjoy or other unfavorable changes in tax law could result in additional compliance obligations and costs.

Discontinuation of preferential tax treatments we currently enjoy or other unfavorable changes in tax law could result in additional compliance obligations and costs. We are currently the beneficiary of a tax holiday in Costa Rica pursuant to which we are subject to a tax at a 0% rate. The tax holiday is effective through December 31, 2030, and it may be extended if certain additional requirements are satisfied. However, there can be no assurance that we will continue to qualify for or receive such favorable tax treatment after the expiration date. If we fail to maintain such favorable tax treatment, we may be subject to tax in Costa Rica at a significantly higher rate.

Risks Related to Ownership of Our Securities

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

The price at which our common shares trade may be volatile. The securities markets in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Additionally, the lack of an active market may impair the value of our common shares, or one's ability to sell shares at the time one wishes to sell them or at a price that one considers reasonable. The market price for our shares may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, Motiva Implants;
- the success of competitive products or technologies;
- results of clinical studies of Motiva Implants or planned products or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing processes or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- negative shifts in the economy affecting the number of aesthetic breast procedures;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our common shares, other comparable companies or our industry generally;
- trading volume of our common shares;

- sales of our common shares by us or our shareholders;
- short selling activities;
- the impact of pandemics, epidemics or other public health crises;
- general economic, industry and market conditions; and
- the other risks described in this “Risk Factors” section.

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

We identified a material weakness in our internal control over financial reporting as of December 31, 2023, and 2022, and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our consolidated financial statements. If we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Risks Related to Being a British Virgin Islands Company

Rights of shareholders under British Virgin Islands law differ from those under U.S. law, and, accordingly, you may have fewer protections as a shareholder.

Our corporate affairs are governed by our amended and restated memorandum and articles of association, the BVI Act, and the common law of the British Virgin Islands. The rights of shareholders to take legal action against our directors, actions by minority shareholders and the fiduciary responsibilities of our directors under British Virgin Islands law are to a large extent governed by the common law of the British Virgin Islands and by the BVI Act. The common law of the British Virgin Islands is derived in part from comparatively limited judicial precedent in the British Virgin Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the British Virgin Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under British Virgin Islands law are not as clearly established as they would be under statutes or judicial precedents in some jurisdictions in the United States. In particular, the British Virgin Islands has a less developed body of securities laws as compared to the United States, and some states (such as Delaware) have more fully developed and judicially interpreted bodies of corporate law. As a result of the foregoing, holders of our ordinary shares may have more difficulty in protecting their interests through actions against our management, directors or major shareholders than they would as shareholders of a U.S. company.

British Virgin Islands companies may not be able to initiate shareholder derivative actions, thereby depriving shareholders of one avenue to protect their interests.

British Virgin Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect of any such action, may result in the rights of shareholders of a British Virgin Islands company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. The British Virgin Islands courts are also unlikely to recognize or enforce judgments of courts in the United States based on certain liability provisions of U.S. securities law, or to impose liabilities based on certain liability provisions of the U.S. securities laws that are penal in nature, in original actions brought in the British Virgin Islands. There is no statutory recognition in the British Virgin Islands of judgments obtained in the United States, although the courts of the British Virgin Islands will generally recognize and enforce the non-penal judgment of a non-U.S. court of competent jurisdiction without retrial on the merits. This means that even if

shareholders were to sue us successfully, they may not be able to recover anything to make up for the losses suffered.

British Virgin Islands law differs from the laws in effect in the United States, and U.S. investors may have difficulty enforcing civil liabilities against us, our directors or members of senior management.

Under our amended and restated memorandum and articles of association, we may indemnify and hold our directors harmless against all claims and suits brought against them, subject to limited exceptions. Furthermore, to the extent allowed by law, the rights and obligations among or between us, any of our current or former directors, officers and employees and any current or former shareholder will be governed exclusively by the laws of the British Virgin Islands and subject to the jurisdiction of the British Virgin Islands courts, unless those rights or obligations do not relate to or arise out of their capacities as such. Although there is doubt as to whether U.S. courts would enforce these provisions in an action brought in the United States, under U.S. securities laws, these provisions could make judgments obtained outside of the British Virgin Islands more difficult to enforce against our assets in the British Virgin Islands or jurisdictions that would apply British Virgin Islands law.

The laws of the British Virgin Islands provide limited protection for minority shareholders, so minority shareholders will have limited or no recourse if they are dissatisfied with the conduct of our affairs.

Under the laws of the British Virgin Islands, there is limited statutory law for the protection of minority shareholders other than the provisions of the BVI Act dealing with shareholder remedies, as summarized under “Description of Share Capital-Shareholders’ Rights Under British Virgin Islands Law Generally.” One protection under statutory law is that shareholders may bring an action to enforce the constituent documents of a British Virgin Islands company and are entitled to have the affairs of the Company conducted in accordance with the BVI Act and the amended and restated memorandum and articles of association of the Company. As such, if those who control the Company have disregarded the requirements of the BVI Act or the provisions of our amended and restated memorandum and articles of association, then the courts will likely grant relief. Generally, the areas in which the courts will intervene are the following: (i) an act complained of which is illegal; (ii) acts that constitute oppression, unfair discrimination or unfair prejudice against the minority where the wrongdoers control the Company; (iii) acts that infringe on the personal rights of the shareholders, such as the right to vote; and (iv) acts where we have not complied with provisions requiring approval of a special or extraordinary majority of shareholders, which are more limited than the rights afforded to minority shareholders under the laws of many states in the United States.

Provisions in our amended and restated memorandum and articles of association and under British Virgin Islands law could make an acquisition of us more difficult and may prevent attempts by our shareholders to replace or remove our current management.

Provisions in our amended and restated memorandum and articles of association may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for our common shares, thereby reducing the market price of our common shares. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our shareholders to replace current members of our management team. Among others, these provisions include the following:

- while we are commencing a phased-in process to declassify our Board of Directors, our Board of Directors is divided into three classes with staggered three-year terms and will not be fully declassified until our 2026 annual meeting of shareholders, which may delay or prevent a change of our management or a change in control;
- our Board of Directors has the right to elect directors to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which will prevent shareholders from being able to fill vacancies on our Board of Directors;
- our shareholders are not able to act by written consent, and, as a result, a holder, or holders, controlling a majority of our shares are not able to take certain actions other than at annual shareholders’ meetings or special shareholders’ meetings;
- our amended and restated memorandum and articles of association do not allow cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates;

- our shareholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a shareholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our Board of Directors is able to issue, without shareholder approval, preferred shares with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in the British Virgin Islands, we are governed by the provisions of BVI Business Companies Act, 2004, as amended, or the BVI Act, which provide for different shareholder rights than a Delaware corporation. See, for example, the risk factor titled "Rights of shareholders under British Virgin Islands law differ from those under U.S. law, and, accordingly, you may have fewer protections as a shareholder."

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

The Audit Committee oversees the cybersecurity program and receives reports from management regarding the Company's cybersecurity policies and procedures on an annual basis. The Audit Committee also receives reports from management on any cybersecurity incidents that may occur.

As part of our cybersecurity program, our IT management reports to the Company's Chief Operating Officer and Chief Executive Officer and is responsible for assessing and managing cybersecurity risks and developing and implementing our cybersecurity program. Our current Head of Global IT has more than 15 years of experience in technology and process improvements, which includes the execution of digital business strategies within highly regulated industries. Our IT management has obtained relevant experience in various sectors such as technology firms, financial institutions, and consulting firms and has actively engaged in continuous learning and professional development initiatives to stay updated on evolving cybersecurity threats and trends. This includes participating in industry conferences, workshops, training programs, and becoming members of professional cybersecurity organizations.

Our cybersecurity program is designed to identify, assess, manage and mitigate risks from cybersecurity threats, and includes the following elements:

- a risk assessment process to identify and assess cybersecurity risks;
- a risk mitigation strategy to address cybersecurity risks;
- an incident response plan to identify, respond to, mitigate and remediate cybersecurity incidents;
- an awareness and training program to educate employees about cybersecurity risks;
- a procedure to procure information technology services, including cloud computing and data storage, from third-party providers with sufficient cybersecurity provisions, and to monitor their cybersecurity process on an ongoing basis; and
- periodic testing and evaluation by external parties we engage to assess the effectiveness of the cybersecurity intrusion protections and make recommendations to improve the security of our information systems.

As a result, we have implemented a multi-layered cybersecurity program that includes administrative, physical, and technical measures to protect our information systems. Through these processes and the other processes described above, including our incident response plan, our management is informed about cybersecurity threats and incidents affecting us.

Our company has implemented robust processes to assess, identify, and manage material cybersecurity risks effectively. These processes are an integral component of our overall risk management system, ensuring that cybersecurity concerns are comprehensively addressed within our broader risk management framework. Risk assessment, identification, and management processes are seamlessly integrated into our overall risk management system. The processes for assessing, identifying, and managing cybersecurity risks are aligned with our strategic objectives and business goals. We foster cross-functional collaboration and communication to facilitate the integration of cybersecurity risk management into various business functions and processes.

We also review our cybersecurity practices, their effectiveness, and the cybersecurity practices of the third-parties we rely on, on an ongoing basis and make changes as necessary to address new risks. However, we cannot guarantee that our efforts will be successful in preventing all cybersecurity incidents.

We are not aware of any risks from cybersecurity threats, including as a result of previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. We can give no assurance that we have detected or protected against all cybersecurity threats or incidents. We are subject to a variety of cybersecurity risks, which could have a material adverse effect on our business, financial condition, and results of operations. See the "Risks Related to Intellectual Property and Data Security" section of Item 1A. Risk Factors for additional discussion on risks affecting our information systems.

ITEM 2. PROPERTIES

Our main executive facilities, which include over 200,000 square feet of office, laboratory, and manufacturing space, are situated in Alajuela, Costa Rica. We also lease office or warehouse spaces in numerous locations worldwide such as Wommelgem, Belgium; Sao Paulo and Rio de Janeiro, Brazil; Stockholm, Sweden; Barcelona, Spain; Rome, Italy; Addison and Austin, Texas, USA; Santa Barbara, California, USA; London, England; Haar, Germany; Cavaillon, France; and Buenos Aires, Argentina, with leases expiring from 2025 to 2031.

ITEM 3. LEGAL PROCEEDINGS

We are and may become from time to time a party to various claims and lawsuits arising in the ordinary course of business, but we are not a party to any material legal proceeding required to be disclosed under Item 103 of Regulation S-K.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common shares have been traded on the Nasdaq Capital Market under the symbol "ESTA" since our initial public offering on July 23, 2018. Prior to this time, there was no public market for our common shares.

Holders

There were 12 shareholders of record of our common shares as of February 26, 2026. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Sales of Unregistered Securities

None.

Dividends

We have not paid any cash dividends on our common shares since inception and do not anticipate paying cash dividends in the foreseeable future.

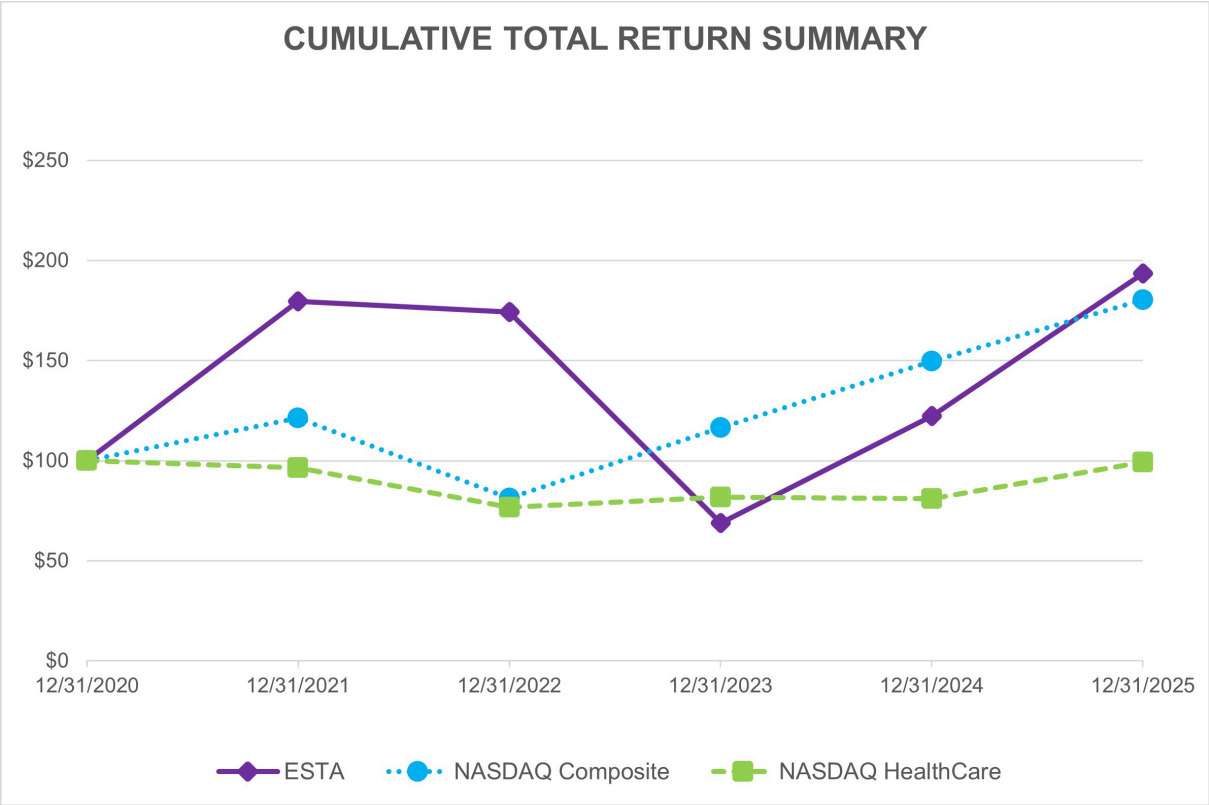
Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of our common shares made during the three months ended December 31, 2025.

Stock Performance Graph

The graph set forth below compares the cumulative total shareholder return on our common stock from December 31, 2020 through 2025, with the cumulative total return of (a) the NASDAQ Health Care Index and (b) the NASDAQ Composite Index, over the same period. This graph assumes an investment of $100 at the close of trading on December 31, 2020 in each of our common stock, the NASDAQ Health Care Index and the NASDAQ Composite Index and assumes the reinvestment of dividends, if any.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from the Nasdaq Stock Market LLC, a financial data provider and a source believed to be reliable. The Nasdaq Stock Market LLC is not responsible for any errors or omissions in such information.



This performance graph shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to liabilities under that section and shall not be deemed to be incorporated by reference into any filing of the registrant under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 6. RESERVED

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

You should read the following discussion and analysis of our financial condition and results of operations together with the consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections contained in this Annual Report on Form 10-K entitled Item 1A. "Risk Factors"; Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations"; and Item 7A. "Quantitative and Qualitative Disclosures about Market Risk". See "Special Note Regarding Forward-Looking Statements" preceding Part I of this Annual Report on Form 10-K.

Overview

Our line of silicone gel-filled breast implants, branded as Motiva Implants, is the centerpiece of our medical technology platform. Our 5-year results from our Motiva U.S. IDE study as well as our patient and practitioner reported post-market surveillance data indicate that Motiva Implants have low rates of adverse events (including rupture, capsular contracture, and implant-related reoperations) that compare favorably with those of our competitors. We believe these proprietary technologies that differentiate our Motiva Implants result in improved safety and aesthetic outcomes and thus drive our revenue growth.

We have devoted a majority of our resources since inception to developing our Motiva Implants, which we began selling in October 2010. We have incurred net losses in each year since inception, and we have financed our operations primarily through equity financings and debt financings.

In September 2024, we received FDA approval to sell Motiva Implants in the United States.

Financial Highlights

Our revenue for the years ended December 31, 2025 and 2024 was $211.1 million and $166.0 million, respectively, an increase of $45.1 million, or 27.2%. Net losses were $51.1 million for the year ended December 31, 2025 as compared to $84.6 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $495.8 million.

Our cash balance as of December 31, 2025 was $75.6 million.

Recent Developments

Regulatory and Operational Updates

On October 14, 2025, we announced the publication of “The 3-Year Results of a 100-Patient Prospective Study of Safety and Effectiveness of Mia Femtech” in the *Aesthetic Surgery Journal*. The study showed a very low rate of complications, with no reports of capsular contracture (Baker Grade III/IV), implant rupture, nipple or breast sensitivity loss, incision-related complications, infection, seroma, rippling, hematoma, or BIA-ALCL; the reoperation rate at 3 years was 1%. Patient and surgeon satisfaction was high, with patients reporting an 87% increase in breast satisfaction at 3 years and 90% of surgeons “very satisfied” with their overall experience and none “dissatisfied”. See “Our Clinical Data—Mia Femtech Clinical Study” below for additional information.

On May 7, 2025, we announced the appointment of Peter Caldini as Chief Executive Officer following the retirement of Juan José Chacón-Quirós as CEO, effective March 1, 2025. Mr. Caldini served as Interim CEO from March 1, 2025 until May 7, 2025. Mr. Chacón-Quirós continued as a member of the Board and as an advisor with the Company.

On March 6, 2025, we partnered with GRAMMY winner Meghan Trainor, generating over 9 billion media impressions and supporting our U.S. market launch.

In February 2025, we launched Preservé, a minimally invasive breast tissue-preserving technology for breast augmentation, revision augmentation and mastopexy augmentation. The initial commercial launch took place in Brazil, with further launches in other countries occurring throughout 2025, including an early experience group in the United States. Launches in additional countries, including a full launch in the United States, are expected in 2026.

Financing Activities

We signed an Inventory Funding Agreement, or Funding Agreement, on May 23, 2025, with RTW Master Fund, LTD., RTW Innovation Master Fund, LTD., and RTW Biotech Opportunities Operating LTD, collectively referred to as the Funding Providers, and RTW Investments, LP, as the funding representative, to finance purchases of silicone raw material to support the manufacture of Motiva Implants in an aggregate amount not to exceed $10 million in a funding period. Under the Funding Agreement, the Funding Providers will finance, upon request, eligible invoices at a 12% annual interest rate for an initial four-month term, or a later date if agreed by the Funding Providers in writing in their sole discretion. We drew $5 million at each of June 20, 2025 and September 26, 2025, and recorded this liability in “Other Liabilities, Short-Term”. On September 25, 2025, the Funding Agreement was amended to extend the due date for the amount received in June 2025 to May 15, 2026.

On September 29, 2025, we entered into a Fourth Amendment to the Credit Agreement, or the Fourth Amendment, which provided for the availability of the Tranche D Term Loans to commence as of the effective date of the amendment, notwithstanding the revenue milestone originally set forth in the Agreement, and (ii) increased, effective September 28, 2025, the minimum liquidity that the Company and its subsidiaries that are guarantors under the Agreement are required to maintain from $25 million to $30 million. The fourth tranche, or the Tranche D Term Loan, of $25 million was advanced in September 2025.

During fiscal 2025, we also entered into short-term insurance premium financing arrangements to fund the payment of business insurance premiums. The aggregate financing provided under these arrangements totaled approximately $3.4 million and bears interest at rates ranging from approximately 7.7% to 8.3% per annum. The borrowings are short-term in nature and mature within ten months of issuance.

Components of Results of Operations

Revenue

We commenced sales of our Motiva Implants in October 2010, and these products have historically accounted for the majority of our revenues. Sales of our Motiva breast implants accounted for over 99% of our revenues for the year ended December 31, 2025, and we expect our revenues to continue to be driven primarily by sales of these products. We primarily derive revenue from sales of our Motiva Implants to two types of customers: (1) medical distributors and (2) direct sales to physicians, hospitals, and clinics.

We recognize revenue related to the sales of products at the time of shipment, except for a portion of our sales revenue that is generated from the sale of consigned inventory maintained at physician, hospital, and clinic locations. For consignment sales, revenue is recognized at the time we are notified by the consignee that the product has been implanted. Our contracts with distributors do not typically contain right of return or price protection and have no post-delivery obligations.

We expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including seasonal fluctuations in demand for Motiva Implants and foreign currency fluctuations.

Cost of Revenue and Gross Margin

Our implants are manufactured at our two facilities in Costa Rica. Cost of revenue is primarily the cost of silicone but also includes other raw materials, packaging, components, quality assurance, labor costs, as well as manufacturing and overhead expenses. Cost of revenue also includes depreciation expense for production equipment and amortization of certain intangible assets.

We calculate gross margin as revenue less cost of revenue for a given period divided by revenue. Our gross margin may fluctuate from period to period depending, in part, on the efficiency and utilization of our manufacturing facilities, fluctuations of foreign currency exchange rates, targeted pricing programs and sales volume based on geography, customer and product type.

Operating Expenses

Sales, General and Administrative

Sales, general and administrative, or SG&A, expenses primarily consist of compensation, including salary, share-based compensation and employee benefits for our sales and marketing personnel, and for administrative personnel that support our general operations such as information technology, executive management, financial accounting, customer service, and human resources personnel. SG&A expenses also includes costs attributable to freight, marketing, sales support, travel, legal services, financial audit fees, insurance costs, and consulting services.

We expect our SG&A expenses to remain significant in absolute dollars as our business grows and we continue to invest in our sales, marketing, medical education, training and general administration resources. We expect our SG&A expenses to decrease as a percentage of our revenue; however, our SG&A expenses may fluctuate from period to period due to the timing of expenses related to our sales and marketing campaigns, as well as expansion into new markets and geographies.

Research and Development

Our research and development, or R&D, activities primarily consist of engineering and research programs associated with our products under development, as well as R&D activities associated with our clinical development activities. Our R&D expenses primarily consist of compensation, including salary, share-based compensation and employee benefits for our R&D and clinical personnel. We also incur significant expenses for supplies, development prototypes, design and testing, clinical study costs and product regulatory and consulting expenses.

We received an approval of an IDE from the FDA in March 2018 to initiate a clinical trial and enrolled the first patient in April 2018. The IDE clinical trial is expected to cost between $30.0 million and $40.0 million over the duration of the clinical trial period of ten years. As of December 31, 2025, approximately $33.5 million has been spent on the trial to date. In addition, as part of the conditions of approval, a post-market study is required as well as continued follow-up of the IDE study subjects for the remainder of the initial ten-year study timeframe. The FDA

is requiring this post-approval study, or PAS, to investigate the general post-market usage and endpoints not addressed during premarket evaluations. This study focuses on women undergoing primary breast augmentation and revision surgeries, along with a control group undergoing an aesthetic procedure other than breast implants. PAS is a decade-long study that will enroll 2,400 patients divided into three cohorts at up to 50 study sites in the United States. Patient participation for the study sites began in April 2025, with the first patients undergoing their surgeries in May 2025. We estimate we will incur between $4.0 million to $5.0 million in connection with the PAS over the next 10 years.

We expect our R&D expenses to remain elevated for the foreseeable future as we continue to advance our products under development, as well as initiate and prepare for additional clinical studies. We also have other products under development for which we may be required to conduct clinical trials in future periods in order to receive regulatory approval to market these products.

Interest Expense

Interest expense consists primarily of cash and non-cash interest related to outstanding debt and amortization of debt discounts. As of December 31, 2025, we had $246.4 million in outstanding principal under our term loan, including interest accrued into the principal balance. See Note 6 “Debt” for additional information.

Other Expense, Net

Other expense, net primarily consists of foreign currency gains/losses and interest income. As of December 31, 2024, it also included $6.0 million of contract termination costs related to cancellation of certain contracts in the fourth quarter of fiscal 2024. See Note 2 “Summary of Significant Accounting Policies” for additional information.

Income Tax Benefit

Income tax benefit primarily reflects income taxes incurred in the foreign jurisdictions in which we operate. In 2025, Motiva USA LLC, our U.S. subsidiary, released its valuation allowance on deferred tax assets, including net operating loss carryforwards, research and development tax credits, capitalized research and development costs, and other book-to-tax differences.

Business Update Regarding Macroeconomic Conditions

- *2025 Results:* As compared to the prior year, demand in fiscal 2025 improved in our EMEA markets, especially direct markets. As compared to fiscal 2024, we also saw an increase in demand in Latin America as demand in Brazil continues to stabilize and strong growth in Argentina continues. Our revenue in our Asia-Pacific market decreased as compared to the corresponding period of the prior year primarily due to our China distributor continuing to sell through inventory purchased in fiscal 2024 for the commercial launch. This performance in China is attributed to several factors, including lower consumer demand for aesthetic procedures. Management, in collaboration with our distribution partner, is dedicated to establishing Motiva as the leading implant in China, mirroring its success in other Asian markets. In the United States, we continue to see strong demand from the plastic surgeon community and positive feedback from plastic surgeons and patients alike. By December 31, 2025, we had successfully secured over 1,500 accounts across the United States, and Motiva Implants generated $45.6 million in sales within the United States for the year ended December 31, 2025.

- *Outlook:* Demand for our products is dependent on the relative strength of the global and regional medical device and aesthetic markets, which are sensitive to general macroeconomic conditions. The current global macroeconomic environment remains complex, with escalating trade tensions, uncertainty regarding tariffs, volatility in the capital markets, fluctuating exchange rates, declining consumer sentiment and elevated inflation and interest rates driving reductions in discretionary spending in the markets we operate. While several regions are currently showing good performance, as explained above, the outlook remains dynamic. Following the commercial launch of Motiva Implants in the United States in October 2024, we have been able to achieve higher selling prices for our Motiva Implants in the United States compared to other geographies. This dynamic has had a positive impact on our gross margins in 2025. Our commercial and operational activities increased following the FDA approval of Motiva Implants. As a

result, we expect overall operating expenses to increase as compared to 2025, although we remain focused on managing operating expenses.

For additional information on the various risks and other uncertain macroeconomic conditions on our business, financial condition and results of operations, please see Part I, Item 1A. “Risk Factors” of this report.

Consolidated Results of Operations

The following table sets forth our results of operations for the years presented, in dollars:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Revenue	$ 211,076	$ 166,025
Cost of revenue	64,768	56,500
Gross profit	146,308	109,525
Operating expenses:		
Sales, general and administrative	165,069	139,806
Research and development	20,247	19,706
Total operating expenses	185,316	159,512
Loss from operations	(39,008)	(49,987)
Interest expense	(25,256)	(20,829)
Other income (expense), net	6,242	(13,812)
Loss before income taxes	(58,022)	(84,628)
Benefit for income taxes	6,958	32
Net loss	$ (51,064)	$ (84,596)

Comparison of the Year Ended December 31, 2025 and 2024

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Revenue	$ 211,076	$ 166,025
Cost of revenue	64,768	56,500
Gross profit	$ 146,308	$ 109,525
Gross margin	69.3 %	66.0 %

Revenue

Revenue increased $45.1 million, or 27.2%, to $211.1 million for the year ended December 31, 2025, as compared to $166.0 million for the year ended December 31, 2024. The increase was primarily due to significantly higher sales in North America after FDA approval of Motiva Implants in September 2024, a 16.4% increase in revenue in the EMEA market and a 14.1% increase in revenue in Latin America partially offset by a 28.6% decrease in Asia-Pacific, due primarily to the timing of distributor purchases and sales.

Cost of Revenue and Gross Margin

Cost of revenue increased $8.3 million, or 14.7%, to $64.8 million for the year ended December 31, 2025, compared to $56.5 million for the year ended December 31, 2024. The increase in cost of revenue is in line with the increase in revenue.

Gross margin increased to 69.3% for the year ended December 31, 2025, compared to 66.0% for the year ended December 31, 2024, primarily due to the favorable impact from sales within the United States due to higher selling prices in that region.

Operating Expenses

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Operating expenses:		
Sales, general and administrative	$ 165,069	$ 139,806
Research and development	20,247	19,706
Total operating expenses	$ 185,316	$ 159,512

Sales, General and Administrative Expense

SG&A expense increased $25.3 million, or 18.1%, to $165.1 million for the year ended December 31, 2025, compared to $139.8 million for the year ended December 31, 2024. The increase was primarily due to a $7.1 million increase in personnel and related costs, a $5.1 million increase in shipping & handling associated with higher sales, a $4.7 million increase in commissions, a $4.4 million increase in expense related to the fair value remeasurement of contingent consideration related the business acquisition of Motiva Benelux BV, a $2.3 million increase in depreciation and amortization expenses, a $1.5 million increase in bad debt expense, a $0.8 million increase in consulting fees, a $0.4 million increase in software implementation costs, and a $0.4 million increase in insurance expenses, partially offset by a $2.2 million decrease in sales and marketing expenses.

Research and Development Expense

R&D expense increased $0.5 million, or 2.5%, to $20.2 million for the year ended December 31, 2025, compared to $19.7 million for the year ended December 31, 2024. The increase in R&D expense was primarily due to a $1.6 million increase in personnel cost and a $0.2 million increase in regulatory affairs costs, partially offset by a $0.8 million decrease in stock compensation costs and a $0.5 million decrease in expenditures related to our IDE clinical trial in the United States.

Interest Expense

Interest expense increased $4.4 million, or 21.6%, to $25.3 million for the year ended December 31, 2025, as compared to $20.8 million for the year ended December 31, 2024. The increase was primarily due to an increase in debt principal.

Benefit for Income Taxes

Income tax benefit increased to $7.0 million for the year ended December 31, 2025 as compared to a tax benefit of $32.0 thousand for the year ended December 31, 2024. The increase in the tax benefit was primarily due to the release of the valuation allowance for one of our U.S. subsidiaries.

Other Income (Expense), Net

Other income (expense), net, decreased $20.0 million to an income of $6.2 million for the year ended December 31, 2025, compared to an expense of $13.8 million for the year ended December 31, 2024. The increase was primarily due to $6.0 million in contract termination costs incurred in the fourth quarter of fiscal 2024 and to the foreign currency fluctuations of the Brazilian real and the euro as compared to the U.S. dollar, resulting in a foreign currency transaction gain of $6.4 million, for the year ended December 31, 2025, compared to a loss of $8.8 million for the year ended December 31, 2024.

Interest income amounted to $0.4 million or the year ended December 31, 2025, as compared to $1.5 million for the year ended December 31, 2024.

Comparison of the Year Ended December 31, 2024 and 2023

The discussion related to our results of operations and changes in financial condition for 2024 compared to 2023 is incorporated by reference to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on February 28, 2025.

Liquidity and Capital Resources

As of December 31, 2025, we had an accumulated deficit of $495.8 million. Since our inception, we have generated losses and expect to continue to generate losses in the near term. We have financed our operations through a combination of equity financings and debt financings, and from cash generated from operations, primarily from the collection of accounts receivable resulting from sales. Our historical cash outflows have primarily been associated with cash used for operating activities such as expansion of our sales and marketing and distributor infrastructure, investing in inventory, R&D activities, asset acquisitions, capital improvements, including our new manufacturing facility and other working capital needs. As of December 31, 2025 and 2024, we had cash of $75.6 million and $90.3 million, respectively.

As described above under "Recent Developments — Financing Activities," in May, 2025, we entered into an Inventory Funding Agreement which allows us to finance purchases of up to $10.0 million of silicone raw material, in a given funding period, for an initial four-month term. Also, in September 2025, we entered into a Fourth Amendment to the Credit Agreement, or the Fourth Amendment, which provided for the availability of the Tranche D Term Loans to commence as of the effective date of the amendment, notwithstanding the revenue milestone originally set forth in the Agreement, and (ii) increased, effective September 28, 2025, the minimum liquidity that the Company and its subsidiaries are guarantors under the Agreement are required to maintain from $25 million to $30 million. The fourth tranche, or the Tranche D Term Loan, of $25 million was advanced in September 2025. See Note 6 "Debt" for additional information regarding the Credit Agreement.

Our short-term liquidity requirements consist primarily of operating expenses and interest payments on the Credit Agreement and other short-term borrowings described above. We believe that our available cash and cash from operations will be sufficient to satisfy our liquidity requirements for at least the next 12 months, including our contractual and other obligations summarized below under "Material Cash Requirements" section. Our long-term liquidity needs consist primarily of operating expenses, including expected increases in SG&A and R&D expenses related to our clinical trials, regulatory compliance and product development and funds necessary to pay for the interest and principal payment on our Term Loans (as defined below). Our liquidity assumptions may prove to be incorrect, and we could utilize our available financial resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the degree and rate of market adoption of our products;
- the cost and timing of our regulatory activities;
- the emergence of new competing technologies and products;
- the costs of R&D activities we undertake to develop and expand our products;
- the costs of commercialization activities, including sales, marketing and manufacturing;
- the level of working capital required to support our growth; and
- our need for additional personnel, information technology or other operating infrastructure to support our growth and operations as a public company.

We may need to raise additional capital to execute our business plan. In April 2023, we filed an automatic shelf registration statement, or Shelf Registration Statement, with the SEC that expires in April 2026, which will allow us to offer and sell our common shares, warrants, rights and units. We may use the Shelf Registration Statement or other capital sources, including other offerings of equity or debt securities or the credit markets, to satisfy future financing needs. If we are unable to raise additional capital when desired, or on terms acceptable to us, our business, results of operations, and financial condition would be adversely affected.

Cash Flows

The discussion related to our cash flows for 2024 is incorporated by reference to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on February 28, 2025.

The following table sets forth the primary sources and uses of cash for each of the years presented below:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (50,890)	$ (58,516)
Investing activities	(7,028)	(15,611)
Financing activities	40,434	125,895
Effect of exchange rate changes on cash	2,709	(1,456)
Net (decrease) increase in cash	$ (14,775)	$ 50,312

Net Cash Used in Operating Activities

Net cash used in operating activities of $50.9 million for the year ended December 31, 2025 was primarily comprised of a net loss of $51.1 million, changes in operating assets and liabilities of $13.2 million, $10.0 million of unrealized foreign currency gain, and a $9.1 million change in provision for deferred income taxes, partially offset by $11.4 million of share-based compensation expense, $9.6 million of non-cash depreciation and amortization expense, a $3.4 million change in allowance for credit losses, $3.4 million of non-cash interest expense due to accretion of debt discounts, a $2.6 million change in provision for inventory obsolescence, $0.9 million of non-cash amortization expense of right-to-use assets, $0.5 million of non-cash loss on contract termination, $0.4 million of stock compensation in lieu of cash fees and a $0.2 million loss from disposal of property and equipment.

Net cash used in operating activities of $58.5 million for the year ended December 31, 2024 was primarily comprised of a net loss of $84.6 million, changes in operating assets and liabilities of $15.5 million, a $2.2 million change in provision for deferred income taxes and $0.6 million of interest capitalized for construction in progress, partially offset by $14.4 million of share-based compensation expense, $6.8 million of non-cash depreciation and amortization expense, $6.4 million of non-cash interest expense due to accretion of debt discounts, $6.0 million of non-cash loss on contract termination, $5.3 million of unrealized foreign currency loss, a $1.8 million change in provision for inventory obsolescence, a $1.7 million change in allowance for credit losses, $1.0 million of stock compensation in lieu of cash fees and $0.7 million of non-cash amortization expense of right-to-use assets.

Net Cash Used in Investing Activities

Net cash used in investing activities of $7.0 million for the year ended December 31, 2025 primarily consisted of $6.0 million in purchases of property and equipment related to the new manufacturing facility, $0.7 million in purchases of intangibles and $0.3 million in cash paid related to business acquisitions of Motiva Benelux BV and Motiva NL BV.

Net cash used in investing activities of $15.6 million for the year ended December 31, 2024 primarily consisted of $7.0 million in purchases of intangibles, $6.1 million in purchases of property and equipment related to the new manufacturing facility and $2.4 million of cash paid for capital expenditures on construction in progress related to our new manufacturing facility in the Coyol Free Zone in Costa Rica.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $40.4 million for the year ended December 31, 2025 primarily consisted of $24.5 million of borrowings under the Tranche D Term Loan of the Credit Agreement, $10.0 million in proceeds received from borrowings under short term notes payable, and $7.6 million in proceeds received for

stock option exercises, partially offset by a $1.0 million repayment of short-term notes payable for insurance premium financing and $0.6 million paid to satisfy tax withholding obligations upon the vesting of restricted stock.

Net cash provided by financing activities of $125.9 million for the year ended December 31, 2024 primarily consisted of $99.5 million of proceeds received for the issuance of common shares, net of underwriters' discount and issuance costs, from our public offering in April 2023, $24.5 million of borrowings under the Tranche C Term Loan of the Credit Agreement and $2.5 million in proceeds received for stock option exercises, partially offset by $0.5 million paid to satisfy tax withholding obligations upon the vesting of restricted stock.

Material Cash Requirements

The following table provides a summary of our material cash requirements from known contractual and other obligations, including commitments for capital expenditures, as of December 31, 2025:

	2026	2027	2028	2029	2030	Thereafter	Total
				(in thousands)			
Debt obligations - principal [1]	$ —	$ 246,367	$ —	$ —	$ —	$ —	$ 246,367
Debt obligations - interest payments [1]	22,988	7,306	—	—	—	—	30,294
Future minimum lease payments [2]	2,097	1,807	948	459	86	37	5,434
License and software commitments [3]	1,998	1,216	674	—	—	—	3,888
Short-term borrowing [4]	13,141	—	—	—	—	—	13,141
Total material cash requirements	$ 40,224	$ 256,696	$ 1,622	$ 459	$ 86	$ 37	$ 299,124

(1) Contractual obligations related to the Credit Agreement. See below under "Indebtedness" and Note 6 "Debt" for additional details.

(2) Contractual obligations related to the minimum lease payments and interest on our operating leases. See Note 7 "Leases" for additional details.

(3) Contractual obligations related to our current contracts for software solutions and support.

(4) Contractual obligations related to a short-term loan for our business insurance premiums and for purchases of silicone raw material.

Indebtedness

On April 26, 2022, or the Closing Date, we entered into the new Credit Agreement, pursuant to which the lenders agreed to make term loans in an aggregate principal amount of up to $225 million, which we collectively refer to as the Term Loans, with the first tranche of $150 million advanced on the Closing Date. Part of the first tranche was used to repay the outstanding principal and interest under our previous credit agreement with Madryn Health Partners, LP in full, including the early repayment penalty of $6.5 million. In December 2022, $25 million was advanced under the second tranche. In October 2024, $25 million was advanced under the third tranche. In September 2025, $25 million was advanced under the fourth tranche. The Term Loans will mature on the 5-year anniversary of the Closing Date and accrue interest at a rate equal to 9% per annum for the first two tranches and 10% for the third and fourth tranches. As of December 31, 2025, $246.4 million was outstanding under the Credit Agreement representing the initial principal of $150 million for the Tranche A Term Loan, $25 million for the Tranche B Term Loan, $25 million for the Tranche C Term Loan, $25 million for the Tranche D Term Loan and $21.4 million of interest accrued into the principal balance. See Note 6 "Debt" for additional information.

Critical Accounting Policies, Significant Judgments and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with the generally accepted accounting principles in the United States of America, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and the disclosure of contingent assets and liabilities. Our estimates are based on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Actual results may differ from these estimates. We believe that the critical accounting policies discussed below are essential to understanding our historical and future performance, as these policies relate to the more significant areas involving management's estimates and judgments.

Revenue Recognition

We recognize revenue related to sales of products to distributors or directly to customers in markets where it has regulatory approval, net of discounts and allowances. The Company recognizes revenue in accordance with Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*. ASC 606 requires the Company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services.

We recognize revenue related to the sales of products to distributors at the time of shipment of the product, which represents the point in time when the distributor has taken ownership and assumed the risk of loss and the required revenue recognition criteria are satisfied. Our distributors are obligated to pay within specified terms regardless of when, or if, they sell the products. Our contracts with distributors typically do not contain right of return or price protection and have no post-delivery obligations.

We recognize revenue when title to the product and risk of loss transfer to customers, provided there are no remaining performance obligations required of us or any written matters requiring customer acceptance. We allow for the return of product from direct customers in certain regions in limited instances within 15 to 60 days after the original sale and records estimated sales returns as a reduction of sales in the same period revenue is recognized. Appropriate reserves are established for anticipated sales returns based on historical experience, recent gross sales and any notification of pending returns. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period is recorded. As of December 31, 2025 and 2024, an allowance of $1.9 million and $0.4 million was recorded for product returns, respectively. Taxes collected from customers for remittance to governmental authorities are excluded from net sales.

A portion of the our revenue is generated from the sale of consigned inventory maintained at physician, hospital, and clinic locations. For these products, revenue is recognized at the time we are notified by the consignee that the product has been implanted, not when the consigned products are delivered to the consignee's warehouse.

We have a limited warranty for the shelf life of breast implants, which is five years from the time of manufacture. Estimated warranty obligations are recorded at the time of sale. We also offer a warranty to patients in the event of rupture and a replacement program for capsular contracture events, provided certain registration requirements are met. Revenue for extended warranties is recognized ratably over the term of the agreement. To date, these warranty and program costs have been de minimis. We will continue to evaluate the warranty reserve policies for adequacy considering claims history.

Deferred revenue primarily consists of payments received in advance of meeting revenue recognition criteria. We have received payments from distributors to provide distribution exclusivity within a geographic area and recognize deferred revenue on a ratable basis over the term of such contractual distribution relationship. Additionally, we have received payments from customers in direct markets prior to surgical implantation and recognize deferred revenue at the time we are notified by the customer that the product has been implanted. For all arrangements, any revenue that has been deferred and is expected to be recognized beyond one year is classified as long-term deferred revenue and included in "Other liabilities, long-term" on the consolidated balance sheets (see Note 3 "Balance Sheet Accounts").

Research and Development

Costs related to research and development, or R&D, activities are expensed as incurred. R&D costs primarily include personnel costs, materials, clinical expenses, regulatory expenses, product development, consulting services, and outside research activities, all of which are directly related to R&D activities.

We estimate IDE clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage clinical trials on its behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable is stated at invoice value less estimated allowances for returns and credit losses. We continually monitor customer payments and maintain an allowance for estimated losses resulting from customers' inability to make required payments. In evaluating our ability to collect outstanding receivable balances, we

consider various factors including the age of the balance, the creditworthiness of the customer, which is assessed based on ongoing credit evaluations and payment history, and the customer's current financial condition. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, an allowance is recorded against amounts due, which reduces the net recognized receivable to the amount reasonably believed to be collectible.

Inventory and Cost of Revenue

Inventory is stated at the lower of cost to purchase or manufacture the inventory or the net realizable value of such inventory. Cost is determined using the standard cost method which approximates actual costs using the first-in, first-out basis. We regularly reviews inventory quantities considering actual losses, projected future demand, and remaining shelf life to record a provision for excess and slow-moving inventory. Provision for inventory obsolescence of $3.9 million and $4.2 million has been recorded as of December 31, 2025 and 2024, respectively.

Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. There were no impairment charges, or changes in estimated useful lives recorded during the years ended December 31, 2025 and 2024.

Income Taxes

We account for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax balances are measured using enacted tax laws and rates expected to apply when the related temporary differences reverse. We establish a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We operate in multiple tax jurisdictions and are subject to examination by various tax authorities. We recognize uncertain tax positions using a two-step approach: (1) a tax position is recognized only if it is more likely than not to be sustained based on its technical merits, and (2) the amount recognized is the largest amount of benefit that is more than 50% likely to be realized upon settlement. Interest and penalties related to uncertain tax positions are recorded in income tax expense. There were no material uncertain tax positions as of December 31, 2025 and 2024.

Effective January 1, 2025, we adopted ASU 2023-09, Improvements to Income Tax Disclosures, on a prospective basis. As a result, our income tax disclosures now include enhanced disaggregation of income taxes paid and a standardized effective tax rate reconciliation, as required by the amended guidance. The adoption did not affect our accounting for income taxes under ASC 740.

Foreign Currency

The financial statements of our foreign subsidiaries whose functional currencies are the local currencies are translated into U.S. dollars for consolidation as follows: assets and liabilities at the exchange rate as of the balance sheet date, shareholders' equity at the historical rates of exchange, and income and expense amounts at the average exchange rate for the period. Translation adjustments resulting from the translation of the subsidiaries' accounts are included in "Accumulated other comprehensive income" as equity in the consolidated balance sheet. Transactions denominated in currencies other than the applicable functional currency are converted to the functional currency at the exchange rate on the transaction date. At period end, monetary assets and liabilities are remeasured to the functional currency using exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities are remeasured at historical exchange rates. Gains and losses resulting from foreign currency transactions are included within "Other income (expense), net" in the consolidated statement of operations. For the year ended December 31, 2025, foreign currency transaction gain amounted to $6.4 million as compared to a foreign currency transaction loss of $8.8 million for the year ended December 31, 2024.

Share-Based Compensation

We measure and recognize compensation expense for all share-based awards in accordance with the provisions of ASC 718, *Stock Compensation*. Share-based awards granted include stock options, restricted stock units, or RSUs, and restricted stock awards, or RSAs. Share-based compensation expense for stock options and RSAs granted to employees is measured at the grant date based on the fair value of the awards and is recognized as an expense ratably on a straight-line basis over the requisite service period. The fair value of options to purchase shares granted to employees is estimated on the grant date using the Black-Scholes option valuation model.

The calculation of share-based compensation expense requires us to make assumptions and judgments about the variables used in the Black-Scholes model, including the expected term, expected volatility of the underlying common shares, risk-free interest rate and dividends.

See Note 10 “Share-Based Compensation” for additional information.

Recent Accounting Pronouncements

Please refer to Note 2 “Summary of Significant Accounting Policies” in the notes to the consolidated financial statements included in this Form 10-K for information on recent accounting pronouncements and the expected impact on our unaudited consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We had cash of $75.6 million and $90.3 million as of December 31, 2025 and 2024, respectively. We manage our cash portfolio for operating and working capital purposes. Our cash balances are held in bank checking accounts, and we believe that we do not have any material exposure to changes in the fair value of our cash portfolio as a result of changes in interest rates.

Foreign Currency Exchange Risk

To date, the majority of our revenue has been denominated in U.S. dollars, Brazilian reals and euros. Some of our operating expenses are subject to fluctuations due to changes in foreign currency exchange rates, particularly changes in the euro and Brazilian real. Fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our consolidated statements of operations. For the year ended December 31, 2025, foreign currency transaction gain amounted to $6.4 million primarily related to the remeasurement of transactions denominated in the U.S. dollar into the Brazilian real and the euro as part of the financial reporting consolidation process under GAAP. We have not engaged in any foreign currency hedging activities. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in foreign currency exchange rates. During the year ended December 31, 2025, the effect of an immediate 10% adverse change in foreign exchange rates on foreign-denominated accounts as of December 31, 2025 would have had an impact of approximately 1.8% on revenues and would have impacted our net loss by a commensurate amount.

Inflation Risk

We do not believe that inflation had a significant impact on our results of operations for any periods presented in our consolidated financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this report beginning on page F-1. An index of those financial statements is included in Part IV, Item 15 below.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2025, the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our

disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 using the criteria established in "Internal Control—Integrated Framework" (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on that assessment, our management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the three months ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Attestation Report of the Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by CBIZ CPAs P.C., an independent registered public accounting firm, as stated in their report which is included below.

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

To the Stockholders and Board of Directors of
Establishment Labs Holdings Inc.

Opinion on Internal Control over Financial Reporting

We have audited Establishment Labs Holdings Inc.'s (the "Company") internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet as of December 31, 2025 and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows and the related notes (collectively referred to as the "financial statements") for the year ended December 31, 2025 of the Company, and our report dated February 27, 2026 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally

accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

/s/ *CBIZ CPAs P.C.*

CBIZ CPAs P.C.

Los Angeles, California

February 27, 2026

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

On December 16, 2025, Juan José Chacón Quirós, former Chief Executive Officer and a current member of the Board of Directors, adopted a Rule 10b5-1 trading plan pursuant to which up to 330,000 common shares may be sold in accordance with the trading plan's specifications. The first half of the shares subject to the plan will sell starting on March 23, 2026 and the remainder will sell starting April 23, 2026, if pre-established stock price thresholds are met. The trading plan will expire once all of the shares have been sold or on March 23, 2027, whichever is earlier. Actual sale transactions will be disclosed publicly through Form 4 filings with the Securities and Exchange Commission, as required.

Avantor Agreement

Effective May 2022, we entered into a master supply agreement with Avantor, Inc. (formerly NuSil Technology LLC), or Avantor, whereby Avantor provides us with NuSil brand medical-grade silicon for specified prices per unit of each relevant component. The material terms of this agreement were previously described in a Current Report on Form 8-K filed by the Company on June 6, 2022. As disclosed in such Current Report on Form 8-K, this master supply agreement has an initial term ending on December 31, 2026 and automatically renews for successive terms of one year each for up to five successive renewal terms, unless the Company or Avantor provides written notice no later than December 31 of the year prior to the expiration of the initial term or the then-current renewal term. On December 29, 2025, Avantor informed the Company that it does not intend to allow the agreement to renew automatically and plans to enter into negotiations regarding future supply terms. While we will negotiate with Avantor, we cannot guarantee whether we will reach an agreement on a timely basis or on favorable terms.

Executive Officer Transition

On February 24, 2026, we announced a strategic leadership transition of Raj Denhoy, current Chief Financial Officer, to Senior Vice President, Global Strategy, and the appointment of Cassandra "Sandra" Harris, 53, to Senior Vice President and Chief Financial Officer, effective March 9, 2026. Ms. Harris will also replace Mr. Denhoy as the Company's principal accounting officer.

Ms. Harris brings extensive global finance and operational leadership experience, including prior service as Chief Financial Officer of Genesco Inc., a wholesale distributor and manufacturer, from 2024 to 2026, and Artisan Design Group, LLC, a national provider of interior finishes, from 2023 to 2024, as well as Chief Financial Officer and Chief Operating Officer of Tupperware Brands Corporation, a global consumer products company, from 2019 to 2022 and 2020 to 2022, respectively. Earlier in her career, she held senior finance and operational roles at VF Corporation, an apparel and footwear company, and began her career in audit at Deloitte & Touche LLP, a professional services firm. Ms. Harris is a Certified Public Accountant and holds a Bachelor of Science in Accounting from Clemson University. In connection with her appointment, Ms. Harris entered into an employment agreement that provides for, among other things, an annual base salary of $550,000, a target annual bonus opportunity of up to 50% of base salary, eligibility for annual equity awards, and a one-time cash award of $700,000 payable in two installments. Ms. Harris has no family relationships with any director or executive officer of the Company, and there are no arrangements or understandings with any person pursuant to which she was selected as an officer of the Company. There are also no related person transactions between Ms. Harris and the Company that would be required to be disclosed pursuant to Item 404(a) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

In his role as Senior Vice President, Global Strategy, Mr. Denhoy will be responsible for key strategic initiatives and long-term growth priorities. This transition is not the result of any disagreement with the Company on any matter relating to its operations, policies, or practices.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Code of Business Conduct and Ethics

Our Board has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our chief executive officer, and other executive and senior financial officers. A copy of the code is posted under "Corporate Governance" in the Investors section of our website at https://establishmentlabs.com. If we make any substantive amendments to, or grant any waivers from, the Code of Business Conduct and Ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K. None of the websites referenced in this Annual Report or the information contained therein is incorporated herein by reference.

The remaining information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Shareholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Shareholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

The information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Shareholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

The information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Shareholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Shareholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

The following statements are filed as part of this Annual Report on Form 10-K:

1. Financial Statements.

A listing of the Consolidated Financial Statements, related notes and Report of Independent Registered Public Accounting is set forth starting on page F-1 in this Annual Report on Form 10-K.

2. Financial Statement Schedules.

All schedules have been omitted since the required information is not present or is not present in amounts sufficient to require submission of a schedule, or because the information required is included in the financial statements or related notes.

3. Index to Exhibits.

Exhibit Number	Description of Exhibit	Incorporation by Reference
3.1	Memorandum and Articles of Association of the Registrant	Incorporated by reference from Registrant's Current Report on Form 8-K filed May 31, 2023.
4.1	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Incorporated by reference from Registrant's Annual Report on Form 10-K filed March 16, 2019.

Exhibit Number	Description of Exhibit	Incorporation by Reference
4.2	Form of Pre-Funded Warrant to Purchase Common Shares (January 2024)	Incorporated by reference from Exhibit 4.1 to Registrant's Current Report on Form 8-K filed January 9, 2024
4.3	Form of Pre-Funded Warrant to Purchase Common Shares (November 2024)	Incorporated by reference from Exhibit 4.1 to Registrant's Current Report on Form 8-K filed on November 12, 2024
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	Incorporated by reference from Registrant's Current Report on Form 8-K filed December 10, 2021.
10.2	2015 Equity Incentive Plan, as adopted December 10, 2015, and the forms of equity agreements thereunder.	Incorporated by reference from Registrant's Form S-1 filed June 21, 2018.
10.3+	2018 Equity Incentive Plan and the forms of equity agreements thereunder.	Incorporated by reference from Registrant's Form S-1/A filed July 9, 2018.
10.4+	2018 Employee Share Purchase Plan.	Incorporated by reference from Registrant's Form S-1/A filed July 9, 2018.
10.5‡	Master Supply Agreement, effective as of May 13, 2022, by and between Establishment Labs S. A. and NuSil Technology LLC	Incorporated by reference from Registrant's Current Report on Form 8-K filed June 6, 2022.
10.6	Design, Architecture & Engineering, and Build-Out Construction Management Agreement by and between ELSA and Zona Franca Coyol, S.A., dated February 11, 2016.	Incorporated by reference from Registrant's Form S-1/A filed July 13, 2018.
10.7	Lease Agreement by and between Establishment Labs, S.A. and Zona Franca Coyol, S.A., dated November 1, 2009, as amended on October 22, 2010, September 24, 2012 and August 7, 2015.	Incorporated by reference from Registrant's Form S-1/A filed July 13, 2018.
10.8+	Employment Agreement between the Registrant and Fillipo "Peter" Caldini dated effective as of August 20, 2024	Incorporated by reference from Registrant's Current Report on Form 8-K filed August 28, 2024.
10.9+	Employment Agreement by and between Registrant and Samuel Ross Mansbach, dated August 22, 2022	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022.
10.10+	Separation Agreement by and between Establishment Labs Holdings Inc. and Juan José Chacón-Quirós, dated August 3, 2025	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025.
10.11+	Separation Agreement by and between Establishment Labs S.A. and Juan José Chacón-Quirós, dated August 4, 2025	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025.
10.12+	Consulting Agreement by and between Establishment Labs Holdings Inc. and Juan José Chacón-Quirós, dated August 3, 2025	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025.
10.13	Deed by and between Establishment Labs, S.A. and Zona Franca El Coyol, S.A., dated as of June 25, 2019.	Incorporated by reference from Registrant's Current Report on Form 8-K filed June 26, 2019.
10.14	Credit Agreement and Guaranty, dated as of April 26, 2022, by and among Establishment Labs Holdings Inc., its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders.	Incorporated by reference from Registrant's Current Report on Form 8-K filed April 28, 2022.
10.15	First Amendment to Credit Agreement, dated as of January 12, 2023, by and among Establishment Labs Holdings Inc., its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders.	Incorporated by reference from Registrant's Annual Report on Form 10-K for the annual period December 31, 2023.

Exhibit Number	Description of Exhibit	Incorporation by Reference
10.16	Second Amendment to Credit Agreement, dated as of February 21, 2024, by and among Establishment Labs Holdings Inc., its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders.	Incorporated by reference from Registrant's Current Report on Form 8-K filed February 22, 2024.
10.17	Third Amendment to Credit Agreement, dated as of November 7, 2024, by and among Establishment Labs Holdings Inc., its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders.	Incorporated by reference from Registrant's Current Report on Form 8-K filed November 12, 2024.
10.18	Fourth Amendment to Credit Agreement and Guaranty, dated as of September 29, 2025, by and among Establishment Labs Holdings Inc., its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders	Incorporated by reference from Registrant's Current Report on Form 8-K filed October 3, 2025.
10.19	U.S. Security Agreement, dated as of April 26, 2022, by Establishment Labs Holdings Inc, each other grantor from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent for the lenders.	Incorporated by reference from Registrant's Current Report on Form 8-K filed April 28, 2022.
10.20	Form of Share Option Agreement (US) under the 2018 Equity Incentive Plan	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022.
10.21+	Form of Share Option Agreement (International) under the 2018 Equity Incentive Plan	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022.
10.22+	Form of Restricted Share Unit Award Agreement (US) under the 2018 Equity Incentive Plan	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022.
10.23+	Form of Restricted Share Unit Award Agreement (International) under the 2018 Equity Incentive Plan	Incorporated by reference from Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022.
10.24+	Employment Agreement by and between Registrant and Cassandra Harris, dated February 23, 2026	Filed herewith.
19.1	Insider Trading Policy	Incorporated by reference from Registrant's Annual Report on Form 10-K filed February 28, 2025.
21.1	List of Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of CBIZ CPAs P.C., Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of Marcum LLP, Independent Registered Public Accounting Firm.	Filed herewith.
31.1	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.

Exhibit Number	Description of Exhibit	Incorporation by Reference
97.1	Policy Regarding the Recoupment of Certain Compensation Payments	Incorporated by reference from Registrant's Annual Report on Form 10-K filed March 4, 2024.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.*

‡ Certain portions that constitute confidential information have been omitted in compliance with Item 601(b)(10) of Regulation S-K.

+ Indicates management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Establishment Labs Holdings Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Establishment Labs Holdings Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations, comprehensive loss**,** stockholders' equity and cash flows for the year 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 as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2025, based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013, and our report dated February 27, 2026*,* expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

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 audit. We are a public accounting firm registered with the 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 audit 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C. (199)

We have served as the Company's auditor since 2016 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Los Angeles, California
February 27, 2026

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Establishment Labs Holdings Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Establishment Labs Holdings Inc. (the "Company") as of as December 31, 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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/ Marcum LLP

MARCUM LLP (688)

We have served as the Company's auditor since 2016 through 2025.

Los Angeles, California
February 28, 2025

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Balance Sheets

(In thousands, except share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 75,572	$ 90,347
Accounts receivable, net of allowance for credit losses of $6,835 and $3,088 at December 31, 2025 and 2024, respectively	77,497	65,002
Inventory, net	85,611	78,766
Prepaid expenses and other current assets	11,260	8,922
Total current assets	249,940	243,037
Long-term assets:		
Property and equipment, net	75,615	78,028
Goodwill	1,209	1,209
Intangible assets, net of accumulated amortization	9,942	11,683
Right-of-use operating lease assets, net	4,339	5,561
Other non-current assets	16,122	7,313
Total assets	$ 357,167	$ 346,831
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 43,109	$ 44,760
Accrued liabilities	18,856	16,536
Other liabilities, short-term	20,177	6,982
Total current liabilities	82,142	68,278
Long-term liabilities:		
Note payable, Oaktree, net of debt discount and issuance costs	247,522	219,577
Operating lease liabilities, non-current	2,820	4,203
Other liabilities, long-term	1,136	1,678
Total liabilities	333,620	293,736
Commitments and contingencies (Note 16)		
Shareholders' equity:		
Common shares – zero par value, unlimited amount of shares authorized at December 31, 2025 and 2024; 29,713,024 and 29,195,439 shares issued at December 31, 2025 and 2024, respectively; 29,304,954 and 28,787,369 shares outstanding at December 31, 2025 and 2024, respectively	433,378	420,364
Additional paid-in-capital	87,624	76,992
Treasury shares, at cost, 408,070 shares held at December 31, 2025 and 2024	(2,854)	(2,854)
Accumulated deficit	(495,756)	(444,692)
Accumulated other comprehensive income	1,155	3,285
Total shareholders' equity	23,547	53,095
Total liabilities and shareholders' equity	$ 357,167	$ 346,831

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

	Year Ended December 31,		
	2025	2024	2023
Revenue	$ 211,076	$ 166,025	$ 165,151
Cost of revenue	64,768	56,500	58,174
Gross profit	146,308	109,525	106,977
Operating expenses:			
Sales, general and administrative	165,069	139,806	145,575
Research and development	20,247	19,706	26,428
Total operating expenses	185,316	159,512	172,003
Loss from operations	(39,008)	(49,987)	(65,026)
Interest income	423	1,477	1,020
Interest expense	(25,256)	(20,829)	(15,393)
Other income (expense), net	5,819	(15,289)	816
Loss before income taxes	(58,022)	(84,628)	(78,583)
Benefit (provision) for income taxes	6,958	32	81
Net loss	$ (51,064)	$ (84,596)	$ (78,502)
Basic and diluted net loss per share	$ (1.72)	$ (3.00)	$ (3.07)
Weighted average outstanding shares used for basic and diluted net loss per share	29,620,022	28,161,761	25,600,029

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Net loss	$ (51,064)	$ (84,596)	$ (78,502)
Other comprehensive income:			
Foreign currency translation gain (loss)	(2,130)	1,322	(752)
Other comprehensive income (loss)	(2,130)	1,322	(752)
Comprehensive loss	$ (53,194)	$ (83,274)	$ (79,254)

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Shareholders' Equity
(In thousands, except share data)

	Common Shares		Treasury Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Shares	Amount				
Balance at January 1, 2023	**24,815,908**	**$ 223,637**	**(408,070)**	**$ (2,854)**	**$ 49,911**	**$ (281,594)**	**$ 2,715**	**$ (8,185)**
Issuance of common shares, net of underwriters' discount and issuance costs	1,265,000	84,538	—	—	—	—	—	84,538
Issuance of common shares in lieu of cash compensation	23,041	745	—	—	—	—	—	745
Stock option exercises	349,967	6,673	—	—	—	—	—	6,673
Share-based compensation	49,351	49	—	—	14,313	—	—	14,362
Shares withheld to cover income tax obligation upon vesting of restricted stock	(8,017)	(8)	—	—	(476)	—	—	(484)
Foreign currency translation loss	—	—	—	—	—	—	(752)	(752)
Net loss	—	—	—	—	—	(78,502)	—	(78,502)
Balance at December 31, 2023	**26,495,250**	**315,634**	**(408,070)**	**(2,854)**	**63,748**	**(360,096)**	**1,963**	**18,395**
Issuance of common shares, net of underwriters' discount and issuance costs	1,867,261	99,484	—	—	—	—	—	99,484
Issuance of common shares in lieu of cash compensation	48,167	2,142	—	—	—	—	—	2,142
Warrant exercises	599,991	600	—	—	(600)	—	—	—
Stock option exercises	134,226	2,454	—	—	—	—	—	2,454
Share-based compensation	61,382	61	—	—	14,343	—	—	14,404
Shares withheld to cover income tax obligation upon vesting of restricted stock	(10,838)	(11)	—	—	(499)	—	—	(510)
Foreign currency translation gain	—	—	—	—	—	—	1,322	1,322
Net loss	—	—	—	—	—	(84,596)	—	(84,596)
Balance at December 31, 2024	**29,195,439**	**420,364**	**(408,070)**	**(2,854)**	**76,992**	**(444,692)**	**3,285**	**53,095**
Issuance of common shares, net of underwriters' discount and issuance costs	76,569	77	—	—	(77)	—	—	—
Issuance of common shares in lieu of cash compensation	115,429	5,279	—	—	—	—	—	5,279
Stock option exercises	256,696	7,589	—	—	—	—	—	7,589
Share-based compensation	84,194	84	—	—	11,331	—	—	11,415
Shares withheld to cover income tax obligation upon vesting of restricted stock	(15,303)	(15)	—	—	(622)	—	—	(637)
Foreign currency translation loss	—	—	—	—	—	—	(2,130)	(2,130)
Net loss	—	—	—	—	—	(51,064)	—	(51,064)
Balance at December 31, 2025	**29,713,024**	**$ 433,378**	**(408,070)**	**$ (2,854)**	**$ 87,624**	**$ (495,756)**	**$ 1,155**	**$ 23,547**

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net loss	$ (51,064)	$ (84,596)	$ (78,502)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	9,563	6,834	4,166
Provision for credit losses	3,352	1,722	1,223
Provision for inventory obsolescence	2,646	1,805	1,392
Change in reserve for PP&E impairment	—	—	(341)
Provision for deferred income taxes	(9,130)	(2,178)	(3,706)
Share-based compensation	11,415	14,404	14,362
Loss from disposal of property and equipment	153	163	280
Unrealized foreign currency (gain)/loss, net	(9,956)	5,302	(4,181)
Amortization of right-to-use asset	911	743	717
Non-cash loss on contract termination	543	6,004	—
Stock compensation in lieu of cash fees	403	964	495
Interest capitalized for construction in progress	—	(555)	(3,567)
Non-cash interest expense and amortization of debt discount	3,445	6,371	13,278
Changes in operating assets and liabilities:			
Accounts receivable	(11,469)	(26,278)	(11,557)
Inventory	(7,060)	(471)	(42,230)
Prepaid expenses and other current assets	1,847	86	2,637
Other assets	454	(483)	318
Accounts payable	(2,296)	6,671	18,957
Accrued liabilities	1,847	4,395	(1,662)
Operating lease liabilities	(887)	(646)	(689)
Other liabilities	4,393	1,227	97
Net cash used in operating activities	(50,890)	(58,516)	(88,513)
Cash flows from investing activities:			
Purchases of property and equipment	(6,049)	(6,114)	(7,908)
Cash used in business acquisitions, net of cash acquired	(307)	(50)	—
Cost incurred for intangible assets	(672)	(7,033)	(1,328)
Capital expenditures on construction in progress	—	(2,414)	(15,311)
Net cash used in investing activities	(7,028)	(15,611)	(24,547)
Cash flows from financing activities:			
Issuance of common stock, net of underwriters' discount and issuance costs	—	99,484	84,538
Borrowings under Oaktree credit agreement, net of debt discount and issuance costs	24,500	24,467	—
Borrowings on short term notes payable	10,000	—	—
Repayments of short term notes payable for insurance premium financing	(1,018)	—	—
Proceeds from stock option exercises	7,589	2,454	2,173

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Tax payments related to shares withheld upon vesting of restricted stock	(637)	(510)	(484)
Net cash provided by financing activities	40,434	125,895	86,227
Effect of exchange rate changes on cash and cash equivalents	2,709	(1,456)	513
Net (decrease)/increase in cash and cash equivalents	(14,775)	50,312	(26,320)
Cash and cash equivalents at beginning of period	90,347	40,035	66,355
Cash and cash equivalents at end of period	$ 75,572	$ 90,347	$ 40,035
Supplemental disclosures:			
Cash paid for interest	$ 20,539	$ 9,806	$ 5,689
Cash paid for income taxes	$ 420	$ 1,735	$ 2,165
Supplemental disclosures of non-cash investing and financing activities:			
Unpaid balance for property and equipment	$ 144	$ 240	$ 2,847
Unpaid balance for intangible assets	$ 581	$ 592	$ 2,907
Equity consideration in an asset acquisition	$ —	$ —	$ 250
Equity consideration issued in a business acquisition	$ 3,556	$ 1,177	$ —
Contingent consideration payable related to a business acquisition	$ 4,474	$ 973	$ —
Consideration payable related to a business acquisition	$ 315	$ 3,262	$ —
Cashless option exercises	$ —	$ —	$ 4,500
Cashless warrant exercises	$ —	$ 600	$ —
Cash payable to settle contract termination	$ —	$ 214	$ —
Liability to issue shares to settle contract termination	$ —	$ 1,320	$ —
Borrowings of short term notes payable for insurance premium financing	$ 3,382	$ —	$ —

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

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2025, 2024 and 2023

1. Formation and Business of the Company

Formation and Business of the Company

Establishment Labs Holdings Inc. along with its wholly owned subsidiaries, or the Company, is a global company that manufactures and markets innovative medical devices for aesthetic and reconstructive plastic surgery. The Company was established in the British Virgin Islands on October 9, 2013, at which time Establishment Labs, S.A., the Costa Rican manufacturing company, was reincorporated as a wholly-owned subsidiary. As of December 31, 2025, the Company also has wholly-owned subsidiaries in the United States (JAMM Technologies, Inc. and Motiva USA LLC), Brazil (Establishment Labs Produtos para Saude Ltda), Belgium (European Distribution Center Motiva BV and Motiva Benelux BV), the Netherlands (Motiva NL BV), France (Motiva Implants France SAS), Sweden (Motiva Nordica AB), Switzerland (JEN-Vault AG), the United Kingdom (Motiva Implants UK Limited), Italy (Motiva Italy S.R.L), Spain (Motiva Implants Spain, S.L.), Austria (Motiva Austria GmbH), Germany (Motiva Germany GmbH) and Argentina (Motiva Argentina S.R.L). Substantially all of the Company's revenues are derived from the sale of silicone gel-filled breast implants, branded as Motiva Implants.

The main manufacturing activities are conducted at manufacturing facilities in Costa Rica. In 2024, the Company completed construction of its newest facility. In 2010, the Company began operating under the Costa Rica free zone regime (Régimen de Zona Franca), which provides for reduced income tax and other tax obligations pursuant to an agreement with the Costa Rican authorities.

The Company's products are approved for sale in Europe, the Middle East, Latin America, Asia and the United States. The Company sells its products internationally through a combination of distributors and direct sales to customers. In October 2024, the Company began selling Motiva Implants for use in breast augmentation for patients in the United States.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the applicable rules and regulations of the Securities and Exchange Commission, or SEC.

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2025, 2024 and 2023

The consolidated financial statements include the Company's accounts and those of its wholly owned subsidiaries as of December 31, 2025 as follows:

Subsidiary	Incorporation/Acquisition Date
Establishment Labs, S.A. (Costa Rica)	January 18, 2004
Motiva USA, LLC (USA)	February 20, 2014
JAMM Technologies, Inc. (USA)	October 27, 2015
Establishment Labs Produtos par Saude Ltda (Brazil)	January 4, 2016
European Distribution Center Motiva BV (Belgium)	March 4, 2016
Motiva Implants France SAS (France)	September 12, 2016
JEN-Vault AG (Switzerland)	November 22, 2016
Motiva Nordica AB (Sweden)	November 2, 2017
Motiva Implants UK Limited (the United Kingdom)	July 31, 2018
Motiva Italy S.R.L (Italy)	July 31, 2018
Motiva Implants Spain, S.L. (Spain)	January 3, 2019
Motiva Austria GmbH (Austria)	January 14, 2019
Motiva Germany GmbH (Germany)	August 1, 2019
Motiva Argentina S.R.L. (Argentina)	February 7, 2020
Motiva Benelux BV (Belgium)	October 1, 2024
Motiva NL BV (Netherlands)	October 1, 2024

All intercompany accounts and transactions have been eliminated in consolidation.

Segments

The chief operating decision maker, or CODM, for the Company is the Chief Executive Officer. The Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity, and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has one single reportable and operating segment structure. The Company and its Chief Executive Officer evaluate performance based primarily on revenue in the geographic regions in which the Company operates. See the consolidated statements of operations for the consolidated financial information and "Revenue Recognition" for revenue by geographic region used in evaluating financial performance. The level of disaggregation and amounts of significant segment expenses that are regularly provided to the CODM are the same as those presented in the consolidated statements of operations. Likewise, the measure of segment assets is reported on the consolidated balance sheets as total assets.

Geographic Concentrations

The Company derives substantially all of its revenues from sales to customers in the United States, Europe, the Middle East, Latin America, and Asia. The Company received approval to sell its Motiva Implants in the United States in September 2024 and Motiva Flora Tissue Expanded in October 2023. The revenue derived in the United States prior to the FDA approvals consisted of microtransponder sales.

For the year ended December 31, 2025, the United States accounted for 21.6% of consolidated revenue, and no other individual country exceeded 10% of consolidated revenue, on a ship-to-destination basis. For the year ended December 31, 2024, no individual country exceeded 10% of consolidated revenue, on a ship-to-destination basis. For the year ended December 31, 2023, Brazil accounted for 13.3%, respectively, of consolidated revenue

and no other individual country exceeded 10% of consolidated revenue, on a ship-to destination basis.

The majority of the Company's consolidated total assets, including cash and tangible assets, is held in the United States. The Company's long-lived assets, which primarily consist of property and equipment and intangible assets located in Costa Rica represented 73% and 78% of the total long-lived assets as of December 31, 2025 and 2024, respectively.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant accounting estimates and management judgments reflected in the consolidated financial statements include items such as accounts receivable valuation and allowances, inventory valuation and allowances, valuation of acquired intangible assets, valuation of long-lived assets, valuation of stock grants and valuation of deferred income tax assets, including tax valuation allowances. Estimates are based on historical experience, where applicable, and other assumptions believed to be reasonable by management. Actual results may differ from those estimates under different assumptions or conditions.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash and accounts receivable. The majority of the Company's cash is held at two financial institutions in the United States. Balances in the Company's cash accounts exceed the Federal Deposit Insurance Corporation, or FDIC, limit of $250,000. The Company has not experienced any losses to its deposits of cash.

Substantially all of the Company's revenue has been derived from sales of its products in international markets, principally Europe, the Middle East, Latin America, and Asia. In the international markets in which the Company operates, the Company uses a combination of distributors and direct sales to customers. The Company performs ongoing credit evaluations of its distributors and customers, does not require collateral, and maintains allowances for potential credit losses on customer accounts when deemed necessary.

Substantially all of the Company's revenues were derived from the sale of Motiva Implants. During the years ended December 31, 2025, 2024 and 2023, no customer accounted for more than 10% of the Company's revenue. One customer accounted for 14.1% of the Company's trade accounts receivable balance as of December 31, 2025. One customer accounted for 17.0% of the Company's trade accounts receivable balance as of December 31, 2024.

The Company relies on Avantor, Inc. (formerly NuSil Technology, LLC), or Avantor, as the sole supplier of medical-grade silicone used in Motiva Implants. During the years ended December 31, 2025, 2024 and 2023, the Company had purchases of $31.6 million, or 55.8% of total purchases, $29.2 million, or 44.7% of total purchases, and $53.7 million, or 68.4% of total purchases, respectively, from Avantor. As of December 31, 2025 and 2024, the Company had an outstanding balance owed to this vendor of $8.9 million and $15.0 million, respectively.

The Company's financial condition and future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, unfavorable economic conditions, uncertainty of continued or new regulatory approval for the Company's current and potential future products, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, access to capital, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearance from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company is denied clearance, clearance is delayed, or if the Company is unable to maintain its existing clearances, these developments could have a material adverse impact on the Company.

Cash and Cash Equivalents

The Company's cash consists of cash maintained in checking and interest-bearing accounts. The majority of the Company's cash is held at two financial institutions in the United States, with balances in excess of FDIC

insurance limits. The Company accounts for financial instruments with original maturities of three months or less at the date of purchase as cash equivalents. The Company held no cash equivalents as of December 31, 2025. The Company held $3.0 million cash equivalents as of December 31, 2024.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable balance is stated at invoice value less estimated allowances for returns and credit losses. The Company continually monitors customer payments and maintains an allowance for estimated losses resulting from customers' inability to make required payments. In evaluating the Company's ability to collect outstanding receivable balances, the Company considers various factors including the age of the balance, the creditworthiness of the customer, which is assessed based on ongoing credit evaluations and payment history, and the customer's current financial condition. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, an allowance is recorded against amounts due, which reduces the net recognized receivable to the amount reasonably believed to be collectible.

A roll-forward of the allowance for credit losses is as follows:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Beginning balance	$ 3,088	$ 1,841	$ 741
Provision for credit losses	3,352	1,722	1,223
Recoveries (write-offs)	395	(475)	(123)
Ending balance	$ 6,835	$ 3,088	$ 1,841

Inventory and Cost of Revenue

Inventory is stated at the lower of cost to purchase or manufacture the inventory or the net realizable value of such inventory. Cost is determined using the standard cost method which approximates actual costs using the first-in, first-out basis. The Company regularly reviews inventory quantities, actual losses, projected future demand, and remaining shelf life to record a provision for obsolete and/or damaged inventory.

A roll-forward of the inventory reserve is as follows:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Beginning balance	$ 4,177	$ 3,930	$ 2,649
Provision for inventory obsolescence	2,646	1,805	1,392
Write-offs	(2,915)	(1,558)	(111)
Ending balance	$ 3,908	$ 4,177	$ 3,930

The Company recognizes the cost of inventory transferred to the customer in cost of revenue when revenue is recognized.

Leases

The Company determines if an arrangement is, or contains, a lease at the inception date of the contract. The Company has elected an expedient to account for each separate lease component and its associated non-lease components as a single lease component for the majority of its asset classes.

The lease term may include periods covered by options to extend or terminate the lease when it is reasonably certain that the Company will exercise a renewal option, or reasonably certain it will not exercise an early termination option. The Company recognizes lease liabilities and right-of-use, or ROU, assets upon commencement for all material leases with a term greater than 12 months. The Company has elected an expedient not to recognize leases with a lease term of 12 months or less on the balance sheet. These short-term leases are expensed on a straight-line basis over the lease term.

Shipping and Handling Costs

Shipping and handling costs are expensed as incurred and are included in selling, general and administrative, or SG&A, expenses. For the years ended December 31, 2025, 2024 and 2023, shipping and handling costs were $13.0 million, $7.2 million and $11.8 million, respectively.

Revenue Recognition

The Company recognizes revenue related to sales of products to distributors or directly to customers in markets where it has regulatory approval, net of discounts and allowances. The Company recognizes revenue in accordance with Accounting Standards Codification, or ASC, *Revenue from Contracts with Customers (Topic 606)*. ASC 606 requires the Company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services.

The Company recognizes revenue related to the sales of products to distributors at the time of shipment of the product, which represents the point in time when the distributor has taken ownership and assumed the risk of loss, and the required revenue recognition criteria are satisfied. The Company's distributors are obligated to pay within specified terms regardless of when, or if, they sell the products. The Company's contracts with distributors typically do not contain right of return or price protection and have no post-delivery obligations.

The Company recognizes revenue when title to the product and risk of loss transfer to customers, provided there are no remaining performance obligations required of the Company or any written matters requiring customer acceptance. The Company allows for the return of products from direct customers in certain regions in limited instances within 15 to 60 days after the original sale and records estimated sales returns as a reduction of sales in the same period revenue is recognized. Appropriate reserves are established for anticipated sales returns based on historical experience, recent gross sales and any notification of pending returns. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period is recorded. As of December 31, 2025 and 2024, an allowance of $1.9 million and $0.4 million was recorded for product returns, respectively. Taxes collected from customers for remittance to governmental authorities are excluded from net sales.

A portion of the Company's revenue is generated from the sale of consigned inventory maintained at physician, hospital, or clinic locations. For these products, revenue is recognized at the time the Company is notified by the consignee that the product has been implanted, not when the consigned products are delivered to the consignee's warehouse.

Revenue was generated in these primary geographic markets:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
EMEA (Europe / Middle East / Africa)	$ 91,052	$ 78,209	$ 80,150
Latin America	39,926	34,998	48,891
Asia-Pacific	34,541	48,408	33,953
North America	45,557	4,410	2,157
Total revenue	$ 211,076	$ 166,025	$ 165,151

The Company has a limited warranty for the shelf life of breast implants, which is five years from the time of manufacture. Estimated warranty obligations are recorded at the time of sale. The Company also offers a warranty to patients in the event of rupture and a replacement program for capsular contracture events, provided certain registration requirements are met. Revenue for extended warranties is recognized ratably over the term of the agreement. To date, these warranty and program costs have been de minimis. The Company will continue to evaluate the warranty reserve policies for adequacy considering claims history.

Deferred revenue primarily consists of payments received in advance of meeting revenue recognition criteria. The Company has received payments from distributors to provide distribution exclusivity within a geographic area and recognizes revenue on a ratable basis over the term of such contractual distribution relationship. Additionally, the Company has received payments from customers in direct markets prior to surgical implantation and recognizes deferred revenue at the time the Company is notified by the customer that the product has been implanted. For all arrangements, any revenue that has been deferred and is expected to be recognized beyond one year is classified as long-term deferred revenue and included in “Other liabilities, long-term” on the consolidated balance sheets (see Note 3).

Research and Development

Costs related to research and development, or R&D, activities are expensed as incurred. R&D costs primarily include personnel costs, materials, clinical expenses, regulatory expenses, product development, consulting services, and outside research activities, all of which are directly related to research and development activities.

The Company estimates IDE clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Selling, General and Administrative Expenses

SG&A expenses include sales and marketing costs, payroll and related benefit costs, insurance expenses, shipping and handling costs, legal and professional fees and administrative overhead.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization.

The Company depreciates owned buildings on a straight-line basis over 50 years of useful life. Depreciation of property and equipment is computed using the straight-line method over the assets’ estimated useful lives of five to ten years. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the remaining lease term after factoring expected renewal periods. Upon retirement or disposal of assets, the costs and related accumulated depreciation are eliminated from the accounts and any gain or loss is recognized in operations. Maintenance and repairs are expensed as incurred. Substantially all of the

Company's manufacturing operations and related property and equipment are located in Costa Rica.

Goodwill and Intangible Assets

The Company records the excess of the acquisition purchase price over the net fair value of the tangible and identifiable intangible assets acquired and liabilities assumed as goodwill. In accordance with ASC 350, *Intangibles - Goodwill and Other,* the Company tests goodwill for impairment annually during the fourth quarter of each year and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. In connection with the annual impairment test for goodwill, the Company elected the option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If the Company determines that it was more likely than not that the fair value of the reporting unit is less than its carrying amount, then the impairment test is performed.

Consistent with the Company's assessment that it has only one reporting segment, the Company has determined that it has only one reporting unit and tests goodwill for impairment at the entity level using the two-step process required by ASC 350. In the first step, the Company compares the carrying amount of the reporting unit to the fair value of the enterprise. If the fair value of the enterprise exceeds the carrying value, goodwill is not considered impaired and no further testing is required. If the carrying value of the enterprise exceeds the fair value, goodwill is potentially impaired, and the second step of the impairment test must be performed. In the second step, the Company compares the implied fair value of the goodwill, as defined by ASC 350, to its carrying amount to determine the impairment loss, if any.

The Company capitalizes certain costs related to intangible assets, such as patents, trademarks and software development costs. The Company follows the provisions of ASC 350-40, *Internal Use Software* for determining whether computer software is internal-use software and on accounting for the costs of computer software originally developed or obtained for internal use. The Company expenses all costs incurred during the preliminary project stage of software development and capitalizes the costs incurred during the application development stage. Costs incurred relating to upgrades and enhancements to the software are capitalized if it is determined that these upgrades or enhancements add additional functionality to the software. Costs incurred to improve and support products after they become available are charged to expense as incurred.

The Company records purchased intangible assets at their respective estimated fair values at the date of acquisition. Purchased finite-lived intangible assets are being amortized using the straight-line method over their remaining estimated useful lives, which range from one to ten years. The Company evaluates the remaining useful lives of intangible assets on a periodic basis to determine whether events or circumstances warrant a revision to the remaining estimated amortization period. The Company tests indefinite-lived intangible assets for impairment on at least an annual basis and whenever circumstances suggest the assets may be impaired. If indicators of impairment are present, the Company evaluates the carrying value of the intangible assets in relation to estimates of future undiscounted cash flows. The Company also evaluates the remaining useful life of an indefinite-lived intangible asset to determine whether events and circumstances continue to support an indefinite useful life.

During the years ended December 31, 2025, 2024 and 2023, there has been no impairment of goodwill or intangible assets based on the qualitative assessments performed by the Company.

Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. There were no impairment charges, or changes in estimated useful lives recorded during the years ended December 31, 2025, 2024 and 2023.

Debt Issuance Costs and Debt Discounts

Costs incurred in connection with the issuance of new debt are capitalized. Capitalizable debt issuance costs paid to third parties and debt discounts, net of amortization, are recorded as a reduction to the long-term debt balance

on the consolidated balance sheets. Amortization expense on capitalized debt issuance costs and debt discounts related to loans are calculated using the effective interest method over the term of the loan commitment and is recorded as interest expense in the consolidated statements of operations.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the financial reporting and tax bases of assets and liabilities, and for operating loss and tax credit carryforwards. Deferred tax balances are measured using enacted tax laws and rates expected to apply when the related temporary differences reverse. The Company establishes a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company operates in multiple tax jurisdictions and is subject to examination by various tax authorities. The Company recognizes uncertain tax positions using a two-step approach: (1) a tax position is recognized only if it is more likely than not to be sustained based on its technical merits, and (2) the amount recognized is the largest amount of benefit that is more than 50% likely to be realized upon settlement. Interest and penalties related to uncertain tax positions are recorded in income tax expense. There were no material uncertain tax positions in the years ended December 31, 2025, 2024 and 2023.

Effective January 1, 2025, the Company adopted ASU 2023-09, *Improvements to Income Tax Disclosure*s, on a prospective basis. As a result, our income tax disclosures now include enhanced disaggregation of income taxes paid and a standardized effective tax rate reconciliation, as required by the amended guidance. The adoption did not affect our accounting for income taxes under ASC 740.

Foreign Currency

The financial statements of the Company's foreign subsidiaries whose functional currencies are the local currencies are translated into U.S. dollars for consolidation as follows: assets and liabilities at the exchange rate as of the balance sheet date, shareholders' equity at the historical rates of exchange, and income and expense amounts at the average exchange rate for the period. Translation adjustments resulting from the translation of the subsidiaries' accounts are included in "Accumulated other comprehensive income" as equity in the consolidated balance sheet. Transactions denominated in currencies other than the applicable functional currency are converted to the functional currency at the exchange rate on the transaction date. At period end, monetary assets and liabilities are remeasured to the functional currency using exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities are remeasured at historical exchange rates. Gains and losses resulting from foreign currency transactions are included within "Other income (expense), net" in the consolidated statement of operations. For the years ended December 31, 2025, 2024 and 2023, foreign currency transaction gain/loss amounted to a gain of $6.4 million, a loss of $8.8 million and a gain of $1.8 million, respectively.

Contract Termination Costs

From time to time the Company may settle certain contracts with third parties. In the second quarter of 2025, the Company terminated a contract with a supplier of raw materials and recorded a $0.5 million loss on contract termination. In the fourth quarter of 2024, the Company entered into a contract termination agreement with a third-party in connection with its Mia products in Europe. In lieu of a cash settlement, the Company and the third-party agreed to settle previous amounts incurred by each respective party from separate and unrelated contracts. As of December 31, 2024, the Company recorded a $1.5 million liability for contract termination payments resulting in a total loss on contract termination of $6.0 million reported under "Other income (expense), net". There were no such costs in the years ended December 31, 2023.

Comprehensive Loss

The Company's comprehensive loss consists of net loss and foreign currency translation adjustments arising from the consolidation of the Company's foreign subsidiaries.

Share-Based Compensation

The Company measures and recognizes compensation expense for all share-based awards in accordance with the provisions of ASC 718, *Stock Compensation*. Share-based awards granted include stock options, restricted stock units, or RSUs, and restricted stock awards, or RSAs. Share-based compensation expense for stock

options, RSUs and RSAs granted to employees is measured at the grant date based on the fair value of the awards and is recognized as an expense ratably on a straight-line basis over the requisite service period. The fair value of options to purchase shares is estimated on the grant date using the Black-Scholes option valuation model.

The calculation of share-based compensation expense requires the Company to make assumptions and judgments about the variables used in the Black-Scholes model, including the expected term, expected volatility of the underlying common shares, risk-free interest rate and dividends.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) attributable to shareholders by the weighted-average number of shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, any shares issuable upon exercise of warrants, stock options and non-vested RSUs or RSAs outstanding under the Company's equity plan are potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for periods where the Company reported a net loss because including the dilutive securities would be anti-dilutive.

Recent Accounting Standards

Periodically, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements upon adoption.

Recently Adopted Accounting Standards

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topics 740): Improvements to Income Tax Disclosures*, which enhances the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid and certain other amendments to improve the effectiveness of income tax disclosures. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company adopted ASU 2023-09 as of December 31, 2025 on a prospective basis. Upon adoption, the Company expanded disclosures under Note 12, "Income Taxes".

Recently Issued Accounting Standards

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which enhances disclosure requirements over the disaggregation of relevant expense categories within the income statement. The new guidance requires tabular presentation of prescribed expense categories such as the purchases of inventory, employee compensation, depreciation, intangible asset amortization, and other specific expense, gains and losses required by existing GAAP, that reconciles to the face of the income statement. It is effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating the potential effect that the updated standard will have on the financial statement disclosures.

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2025, 2024 and 2023

3. Balance Sheet Accounts

Inventory, Net

	December 31,	
	2025	2024
	(in thousands)	
Raw materials	$ 35,161	$ 41,310
Work in process	2,842	2,454
Finished goods	47,608	35,002
Total inventory, net	$ 85,611	$ 78,766

As of December 31, 2025 and 2024, $14.1 million and $9.0 million of inventory was on consignment, respectively.

Prepaid Expenses and Other Current Assets

	December 31,	
	2025	2024
	(in thousands)	
Prepaid insurance	$ 3,072	$ 2,768
Prepaid services	653	571
Prepaid taxes	1,392	458
Prepaid assets	1,629	505
Prepaid raw materials and accessories	384	1,005
Prepaid U.S. clinical trial costs	120	184
Prepaid warranty and distribution rights	379	409
Prepaid software	1,146	408
Other	2,485	2,614
Total prepaid expenses	$ 11,260	$ 8,922

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
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Property and Equipment, Net

	December 31,	
	2025	2024
	(in thousands)	
Machinery and equipment	$ 23,083	$ 22,764
Building improvements	17,361	16,902
Furniture and fixtures	17,645	14,772
Building	37,227	37,227
Leasehold improvements	2,537	2,516
Land	3,694	3,694
Vehicles	281	269
Total	101,828	98,144
Less: Accumulated depreciation and amortization	(26,213)	(20,116)
Total property and equipment, net	$ 75,615	$ 78,028

For the years ended December 31, 2025, 2024 and 2023, depreciation and amortization expense related to property and equipment was $6.2 million, $4.7 million and $2.8 million, respectively.

In August 2021, the Company entered into a contract with the Zona Franca Coyol, S.A., or ZFC, to begin construction of a new manufacturing facility in the Coyol Free Zone, or the CFZ, in Costa Rica. The construction for this facility was completed in June 2024. The Company also has the option to buy an adjacent lot of land for approximately $2.8 million and engage ZFC to construct an additional manufacturing facility.

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2025, 2024 and 2023

Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Performance bonus	$ 6,703	$ 6,235
Payroll and related expenses	5,129	4,832
Operating lease liabilities - current	1,712	1,514
Commissions	1,889	1,312
Professional and legal services	1,891	876
Warranty reserve	288	141
Taxes	377	153
Other	867	1,473
Total accrued liabilities	$ 18,856	$ 16,536

Other Liabilities, Short-Term

Other liabilities, short-term consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Deferred revenue	$ 1,208	$ 1,749
Borrowings of short term notes payable for purchases of silicone raw material	10,000	—
Borrowings of short term notes payable for insurance premium financing	2,413	—
Consideration payable for business acquisitions	315	2,774
Contingent consideration payable for business acquisitions	4,474	737
Other	1,767	1,722
Total other liabilities, short-term	$ 20,177	$ 6,982

The Company signed an Inventory Funding Agreement, or Funding Agreement, on May 23, 2025, with RTW Master Fund, LTD., RTW Innovation Master Fund, LTD., and RTW Biotech Opportunities Operating LTD, collectively referred to as the Funding Providers, and RTW Investments, LP, as the funding representative, to finance purchases of silicone raw material to support the manufacture of Motiva Implants in an aggregate amount not to exceed $10.0 million in a funding period. Under the Funding Agreement, the Funding Providers will finance, upon request, eligible invoices at a 12.0% annual interest rate for an initial four-month term, or a later date if agreed by the Funding Providers in writing in their sole discretion. The Company drew $5.0 million at each of June 20, 2025 and September 26, 2025 and recorded this liability in “Other Liabilities, Short-Term”. On September 25, 2025, the Funding Agreement was amended to extend the due date for the amount received in June 2025 to May 15, 2026.

During fiscal 2025, the Company entered into short-term insurance premium financing arrangements to fund the payment of business insurance premiums. The aggregate financing provided under these arrangements totaled approximately $3.4 million and bears interest at rates ranging from approximately 7.7% to 8.3% per annum. The borrowings are short-term in nature and mature within ten months of issuance.

Other Liabilities, Long-Term

Other liabilities, long-term consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Deferred revenue	$ 1,136	$ 1,124
Consideration payable for business acquisitions	—	278
Contingent consideration payable for business acquisitions	—	174
Other	—	102
Total other liabilities, long-term	$ 1,136	$ 1,678

4. Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. Intangible assets resulting from the acquisitions of entities accounted for using the acquisition method of accounting are recorded at the estimated fair value of the assets acquired. Purchased intangibles include certain patents and license rights, 510(k) authorization by the FDA to sell a medical device and other intangible assets.

The Company's goodwill and most intangibles at December 31, 2025 are the result of previous asset and business acquisitions. Finite-lived intangibles are amortized over their estimated useful lives based on expected future benefit.

In addition to the intangibles acquired, the Company capitalized certain patent and license rights as identified intangibles based on patent and license rights agreements entered into over the past several years. Additionally, the Company capitalized certain software development costs.

Changes in the carrying amount of goodwill during the year ended December 31, 2025 were as follows:

	Balance as of January 1, 2025	Additions	Accumulated Impairment Losses	Balance as of December 31, 2025
	(in thousands)			
Goodwill	$ 1,209	$ —	$ —	$ 1,209

ESTABLISHMENT LABS HOLDINGS, INC.

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The carrying amounts of these intangible assets other than goodwill as of December 31, 2025 were as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Estimated Useful Lives
		(in thousands)		(in years)
Patents and license rights	$ 2,033	$ (1,593)	$ 440	7-12
Customer relationships	3,658	(2,142)	1,516	4-10
510(k) authorization	567	(481)	86	15
Developed technology	62	(62)	—	10
Capitalized software development costs	14,678	(7,480)	7,198	2-5
Other	183	(92)	91	2-5
Capitalized software development costs not yet amortized	170	—	170	
Patents and license rights not yet amortized	441	—	441	
Total intangibles other than goodwill	$ 21,792	$ (11,850)	$ 9,942	

The carrying amounts of intangible assets other than goodwill as of December 31, 2024 were as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Estimated Useful Lives
		(in thousands)		(in years)
Patents and license rights	$ 2,033	$ (1,509)	$ 524	7-12
Customer relationships	3,466	(1,997)	1,469	4-10
510(k) authorization	567	(345)	222	15
Developed technology	62	(62)	—	10
Capitalized software development costs	13,559	(4,839)	8,720	2-5
Other	183	(91)	92	2-5
Capitalized patents and license rights not yet amortized	215	—	215	
Patents and license rights not yet amortized	441	—	441	
Total intangibles other than goodwill	$ 20,526	$ (8,843)	$ 11,683	

The amortization expense associated with intangible assets was $3.3 million, $2.1 million, $1.2 million for the years ended December 31, 2025, 2024 and 2023, respectively. Non-product related amortization is recorded in SG&A while product related amortization is recorded in cost of revenue.

As of December 31, 2025, the amortization expense related to identifiable intangible assets, with definite useful lives, in future periods is expected to be as follows:

Year Ending December 31,	(in thousands)
2026	$ 2,877
2027	2,314
2028	1,951
2029	950
2030	258
Thereafter	981
Total expected future amortization expense	$ 9,331

The Company evaluates the recoverability of goodwill and indefinite-lived intangible assets annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. During the three years ended December 31, 2025, there was no impairment of goodwill or intangible assets based on the qualitative assessments performed by the Company. As of December 31, 2025, no triggering events have occurred which would indicate that the acquired intangible asset values may not be recoverable.

5. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or an exit price 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 fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy at December 31, 2025 and 2024:

	Fair Value Measurements at December 31, 2025			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Liabilities				
Acquisition-related contingent consideration	$ 4,474	—	—	$ 4,474

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Liabilities				
Acquisition-related contingent consideration	$ 973	—	—	$ 973

The fair value measurement of contingent consideration related to the business acquisition completed in fiscal 2024 represents the contingent consideration arrangement from the Company's acquisition of Motiva Benelux BV, a distribution company in Belgium, and Motiva NL B.V., a distribution company in the Netherlands, on October 1, 2024. Under this contingent consideration arrangement, the Company is required to pay the former owners an amount equal to the total revenue for fiscal year 2024 and 2025 multiplied by a multiple based on the relevant revenue growth rate realized in that particular fiscal year versus the prior year (ratio ranges from 0.5 to 0.9). The potential undiscounted amount of all future contingent payments that the Company could be required to make is not capped.

The fair value of the contingent consideration arrangement of $4.5 million as of December 31, 2025 was calculated using these inputs: (a) 2025 actual revenue of approximately $9.5 million; (b) growth ratio of 0.9 based on average revenue growth over the last two years; and (c) the fact that operating expense targets were met. The Company retains the option to settle the outstanding liability either in cash or in the Company's common shares.

The fair value of the contingent consideration arrangement of $1.0 million as of December 31, 2024 was estimated by applying the income approach which used significant inputs that are not observable in the market and thus represents a Level 3 measurement. Key assumptions included (a) a discount rate of 12.5 percent; (b) 2024 revenue of approximately $6.0 million (actual, assumed to be reliably forecasted as of the date of valuation); (c) 2025 revenue forecasted using a normal distribution with approximately $6.4 million as the base case and a range determined based on volatility of 10%; and (d) an assumption that operating expense targets will be met. The Company settled the outstanding liability in early fiscal 2025. See Note 11 for additional information on the business acquisition.

The estimates are based, in part, on subjective assumptions and could differ materially in the future. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2025 and 2024.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows:

	Acquisition-related Contingent Consideration
	(in thousands)
Balance at December 31, 2024	$ 973
Settlement	(787)
Additional liability	4,277
Change in fair value	11
Balance at December 31, 2025	$ 4,474

6. Debt

Oaktree Debt

On April 26, 2022, or the Closing Date, the Company entered into a Credit Agreement and Guaranty, or the Credit Agreement, together with certain of its subsidiaries party thereto as guarantors, the lenders from time to time party thereto, or the Lenders, and Oaktree Fund Administration, LLC, as administrative agent for the Lenders, or the Administrative Agent, pursuant to which the Lenders agreed to make term loans to the Company in an aggregate principal amount of up to $225 million, or collectively, the Term Loans.

On February 21, 2024, the Company entered into a Second Amendment to the Credit Agreement, or the Second Amendment, which amends terms applicable to the two remaining available tranches during the date of agreement, Tranche C Term Loans and Tranche D Term Loans. The terms of the Tranche A Term Loans and Tranche B Term Loans were not modified.

On November 7, 2024, the Company entered into a Third Amendment to the Credit Agreement, or the Third Amendment, which amends terms applicable to the remaining available tranche during the date of agreement, Tranche D Term Loans. The terms of the Tranche A Term Loans, Tranche B Term Loans and Tranche C Term Loans were not modified.

On September 29, 2025, the Company entered into a Fourth Amendment to the Credit Agreement, or the Fourth Amendment, which provides for the availability of the Tranche D Term Loans to commence as of the effective date of the amendment, notwithstanding the revenue milestone originally set forth in the Agreement, and (ii) increases, effective September 28, 2025, the minimum liquidity that the Company and its subsidiaries are guarantors under the Agreement are required to maintain from $25 million to $30 million.

Pursuant to the terms of the Credit Agreement, the Term Loans will be advanced in four tranches:

- The first tranche, or the Tranche A Term Loan, was advanced in the amount of $150 million on the Closing Date. A portion of the first tranche was used to repay the outstanding principal and interest under the Company's credit agreement with Madryn Health Partners, LP, as administrative agent, and a syndicate of lenders in full, including the early repayment penalty of $6.5 million.
- The second tranche, or the Tranche B Term Loan, of $25 million was advanced in December 2022 at the Company's election upon satisfaction of specified gross sales thresholds and subject to the other terms and conditions of the Credit Agreement.
- The third tranche, or the Tranche C Term Loan, of $25 million was advanced in October 2024 at the Company's election following the Administrative Agent's receipt of evidence that specified FDA's approval of Motiva Implants for augmentation use in the United States had been issued, subject to the other terms and conditions of the Credit Agreement and the Second Amendment.
- The fourth tranche, or the Tranche D Term Loan, of $25 million was advanced in September 2025 at the Company's election following the Fourth Amendment, subject to the other terms and conditions of the Credit Agreement, as amended.

The Term Loans will mature on the 5-year anniversary of the Closing Date, or the Maturity Date. The Term Loans accrue interest at a rate equal to 9% per annum for Tranche A and Tranche B, 10% per annum for Tranche C and Tranche D, or, at any time following the Tranche C Funding Milestone and the Administrative Agent's receipt of evidence that a gross sale threshold of $225 million in trailing twelve month gross sales have been met, 8.25% per annum. Accrued interest is due and payable in cash on the last business day of March, June, September, and December of each year; provided, however, that prior to the second anniversary of the Closing Date, the Company may pay an amount of interest on the outstanding Tranche A Term Loans and Tranche B Term Loans corresponding to 600 basis points of the interest rate in kind, or PIK, on each applicable payment date, subject to prior written notice delivered to the Administrative Agent, which has been delivered. Each of the Term Loans will be subject to the original issue discount of 2% of the principal amount thereof upon the drawing of each applicable tranche. Upon any payment or prepayment in full or in part of the Term Loans, whether voluntary or involuntary, the Company is required to pay an exit fee equal to 3% of the principal amount of the Term Loan paid, or the Exit Fee.

The Company may elect to prepay all or any portion of the amounts owed prior to the Maturity Date, provided that the Company provides notice to the Administrative Agent, the amount is not less than $5 million, and the amount is accompanied by all accrued and unpaid interest thereon through the date of prepayment, plus the applicable yield protection premium and the applicable Exit Fee. Prepayments of the Tranche A Term Loans and Tranche B Term Loans prior to the second anniversary of the Closing Date, or prepayments of the Tranche C Term Loans or Tranche D Term Loans prior to the one-year anniversary of the applicable funding date will be accompanied by a yield protection premium equal to the sum of all interest that would have accrued through such second anniversary plus 4% of the principal amount so prepaid. Prepayments of the Term Loans after the second anniversary of the Closing Date in the case of Tranche A Term Loans and Tranche B Term Loans or the one year anniversary of the applicable funding date in the case of the Tranche C Term Loans and the Tranche D Term Loans but before, in each case, the third anniversary of the Closing Date, will be accompanied by a yield protection premium equal to 4% of the principal amount so prepaid if made prior to the third anniversary of the Closing Date, 2% if made on or after the 3rd anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, and 0% if made on or after the 4th anniversary of the Closing Date. If the Term Loans are accelerated following the occurrence of an event of default, the Company shall immediately pay to Lenders the sum of all obligations for principal, accrued interest, the applicable yield maintenance premium and the applicable Exit Fee. Under the Second Amendment, Tranche D Term Loans were modified to provide for a make whole plus 4% for any prepayments of the Tranche C Term Loans and Tranche D Term Loans during the one year period after their advance. The existing prepayment premium schedule was otherwise preserved. The Third Amendment did not modify the prepayment premium schedule.

Pursuant to the Credit Agreement, the obligations of the Company are guaranteed by its subsidiaries that are party thereto as guarantors. On the Closing Date, the Company and such subsidiaries entered into a U.S. Security Agreement in favor of the Administrative Agent on behalf of Lenders, or the U.S. Security Agreement. Pursuant to the U.S. Security Agreement, the Company and its subsidiaries party thereto granted the Administrative Agent a security interest in substantially all of its personal property, rights and assets to secure the payment of all amounts owed to Lenders under the Credit Agreement.

The Credit Agreement contains customary affirmative and restrictive covenants and representations and warranties. The Company and its subsidiaries are bound by certain affirmative covenants setting forth actions that are required during the term of the Credit Agreement, including, without limitation, certain information delivery requirements, obligations to maintain certain insurance, and certain notice requirements. Additionally, the Company and its subsidiaries are bound by certain restrictive covenants setting forth actions that are not permitted to be taken during the term of the Credit Agreement without prior written consent, including, without limitation, incurring certain additional indebtedness, consummating certain mergers, acquisitions or other business combination transactions, or incurring any non-permitted lien or other encumbrance on the assets of the Company or any of its subsidiaries. The Credit Agreement also contains other customary provisions, such as confidentiality obligations and indemnification rights for the benefit of Lenders. The Credit Agreement contains financial covenants requiring (a) the Company to maintain minimum liquidity of at least $20 million from and after the Closing Date or $25 million from and after the funding of the Tranche B Term Loans, and (b) for each fiscal quarter until gross sales of the Company and its subsidiaries for any 12-consecutive month period are no less than $200 million, minimum gross sales of the Company and its subsidiaries for each consecutive 12-month period ending on the last day of each fiscal quarter in excess of 50% of specified target gross sales for such period. The Credit Agreement provides for a customary equity cure right in the event the Company fails to comply with the minimum gross sales covenant.

The effective interest rate under the Credit Agreement is 10.9%, and the weighted average interest rate is 9.2%. The Company elected to pay interest in kind on up to two-thirds of cash interest payments prior to the second anniversary of the Closing Date, resulting in a minimum initial cash interest rate of 3.0% for the Tranche A Term Loans and Tranche B Term Loans and 4.0% for the Tranche C Term Loans. The Company incurred $24.5 million, $21.1 million and $16.9 million in interest expense in connection with the Credit Agreement during the years ended December 31, 2025, 2024 and 2023, respectively. No principal payments are due on the Term Loans until the final maturity date on April 26, 2027.

As of December 31, 2025, $246.4 million was outstanding under the Credit Agreement representing the initial principal of $150 million for the Tranche A Term Loan, $25 million for the Tranche B Term Loan, $25 million for the

Tranche C Term Loan, $25 million for the Tranche D Term Loan and $21.4 million of interest accrued into the principal balance.

The Company recorded Oaktree debt on the consolidated balance sheets as follows:

	December 31,	
	2025	2024
	(in thousands)	
Principal	$ 246,367	$ 221,367
Net unamortized prepayment premium (debt discount and issuance costs)	1,155	(1,790)
Net carrying value of Oaktree debt	$ 247,522	$ 219,577

As of December 31, 2025, the Company was in compliance with all financial debt covenants.

7. Leases

The Company recognizes lease liabilities and ROU assets upon commencement for all material leases with a term greater than 12 months. The Company has elected an expedient not to recognize leases with a lease term of 12 months or less on the balance sheet. These short-term leases are expensed on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date of the lease based on the present value of lease payments over the lease term. When the rate implicit to the lease cannot be readily determined, the Company utilizes its incremental borrowing rate in determining the present value of the future lease payments. Lease liabilities are accreted each period and reduced for payments. The ROU asset also includes other adjustments, such as for the effects of escalating rents, rent abatement or initial lease costs. The lease term may include periods covered by options to extend or terminate the lease when it is reasonably certain that the Company will exercise a renewal option, or reasonably certain it will not exercise an early termination option. For operating leases, lease expense for minimum lease payments is recognized on a straight-line basis over the expected lease term. For finance leases, the ROU asset depreciates on a straight-line basis over the shorter of the lease term or useful life of the ROU asset and the lease liability accretes interest based on the interest method using the discount rate determined at lease commencement. The Company's finance leases are not material.

The Company has operating leases for facilities and office spaces. Operating lease assets and the related lease liabilities are included within the ROU operating lease assets on the consolidated balance sheets. The determination of whether an arrangement is, or contains, a lease is performed at the inception of the arrangement. The Company has operating leases for certain facilities and office spaces to be used in its operations, with remaining lease terms ranging from monthly to 6 years. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include renewal options at the election of the Company to renew or extend the lease for additional years. These optional periods have not been considered in the determination of the ROU or lease liabilities associated with these leases as management did not consider it reasonably certain it would exercise the options.

During the years ended December 31, 2025, 2024 and 2023, the Company earned income from subleasing a warehouse facility for the remaining life of an existing master lease. The sublease agreement did not release the Company from its obligations under the master lease, and no modifications were made to the lease agreement. Income from the sublease is recognized on a straight-line basis over the term of the agreement.

The Company's lease and sublease agreements do not contain any termination options, material residual value guarantees, material bargain purchase options or material restrictive covenants. The Company does not have any lease transactions with related parties.

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2025, 2024 and 2023

Total lease cost includes the following components for the years ended December 31, 2025, 2024 and 2023:

	2025	2024	2023
		(in thousands)	
Operating lease expense cost	$ 2,113	$ 1,481	$ 1,079
Sublease income	(311)	(311)	(233)
Total lease cost, net of sublease income	$ 1,802	$ 1,170	$ 846

	December 31,	
	2025	2024
	(in thousands)	
Supplemental balance sheet information		
Operating lease right-of-use assets	$ 4,339	$ 5,561
Operating lease liabilities - short-term	1,712	1,514
Operating lease liabilities - long-term	2,820	4,203
Total operating lease liabilities	$ 4,532	$ 5,717
Weighted-average remaining lease term (years)		
Operating leases	2.7	3.4
Weighted-average discount rate (%)		
Operating leases	11.2 %	11.1 %

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash outflows from operating leases	$ 2,117	$ 1,384	$ 1,052
Operating cash inflows from subleases	(332)	(320)	(214)
Operating cash outflows from operating leases, net of sublease income	$ 1,785	$ 1,064	$ 838
ROU assets obtained in exchange for new lease liabilities			
Operating leases	$ 335	$ 3,115	$ 478

Maturities of lease liabilities as of December 31, 2025 were as follows:

Years Ending December 31,	Operating Leases (in thousands)
2026	$ 2,097
2027	1,807
2028	948
2029	459
2030	86
Thereafter	37
Total future minimum lease payments	5,434
Less: Amount of lease payments representing interest	(902)
Present value of future minimum lease payments	$ 4,532

The undiscounted future cash receipts from the Company's sublease as of December 31, 2025 were as follows:

Years Ending December 31,	Sublease (in thousands)
2026	$ 343
2027	355
2028	368
2029	316
Thereafter	—
Total undiscounted future sublease cash receipts	$ 1,382

8. Shareholders' Equity

Under the Company's Amended and Restated Memorandum of Association and Articles of Association, or Articles, the Company has authorized an unlimited number of common shares with no par value.

As of December 31, 2025 and 2024, 29,713,024 and 29,195,439 common shares, respectively, were issued and 29,304,954 and 28,787,369 common shares, respectively, were outstanding.

During the year ended December 31, 2025, the Company granted stock options and restricted stock to employees and contractors (see Note 10).

On November 7, 2024, the Company entered into a securities purchase agreement with a limited number of purchasers in connection with a registered direct offering of 765,696 common shares of the Company at a purchase price of $45.71 per share and pre-funded warrants to purchase up to 328,154 common shares at a price of $45.709 per share. On August 31, 2025, the Company issued 76,569 additional common shares and additional pre-funded warrants to purchase up to 32,814 common shares. These additional securities were issued in accordance with the securities purchase agreement for no additional consideration since the average closing price of the Company's common shares on The Nasdaq Capital Market during the period from January 1, 2025 to August 31, 2025 did not exceed $45.71, which is the price per common share sold in the offering. The pre-funded warrants issued in the offering may be exercised immediately at a price of $0.001 per share until exercised in full. Net proceeds to the Company from the offering, after deducting offering expenses, were approximately $49.7 million.

On January 9, 2024, the Company entered into a securities purchase agreement with select institutional accredited investors pursuant to which it agreed to sell to the investors in a private placement 1,101,565 common shares at a price of $25.00 per share and pre-funded warrants to purchase up to 898,435 common shares at a price of $24.999 per share. The pre-funded warrants were able to be exercised immediately at a price of $0.001 per share until exercised in full. Net proceeds to the Company from the offering, after deducting offering expenses, were approximately $49.7 million.

The Company had reserved common shares for future issuances at December 31:

	2025	2024
Warrants to purchase common shares	659,403	626,589
Options to purchase common shares	1,428,878	1,413,948
Remaining shares available under the 2018 Equity Incentive Plan	2,230,340	2,068,033
Shares issuable on vesting of grants of RSUs	331,295	295,705
Remaining shares available under the 2018 ESPP	1,409,000	1,222,000
Total common shares reserved for future issuances	6,058,916	5,626,275

9. Warrants

In January 2024, the Company issued pre-funded warrants for the purchase of up to 898,435 common shares to select institutional accredited investors at a fixed exercise price of $0.001 per share. In November 2024, the Company issued pre-funded warrants for the purchase of up to 360,968 common shares to a limited number of purchasers at a fixed exercise price of $0.001 per share.

In September 2025, the Company issued pre-funded warrants for the purchase of up to 32,814 common shares to a select investors at a fixed exercise price of $0.001 per share as part of a price protection stipulation within the securities purchase agreement entered into in November 2024.

During the year ended December 31, 2025, zero warrants were exercised. During the year ended December 31, 2024, warrants to purchase net 600,000 shares were exercised to obtain 599,991 shares.

As of December 31, 2025, warrants to purchase up to 659,403 common shares were outstanding and exercisable, as set forth in the table below. As of December 31, 2024, 626,589 warrants were outstanding and exercisable.

Warrant Holder	Issue Date	Shares	Exercise Price	Expiration Date
RTW Master Fund, Ltd.	1/9/2024	164,367	$ 0.001	*
RTW Innovation Master Fund, Ltd.	1/9/2024	134,068	$ 0.001	*
RTW Master Fund, Ltd.	11/7/2024	164,077	$ 0.001	*
RTW Innovation Master Fund, Ltd.	11/7/2024	134,543	$ 0.001	*
RTW Biotech Opportunities Operating Ltd.	11/7/2024	29,534	$ 0.001	*
RTW Master Fund, Ltd.	9/5/2025	16,407	$ 0.001	*
RTW Innovation Master Fund, Ltd.	9/5/2025	13,454	$ 0.001	*
RTW Biotech Opportunities Operating Ltd.	9/5/2025	2,953	$ 0.001	*

* The warrants are exercisable immediately and until exercised in full.

10. Share-Based Compensation

In 2015, the Board of Directors approved and adopted the 2015 Equity Incentive Plan, or 2015 Plan. Pursuant to the 2015 Plan, the Company granted RSAs and stock options to members of the Board of Directors, employees and consultants.

In 2018, the Board of Directors terminated the 2015 Plan and approved the 2018 Equity Incentive Plan, or the 2018 Plan, with an initial reserve of 1,500,000 common shares. Under the 2018 Plan, the Company may grant stock options, equity appreciation rights, RSUs and RSAs. If an award granted under the 2018 Plan expires, terminates, is unexercised, or is forfeited, or if any shares are surrendered in connection with an incentive award, the shares subject to such award and the surrendered shares become available for further awards under the 2018 Plan.

Pursuant to the “evergreen” provision contained in the 2018 Plan, the number of common shares reserved for issuance under the 2018 Plan automatically increases on first day of each fiscal year, commencing on January 1, 2019, in an amount equal to the least of (1) 750,000 shares, (2) 4% of the total number of the Company’s common shares outstanding on the last day of the preceding fiscal year, or (3) a number of common shares as may be determined by the Company’s Board of Directors prior to any such increase date. On each of January 1, 2019 through 2025 the number of common shares authorized for issuance increased automatically by 750,000 shares in accordance with the “evergreen” provision, increasing the maximum number of common shares reserved under the 2018 Plan to 6,750,000 as of December 31, 2025.

During the periods presented, the Company recorded the following share-based compensation expense for stock options, RSUs and RSAs:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Sales, general and administrative	$ 9,844	$ 12,073	$ 12,101
Research and development	1,571	2,331	2,261
Total stock compensation expense	$ 11,415	$ 14,404	$ 14,362

Stock Options

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2024	1,413,948	$ 47.96	6.30	$ 14,010
Granted (weighted-average fair value of $21.26 per share)	327,392	35.84		
Exercised	(256,696)	29.57		
Forfeited/canceled	(56,397)	52.24		
Balance at December 31, 2025	1,428,247	$ 48.16	6.16	$ 35,902

As of December 31, 2025, 902,758 options were vested and exercisable with a weighted-average exercise price of $51.00 per share and a total aggregate intrinsic value of $20.3 million.

During the year ended December 31, 2025, 256,696 options were exercised at a weighted-average price of $29.57 per share. The intrinsic value of the options exercised during the years ended December 31, 2025, 2024,

and 2023 was $9.3 million, $4.1 million, and $5.1 million, respectively. Upon the exercise of stock options, the Company issued new shares from its authorized shares.

At December 31, 2025, unrecognized compensation expense was $8.5 million related to stock options granted to employees and members of the Board of Directors and $1.8 million related to stock options granted to consultants. The weighted-average period over which such compensation expense will be recognized is 2.6 years.

Stock Options Granted to Employees

Share-based compensation expense for employees is based on the grant date fair value. The Company recognizes compensation expense for all share-based awards ratably on a straight-line basis over the requisite service period of the awards, which is generally the vesting term of four years. During the year ended December 31, 2025, 2024 and 2023, the Company recognized $5.4 million, $7.4 million and $8.7 million, respectively, of share-based compensation expense for stock options granted to employees.

The Company uses the Black-Scholes option valuation model to value options granted to employees and consultants, which requires the use of highly subjective assumptions to determine the fair value of share-based awards. The assumptions used in the Company's option-pricing model represent management's best estimates. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment. If factors change and different assumptions are used, the Company's share-based compensation expense could be materially different in the future. The assumptions and estimates that the Company uses in the Black-Scholes model are as follows:

- *Fair Value of Common Shares.* The closing price of the Company's publicly-traded common shares on the date of grant is used as the fair value of the shares. The Board of Directors intended all options granted to be exercisable at a price per share not less than the estimated per share fair value of the shares underlying those options on the date of grant.
- *Risk-Free Interest Rate.* The Company bases the risk-free interest rate used in the Black-Scholes valuation model on the implied yield available on U.S. Treasury zero-coupon issues with a term equivalent to that of the term of the options for each option group on the measurement date.
- *Term.* For employee stock options, the expected term represents the period that the Company's share-based awards are expected to be outstanding. Because of the limitations on the sale or transfer of the Company's shares during the period the Company was a privately held company, the Company does not believe its historical exercise pattern is indicative of the pattern it experiences as a publicly traded company. The Company consequently uses the Staff Accounting Bulletin 110, or SAB 110, simplified method to calculate the expected term of employee stock options, which is the average of the contractual term and vesting period. The Company plans to continue to use the SAB 110 simplified method until it has sufficient trading history as a publicly traded company. For consultant stock options, the term used is equal to the remaining contractual term on the measurement date.
- *Volatility.* The Company determines the price volatility based on the historical volatilities of industry peers as it does not have sufficient trading history for its shares. Industry peers consist of several public companies in the medical device industry with comparable characteristics, including revenue growth, operating model and working capital requirements. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies until a sufficient amount of historical information regarding the volatility of its own shares becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common share prices are publicly available would be utilized in the calculation. The volatility is calculated based on the term on the measurement date.
- *Dividend Yield.* The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. The Company has no expectation that it will declare dividends on its common shares, and therefore has used an expected dividend yield of zero.

The fair value of stock options granted to employees was estimated using the following assumptions:

	Year Ended December 31,		
	2025	2024	2023
Volatility	55% - 56%	63% - 122%	62% - 71%
Risk-free interest rate	3.8% - 4.3%	3.7% - 4.8%	3.4% - 4.4%
Term (in years)	6.25	6.25	6.25
Dividend yield	—	—	—

Stock Options Granted to Non-Employees

Share-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned using an accelerated attribution method. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered. For the years ended December 31, 2025, 2024 and 2023, the Company recognized expense of $0.8 million, $0.7 million and $0.9 million, respectively, for stock options granted to consultants.

The fair value of stock options granted to consultants was estimated using the following assumptions during the following periods presented:

	Year Ended December 31,		
	2025	2024	2023
Volatility	54% - 55%	57% - 102%	60% - 65%
Risk-free interest rate	4.1% - 4.5%	4.2% - 4.5%	4.0% - 4.1%
Term (in years)	10	10	10
Dividend yield	—	—	—

Restricted Stock

Each vested RSU entitles the holder to be issued one common share. These awards vest according to a vesting schedule determined by the Board of Directors or the Compensation Committee of the Company's Board of Directors, generally over a one to four year period.

The following table represents RSU activity for fiscal 2025:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding unvested at December 31, 2024	295,705	$ 48.53
Granted	185,170	36.10
Vested	(84,194)	55.86
Forfeited/canceled	(65,744)	47.83
Outstanding unvested at December 31, 2025	330,937	$ 39.85

The fair value of RSUs is the grant date market value of common shares. The Company recognizes share-based compensation expense related to RSUs using a straight-line method over the vesting term of the awards. The share-based compensation expense for RSUs that vested during the years ended December 31, 2025, 2024 and 2023 was $5.3 million, $6.4 million and $4.8 million, respectively, which was calculated based on the market value of the Company's common shares on the applicable grant date.

As of December 31, 2025, the Company had unrecognized share-based compensation cost of approximately $9.6 million associated with unvested awards of RSUs. This cost is expected to be recognized over a weighted-average period of approximately 2.4 years.

11. Business Combinations

On October 1, 2024, European Distribution Center Motiva BV, or EDC, a wholly owned subsidiary of the Company, acquired 100% of the outstanding common shares of both Motiva Benelux BV, a distribution company in Belgium, and Motiva NL B.V., a distribution company in the Netherlands. The acquisition will allow the Company to expand its market in Europe and achieve synergies and cost reductions by removing redundant processes.

The acquisition's total consideration was valued at approximately $7.8 million and consisted of the following: (1) an initial payment of approximately $0.2 million in cash made on October 1, 2024, (2) a payment of $1.2 million in the Company's common shares made in October 2024; (2) a payment of $0.3 million in cash and $2.6 million in the Company's common shares made in January 2025; (3) a payment of $0.8 million due in April 2025; (4) a true-up amount payable or receivable in March 2026, based on meeting revenue and operational expense targets for fiscal 2025 currently estimated to be approximately $0.5 million; and (5) $2.2 million receivable settled on the acquisition date. The Company retains the option to settle the outstanding payments either in cash or in the Company's common shares.

The Company had an established relationship with Motiva Benelux prior to the acquisition, with Motiva Benelux distributing the Company's products in certain European markets. On the acquisition date, the Company had receivables totaling around $2.2 million from Motiva Benelux. Due to the acquisition, this amount was considered settled at its fair value, which the Company assessed to be equal to the book value.

The contingent consideration arrangement requires the Company to pay the former owners an amount equal to the total revenue for fiscal year 2024 and 2025 multiplied by a multiple based on the relevant revenue growth rate realized in that particular fiscal year versus the prior year (ratio ranges from 0.5 to 0.9). The amount will be decreased if the operational expense targets for fiscal 2025 are not met.

The potential undiscounted amount of all future contingent payments that the Company could be required to make is not capped. The fair value of the contingent consideration arrangement of $1.0 million on the acquisition date was estimated by applying the income approach which used significant inputs that are not observable in the market (Level 3 inputs). Key assumptions included (a) a discount rate of 12.5%; (b) 2024 revenue of approximately $6.0 million (actual, assumed to be reliably forecasted as of the date of valuation); (c) 2025 revenue of approximately $9.5 million; and (d) that operating expense targets were met. As of December 31, 2024, the consideration payable related to the 2024 revenue milestone of $1.0 million has been settled.

As of December 31, 2025, the amount recognized for the contingent consideration arrangement, the range of outcomes, and the assumptions used to develop the estimates had changed. The fair value of the contingent consideration arrangement of $4.5 million as of December 31, 2025 was calculated using these inputs: (a) 2025 actual revenue of approximately $9.5 million; (b) growth ratio of 0.9 based on average revenue growth over the last two years; and (c) the fact that operating expense targets were met. The Company retains the option to settle the outstanding liability either in cash or in the Company's common shares. As of December 31, 2025, the Company recognized an expense of $4.3 million in SG&A expenses related to the changes in the fair value of the contingent consideration.

The following table summarizes the consideration paid and payable at the acquisition date of October 1, 2024:

	(in thousands)
Consideration:	
Cash paid	$ 221
Equity issued (26,018 common shares)	1,177
Contingent consideration payable	973
Consideration payable	3,262
Fair value of trade receivable considered settled	2,184
Total consideration	$ 7,817

The fair value of the common shares issued as part of the consideration paid for the acquisition was determined as the volume-weighted average price of closing market price of Company's common shares over the 30 days prior to the acquisition date.

On January 13, 2025, the Company paid approximately $0.3 million in cash and approximately $2.4 million in the Company's common stock. On June 30, 2025, the Company paid approximately $0.9 million in the Company's common stock.

The following table summarizes the consideration still payable at December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Contingent consideration payable	$ 4,474	$ 973
Consideration payable	315	3,262
Total liabilities	$ 4,789	$ 4,235

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date of October 1, 2024:

	(in thousands)
Recognized amounts of identifiable assets acquired and liabilities assumed:	
Financial assets	$ 904
Inventory	4,946
Property, plant, and equipment	125
Intangible assets	1,527
Financial liabilities	(482)
Total identifiable net assets	$ 7,020
Recognized goodwill:	
Goodwill	$ 797

The fair value of the inventory acquired was determined as estimated selling price of the inventory less reasonable profit allowance for the selling effort.

Property, plant, and equipment acquired in a business combination is intended to be held and used and was recognized and measured at fair value and primarily consisted of vehicles and furniture and fixtures.

The fair value of the acquired identifiable intangible assets of $1,527 was related to customer-related intangibles (i.e., customer lists and related customer relationships) and is amortized over the estimated useful life of 10 years. The fair value was determined using the distributor method of the income approach with significant assumptions being discount rate of 17.5% and revenue attrition rate of 25.0%.

Financial liabilities of $0.5 million primarily consisted of accounts payable of $0.2 million, accrued liabilities primarily related to salaries and fringes of $0.2 million and a loan payable of $0.1 million. As of December 31, 2025, there has been no change since October 1, 2024, in the amount recognized for the liability or any change in the range of outcomes or assumptions used to develop the estimates.

The goodwill of $0.8 million arising from the acquisition consists largely of the synergies and economies of scale expected from combining the operations of the Company and the acquired entities. None of the goodwill recognized is expected to be deductible for income tax purposes. As of December 31, 2025, there were no changes in the recognized amounts of goodwill resulting from the acquisition.

Acquisition-related costs of $0.3 million were included in selling, general, and administrative expenses in Company's income statement for the year ending December 31, 2024.

The Company recognized $1.8 million in revenues and $0.5 million in earnings in its consolidated income statement for the year ended December 31, 2024 from the activities of the acquired entities since the acquisition date of October 1, 2024.

12. Income Taxes

Effective January 1, 2025, the Company adopted ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*. Under the transition provisions, the amendments are applied prospectively for public business entities for annual periods beginning after December 15, 2024. Upon adoption, the Company is required to present an expanded, tabular effective tax rate reconciliation that includes both dollar amounts and percentage-point effects and is disaggregated into specified categories, with any reconciling item equal to or exceeding 5% of expected tax presented separately by nature or jurisdiction. The Company is also required to disclose income taxes paid (net of refunds received), disaggregated into U.S. federal, U.S. state and local, and foreign amounts, with separate disclosure of any individual jurisdiction that represents 5% or more of total cash taxes paid. Consistent with the prospective transition guidance, these enhanced disclosures are presented for the year ended December 31, 2025 only, while prior periods continue to be presented under the income tax disclosure requirements that were in effect for those periods.

For the year ended December 31, loss before income tax consisted of the following:

	2025
	(in thousands)
Costa Rica operations	$ (24,542)
U.S. operations	2,792
Other foreign operations	(36,272)
Total loss before income taxes	$ (58,022)

	2024	2023
	(in thousands)	
Costa Rica operations	$ (60,665)	$ (13,556)
Non-Costa Rica operations	(23,963)	(65,027)
Total loss before income taxes	$ (84,628)	$ (78,583)

For the year ended December 31, the income tax benefit consisted of the following:

	2025
	(in thousands)
Current:	
Costa Rica	$ 112
United States	270
Other foreign	2,095
Total current	2,477
Deferred:	
Costa Rica	—
United States	(8,790)
Other foreign	(645)
Total deferred	(9,435)
Total benefit for income taxes	$ (6,958)

	2024	2023
	(in thousands)	
Current:		
Costa Rica	$ 183	$ 297
Non-Costa Rica	1,963	3,328
Total current	2,146	3,625
Deferred:		
Costa Rica	—	—
Non-Costa Rica	(2,178)	(3,706)
Total deferred	(2,178)	(3,706)
Total (benefit) provision for income taxes	$ (32)	$ (81)

The items accounting for the difference between income taxes computed at the Costa Rica statutory income tax

rate and the income tax benefit consisted of the following for the year ended December 31:

	Year Ended December 31, 2025 (in thousands)	
Tax benefit at Costa Rica statutory rate	$ (17,406)	30.0 %
State and local income taxes, net of federal (national) tax effects	—	—
Foreign tax effects		
United States		
Valuation allowance release	(9,384)	16.2
Other	27	—
BVI		
Foreign tax rate differential	12,283	(21.2)
Other foreign jurisdictions		
Other	49	(0.1)
Effect of change in tax law or rates (Costa Rica)	—	—
Tax credits	—	—
Changes in valuation allowance	—	—
Nontaxable or nondeductible items		
Costa Rica tax holiday benefit	7,473	(12.9)
Total benefit for income taxes	$ (6,958)	12.0 %

	2024 (in thousands)		2023	
Tax benefit at Costa Rica statutory rate	$ (25,388)	30.0 %	$ (23,575)	30.0 %
Foreign tax rate differential	7,166	(8.5)	18,070	(22.9)
Tax rate changes	(446)	0.5	(7)	—
Return to provision adjustment	(561)	0.7	(539)	0.7
Tax credits	—	—	—	—
Change in valuation allowance	(14,157)	16.7	438	(0.6)
Tax holiday adjustment (benefit)	18,373	(21.7)	4,386	(5.6)
U.S. stock compensation	227	(0.3)	984	(1.3)
Prior year true-up	14,744	(17.4)	—	—
Other	10	—	162	(0.2)
Total provision (benefit) for income taxes	$ (32)	— %	$ (81)	0.1 %

The Company's tax holiday benefit was related to the Company's subsidiary in Costa Rica which enjoyed a zero percent tax rate, with the exception of certain types of income, for the years ended December 31, 2025, 2024 and 2023. The zero percent tax holiday, as extended, is effective for a period of 12 years through the year 2030.

During 2025, the Company concluded that the U.S. deferred tax assets of Motiva USA LLC are

more-likely-than-not realizable based on achieving a three-year cumulative income position and updated forecasts of future taxable income. As a result, the Company released the full U.S. valuation allowance, generating a discrete deferred tax benefit of approximately $9.4 million, which is presented above as a separate reconciling item in accordance with ASU 2023-09.

For the year ended December 31, income taxes paid consisted of the following:

	2025
	(in thousands)
Costa Rica	93
Foreign – by jurisdiction ≥5%:	
U.S. federal	78
U.S. state and local	—
Spain	83
Sweden	29
Germany	57
France	55
Italy	21
Belgium	—
Foreign – all other jurisdictions	4
Total cash paid for income taxes	$ 420

As of December 31, the components of the Company's deferred tax assets and liabilities are as follows:

	2025	2024
	(in thousands)	
Accruals and reserves	$ 345	$ 563
Fixed assets	(1,284)	(1,036)
Intangibles	116	105
Stock compensation	4,613	3,763
Net operating loss	9,247	10,742
R&D credits	325	325
Allowance for credit losses	1,653	593
Other	97	56
Valuation allowance	—	(9,223)
Total net deferred tax assets (included in "Other non-current assets")	$ 15,112	$ 5,888

As of December 31, 2025, the Company released the full valuation allowance previously recorded against the deferred tax assets of Motiva USA LLC. This determination was based on the subsidiary's achievement of a three-year cumulative pretax income position, sustained operating improvements, and management's supportable forecast of future taxable income, which together provided sufficient positive evidence under ASC 740 to outweigh the negative evidence of historical losses. The release resulted in a non-cash deferred tax benefit of

approximately $9.4 million, recognized as a discrete item within income tax expense and presented separately in the effective tax rate reconciliation. Following the release, the valuation allowance balance at December 31, 2025 was $0.

As of December 31, 2025, the Company had U.S. federal and California research and development credit carryforwards totaling approximately $0.5 million. Federal research credits begin to expire in 2037, while California research credits may be carried forward indefinitely. At December 31, 2025, the Company also had net operating loss carryforwards of approximately $21.4 million for U.S. federal purposes, $11.1 million for U.S. state purposes, $1.5 million in Argentina, and $10.6 million in Brazil. U.S. federal NOLs generated in tax years beginning after 2017 may be carried forward indefinitely, subject to an annual limitation on deductibility. Certain U.S. state NOLs generated prior to 2018 will begin to expire in 2030. Brazil NOLs may be carried forward indefinitely, subject to annual deductibility limits.

During the year ended December 31, 2024, the Company recorded an $80 million intercompany true-up adjustment related to transfer-pricing corrections for prior years, which reduced the U.S. federal NOL position and increased taxable income in Costa Rica. This adjustment was offset by the valuation allowance and therefore did not affect the 2024 income tax provision. Because Motiva USA had no sales prior to 2024 and therefore negligible state apportionment in most jurisdictions, the state income tax impact of this adjustment was minimal.

The utilization of U.S. federal and state NOLs and credit carryforwards may be limited under Internal Revenue Code Sections 382 and 383 in the event of an “ownership change.” An ownership change generally occurs when the percentage of the Company’s stock owned by one or more “five-percent shareholders” increases by more than 50 percentage points over a rolling three-year testing period. Based on the Company’s evaluation to date, management does not believe an ownership change has occurred that would materially limit the Company’s ability to utilize its tax attributes; however, the Company has not completed a formal Section 382/383 analysis. Future changes in ownership, some of which may be outside the Company’s control, could result in such limitations, and the Company cannot provide assurance that all existing tax attributes will be fully available for use.

The Company continues to benefit from a tax holiday in Costa Rica, under which qualifying income is taxed at a 0% rate through December 31, 2030, subject to ongoing compliance with the regime’s requirements. As a result of the tax holiday, income that would otherwise have been taxed at the Costa Rica statutory rate generates no current tax expense. The tax holiday reduced income tax expense by approximately $7.5 million in 2025 and $18.4 million in 2024. If the Company fails to maintain eligibility, income generated in Costa Rica could become subject to the statutory rate, which could materially increase the Company’s tax expense.

The Company operates in multiple jurisdictions and is subject to examination by U.S. and foreign tax authorities. Tax authorities may challenge the Company’s tax positions, including the characterization of intercompany transactions, transfer-pricing policies, and other positions involving judgment under applicable tax laws. An adverse resolution of any examination could result in additional tax liabilities, interest and penalties, and could materially affect the Company’s results of operations. The Company’s determination of its worldwide provision for income taxes requires significant judgment, and the ultimate tax determination for many transactions may be uncertain.

Accounting for Uncertainty in Income Taxes

The Company recognizes uncertain tax positions in accordance with ASC 740-10. As of December 31, 2025 and 2024, the Company had no unrecognized tax benefits. No interest or penalties were accrued or recognized during the periods presented, and no material changes to unrecognized tax positions are expected within the next 12 months.

As of December 31, 2025, the Company is subject to taxation in Costa Rica, Belgium, France, Brazil, the United Kingdom, Sweden, Italy, Germany, Austria, Spain, Argentina, Switzerland, the Netherlands, and the United States. Fiscal years 2019 through 2025 remain open to examination in these jurisdictions.

13. Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share for the periods presented:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands, except share and per share data)		
Numerator:			
Net loss	$ (51,064)	$ (84,596)	$ (78,502)
Denominator:			
Weighted average common shares used for basic and diluted earnings per share	29,620,022	28,161,761	25,600,029
Net loss per share:			
Basic and diluted	$ (1.72)	$ (3.00)	$ (3.07)

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares and dilutive share equivalents outstanding for the period, determined using the treasury-share method and the as-if converted method, for convertible securities, if inclusion of these is dilutive.

If the Company reports a net loss, diluted net loss per share is the same as basic net loss per share for those periods because including the dilutive securities would be anti-dilutive.

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares:

	Year Ended December 31,		
	2025	2024	2023
Options to purchase common shares	1,428,878	1,413,948	1,487,387
Shares issuable on vesting of grants of RSUs	331,295	295,705	196,177
Total potentially dilutive shares outstanding	1,760,173	1,709,653	1,683,564

14. Related Party Transactions

During the years ended December 31, 2025, 2024 and 2023, the Company recorded revenue of $1.2 million, $1.1 million and $1.2 million, respectively, for product sales to Herramientas Medicas, S.A., a distribution company owned by a family member of the former (until March 2025) Chief Executive Officer of the Company. Accounts receivable owed to the Company from this distribution company amounted to approximately $0.4 million each as of December 31, 2025 and 2024.

In 2016, the Company also entered into a separate agreement with Dr. Chacón Quirós, the brother of the Company's former Chief Executive Officer Juan José Chacón Quirós, to maintain his clinic in Costa Rica as a MotivaImagine Excellence Center and to host and train physicians in the use of the Company products in relevant procedures, among other services, in exchange for cash reimbursement of up to $4,500 per day that such services are rendered. In August 2022, the Company entered into a new agreement with Dr. Chacón Quirós, replacing the original agreement, to continue the training services in exchange for cash reimbursement of his hourly rate of $531 when such services are rendered. During the years ended December 31, 2025, 2024 and

2023, the Company paid Dr. Chacón Quirós approximately $0.1 million, $0.2 million and $0.4 million, respectively, for services rendered.

Following his retirement on March 1, 2025, Establishment Labs Holdings Inc. and its subsidiary, Establishment Labs S.A., each entered into separation agreements with its former CEO, Juan José Chacón-Quirós, on August 3 and August 4, 2025, respectively, to formally terminate his employment effective April 30, 2025. The agreements provide for the continued vesting of outstanding equity awards while Mr. Chacón-Quirós serves as a consultant or a member of the Board of Directors, as well as certain customary restrictive covenants. Concurrently, Establishment Labs Holdings Inc. and Mr. Chacón-Quirós entered into a consulting agreement, effective June 1, 2025, for advisory and advocacy services, with a one-year term that automatically renews through May 31, 2028, unless terminated by either party. Under the consulting agreement, Mr. Chacón-Quirós will receive $750,000 per year, paid in equal monthly installments, and an annual equity award with a target value of $750,000, subject to vesting schedules and terms at the Company's discretion.

On May 14, 2025, the Company granted a stock option award for 36,027 options with a grant date fair value of $0.9 million to Nicholas Lewin, a member of the board of directors, as compensation for consulting services he performs for the Company in addition to his services as a non-employee director.

15. Employee Benefits

Short-term employee benefits, including vacation (paid absences) and year-end bonuses (also known as 13th month salary), are current liabilities included in accrued liabilities on the consolidated balance sheets and are calculated at the non-discounted amount that the Company expects to pay as a result of uncharged employee salaries or retentions.

Regarding employee termination benefits, Costa Rica labor laws establish the payment of benefits in case of death, retirement or termination without cause. This compensation is calculated according to time served in the Company and the corresponding salary in the last six months of employment and is equal to between 19.5 and 22 days' salary for each year served, up to a maximum of 8 years.

Company policy recognizes termination benefits as expenses of the period during which the termination occurs, when the legal obligation is assumed due to the aforementioned events.

As of December 31, 2025, the Company has 46 employees in Brazil and 8 employees in Argentina who were represented by a labor union.

16. Commitments and Contingencies

Contingencies

Periodically, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. As of December 31, 2025, there have been no material contingent liabilities, individually or in aggregate, in the Company's financial condition, results of operations or cash flows. As of December 31, 2024, contingent liabilities were not material, individually or in aggregate, to the Company's financial condition, results of operations or cash flows. However, any monetary liability or financial impact to the Company from these contingent liabilities could differ materially from the Company's expectations.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future that have not yet been made.

The Company has entered into indemnification agreements with its directors and officers that may require the

Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. No liability associated with such indemnifications has been recorded to date.

17. Subsequent Events

On February 24, 2026, the Company announced a strategic leadership transition of Raj Denhoy, current Chief Financial Officer, to Senior Vice President, Global Strategy, and the appointment of Cassandra “Sandra” Harris, 53, to Senior Vice President and Chief Financial Officer, effective March 9, 2026. Ms. Harris will also replace Mr. Denhoy as the Company’s principal accounting officer.

Ms. Harris brings extensive global finance and operational leadership experience, including prior service as Chief Financial Officer of Genesco Inc., a wholesale distributor and manufacturer, from 2024 to 2026, and Artisan Design Group, LLC, a national provider of interior finishes, from 2023 to 2024, as well as Chief Financial Officer and Chief Operating Officer of Tupperware Brands Corporation, a global consumer products company, from 2019 to 2022 and 2020 to 2022, respectively. Earlier in her career, she held senior finance and operational roles at VF Corporation, an apparel and footwear company, and began her career in audit at Deloitte & Touche LLP, a professional services firm. Ms. Harris is a Certified Public Accountant and holds a Bachelor of Science in Accounting from Clemson University. In connection with her appointment, Ms. Harris entered into an employment agreement that provides for, among other things, an annual base salary of $550,000, a target annual bonus opportunity of up to 50% of base salary, eligibility for annual equity awards, and a one-time cash award of $700,000 payable in two installments. Ms. Harris has no family relationships with any director or executive officer of the Company, and there are no arrangements or understandings with any person pursuant to which she was selected as an officer of the Company. There are also no related person transactions between Ms. Harris and the Company that would be required to be disclosed pursuant to Item 404(a) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

In his role as Senior Vice President, Global Strategy, Mr. Denhoy will be responsible for key strategic initiatives and long-term growth priorities. This transition is not the result of any disagreement with the Company on any matter relating to its operations, policies, or practices.

SIGNATURES

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

ESTABLISHMENT LABS HOLDINGS INC.

Dated: February 27, 2026

By: */s/ Filippo "Peter" Caldini*
Name: Filippo "Peter" Caldini
Title: Chief Executive Officer and Director

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

Signature	Title	Date
/s/ Filippo "Peter" Caldini Filippo "Peter" Caldini	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2026
/s/ Rajbir S. Denhoy Rajbir S. Denhoy	Chief Financial Officer (Principal Financial and Accounting Officer) (Authorized Representative in the United States)	February 27, 2026
/s/ Nicholas Lewin Nicholas Lewin	Chairman of the Board of Directors	February 27, 2026
/s/ Juan José Chacón Quirós Juan José Chacón Quirós	Director	February 27, 2026
/s/ Ann Custin Ann Custin	Director	February 27, 2026
/s/ Leslie Gillin Leslie Gillin	Director	February 27, 2026
/s/ Edward Schutter Edward Schutter	Director	February 27, 2026
/s/ Bryan Slotkin Bryan Slotkin	Director	February 27, 2026

EXHIBIT 21.1

SUBSIDIARIES OF ESTABLISHMENT LABS HOLDINGS INC.

Name of Subsidiary	Jurisdiction of Organization
Establishment Labs, S.A.	Costa Rica
Motiva USA, LLC	Delaware
JAMM Technologies, Inc.	Delaware
Establishment Labs Produtos par Saude Ltda **	Brazil
European Distribution Center Motiva BV *	Belgium
Motiva Implants France SAS	France
Motiva Nordica AB **	Sweden
Motiva Implants UK Limited	The United Kingdom
Motiva Italy S.R.L	Italy
Motiva Implants Spain, S.L.	Spain
Motiva Austria GmbH	Austria
Motiva Germany GmbH	Germany
Motiva Argentina S.R.L.***	Argentina
Motiva Benelux BV **	Belgium
Motiva NL BV **	Netherlands

* Establishment Labs Holdings Inc. and Establishment Labs, S.A. own 99% and 1%, respectively, of European Distribution Center Motiva BV
** European Distribution Center Motiva BV owns 100% of the referenced entity.
*** Establishment Labs Holdings Inc. and Establishment Labs, S.A. own 99.77% and 0.23%, respectively, of Motiva Argentina S.R.L.

EXHIBIT 23.1

Independent Registered Public Accounting Firm's Consent

We consent to the incorporation by reference in the Registration Statement on Form S-3ASR (File No. 333-271418) and Forms S-8 (File Nos. 333-226340, 333-230419, 333-237219, 333-254283, 333-263149, 333-270196, 333-277667, and 333-285415) of our reports dated February 27, 2026, relating to the consolidated financial statements of Establishment Labs Holdings Inc. (the "Company") and the effectiveness of internal control over financial reporting of the Company appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

Los Angeles, California

February 27, 2026

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Filippo "Peter" Caldini, certify that:

1. I have reviewed this Annual Report on Form 10-K of Establishment Labs Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2026

/s/ Filippo "Peter" Caldini
Filippo "Peter" Caldini
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rajbir S. Denhoy, certify that:

1. I have reviewed this Annual Report on Form 10-K of Establishment Labs Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2026

/s/ Rajbir S. Denhoy
Rajbir S. Denhoy
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Filippo "Peter" Caldini, as Chief Executive Officer, and Rajbir S. Denhoy, as Chief Financial Officer, of Establishment Labs Holdings Inc. (the "Company"), hereby certifies that to the best of his and her knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2025, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2026

/s/ Filippo "Peter" Caldini
Filippo "Peter" Caldini
Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2026

/s/ Rajbir S. Denhoy
Rajbir S. Denhoy
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Establishment Labs Holdings Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

ESTABLISHMENT LABS HOLDINGS INC. EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is made and entered into as of February 23, 2026 (the "Effective Date"), by and between ESTABLISHMENT LABS HOLDINGS INC., a British Virgin Islands company (the "Company") and Cassandra E. Harris, an individual (the "Executive").

Background

WHEREAS, the Company desires to employ the Executive for the term hereof;

WHEREAS, the Executive desires to be employed by the Company in accordance with the terms hereof; and

WHEREAS, the Company and the Executive mutually intend to set forth herein the terms and conditions of the Executive's employment with the Company.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Executive agree as follows:

1. Employment. The Company hereby agrees to employ the Executive, and the Executive hereby accepts such employment with the Company subject to the terms and conditions set forth herein. During the Term (as defined in **Section 2**), the Executive shall serve in the capacity of Senior Vice President and Chief Financial Officer of the Company and shall report directly to the Chief Executive Officer. The Executive's duties hereunder will be those normally incident to the Executive's position and such other duties as may be reasonably assigned to her from time to time by the Chief Executive Officer. During the Term, except for illness and vacation periods, the Executive shall devote all of her business time, attention, skill and efforts to the faithful performance of her duties hereunder. The Executive shall not be involved with any community or professional organizations or serve as a director for any other entities, other than those activities and investments that do not impair the ability of the Executive to perform the duties of her position. The parties understand and agree that the Executive is primarily providing services out of the United States, and for employment purposes, Motiva USA, LLC shall employ the Executive, maintain her employment records, pay her cash compensation and provide her benefits.

2. Term / Termination.

(a) *Term*. The term of the Executive's employment (the "Term") shall commence on March 9, 2026 or such other earlier date mutually agreed between the parties, and shall continue in full force and effect until terminated in accordance with **Sections 2(b)**, **2(c)**, **2(d)**, **2(e)** or **2(f)** below.

(b) *Termination for Cause*. The Executive's employment may be terminated by the Company for "Cause." For purposes of this Agreement, "Cause" shall mean (i) the

Executive's conviction of, or pleading guilty or nolo contendere to, a felony or other crime involving moral turpitude, (ii) the Executive's engagement in fraud, dishonesty, embezzlement, insubordination, or misconduct, (iii) the failure of the Executive to perform her assigned duties or follow the reasonable and lawful directives of the Chief Executive Officer or Board of Directors of the Company (the "Board of Directors"), which failure is not cured within ten (10) days of written notice from the Company of such failure, (iv) the material breach by the Executive of her obligations hereunder or under any material provision of the Company's Code of Business Conduct and Ethics or any related agreements with any Company Group member, which breach (to the extent curable) is not cured within ten (10) days of written notice from the Company of such breach, or (v) any of the grounds for a for-Cause termination described in the applicable labor code. The Executive shall not be deemed to have been terminated for Cause unless and until there shall have been delivered to him written notice of such termination.

(c) *Termination by Executive for Good Reason*. The Executive's employment may be terminated by the Executive for "Good Reason" if the Executive resigns from her employment with the Company in accordance with the following sentence after the occurrence of any of the following events, without the Executive's consent:

(i) a material diminution by the Company of the responsibility, importance or scope of the Executive's functions, duties or position with the Company from the position and attributes thereof described in **Section 1**;

(ii) a breach by the Company of any material provision hereof; or

(iii)a reduction of the Executive's Base Compensation (as defined in **Section 3(a)** below), except for a reduction due to unforeseen circumstances that create a financial constraint on the Company, provided that such reduction applies proportionately for all similarly situated executives.

In order for the Executive's resignation to constitute a resignation for "Good Reason," the Executive must first provide the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within thirty (30) days of the initial existence of such grounds for "Good Reason" and a period of thirty (30) days following the date of such notice to cure such grounds (the "Cure Period"), such grounds must not have been cured by the expiration of the Cure Period, and the Executive must resign within thirty (30) days following the expiration of the Cure Period.

(d) *Termination by Reason of Death or Disability*. The Executive's employment will automatically terminate upon the death of the Executive. The Company may terminate the Executive's employment immediately upon written notice to the Executive upon the Disability of the Executive. For purposes of this **Section 2(d)**, the term "Disability" shall mean the inability or failure of the Executive to perform the essential functions of her position of employment with the Company with or without reasonable accommodation as a result of a mental or physical disability for a total of ninety (90) or more days (whether or not consecutive) during any twelve (12) months, all as determined in good faith by a majority of the disinterested members of the Board of Directors; *provided*, *however*, if the Company or a member of the Company Group

maintains a policy insuring against the disability of Executive, then “Disability” shall have the same meaning as in such policy.

Termination by Company without Cause. The Executive’s employment

may be terminated by the Company without Cause, at any time, for any reason or for no reason, upon the payment by the Company of the Accrued Compensation and the amounts, if any, required by Section 8.

(e) *Termination by Executive without Good Reason*. The Executive's employment may be terminated by the Executive without Good Reason, at any time, upon thirty
(30) days' prior written notice of termination. Upon receipt of the Executive's written notice of termination, the Company may immediately terminate the Executive's employment, which termination shall be deemed for "Cause."

3. Compensation. The Company shall pay the Executive as compensation, in consideration for all her services hereunder, the amounts described in this **Section 3**:

(a) *Base Compensation*. The Executive will be paid a base salary equivalent to USD $550,000 per annum (the "Base Compensation"). Payments shall be paid to the Executive in equal installments not less frequently than monthly, in accordance with the Company's payroll practices in effect from time to time. Any compensation which may be paid to the Executive under any additional compensation or incentive plans of the Company or which may otherwise be authorized from time to time by the Board of Directors shall be in addition to the Base Compensation to which the Executive is entitled to under this Agreement.

(b) *Incentive Compensation (Annual Bonus)*. The Executive shall also be eligible to receive an annual bonus (the "Annual Bonus") as additional annual compensation in an amount up to 50% of the Base Compensation (the "Target Bonus"), upon the verification of the achievement of certain individual targets and goals by the Executive and certain targets and milestones by the Company. Such targets and goals shall be established in writing by the Company. The determination of whether such targets have been achieved shall be determined by the Company in its sole discretion. The Executive shall be entitled to such Annual Bonus for a particular fiscal year only if the Executive is employed by the Company through the end of the applicable fiscal year, except as expressly contemplated in **Section 8**. Any such Annual Bonus to which the Executive is entitled with respect to a particular fiscal year shall be paid no later than March 15 of the year following such fiscal year.

(c) *Annual Equity Award*. The Executive shall also be eligible to receive an equity award (the "Annual Equity Award") as additional annual compensation in an amount up to 200% of the Base Compensation, with such value allocated 50% to Restricted Stock Units and 50% to stock options, pursuant to any plans or arrangements the Company may have in effect from time to time. Notwithstanding anything to the contrary in this Agreement, the Board of Directors (or a committee of the Board of Directors) will determine in its discretion the terms and conditions of the Annual Equity Award, whether the Executive will be granted any additional equity awards, and the terms and conditions of any such additional equity award, each in accordance with the terms and conditions of any applicable plan or arrangement that may be in effect from time to time.

(d) *New Hire Cash Award*. In connection with the Executive's commencement of employment, the Company shall make a one-time new hire cash award totaling USD $700,000,

payable in two equal installments, with the first payment of USD $350,000 payable as of the commencement of the Term and the second payment of USD $350,000 payable as of January 2, 2027.

(e) *Participation in Plans*. During the Executive's employment with the

Company, the Executive shall be entitled to participate in all savings and retirement plans, policies and programs maintained in force by the Company, including any qualified pension, profit sharing or other retirement plans, non-qualified retirement and deferred compensation plans, and other similar retirement and welfare benefit plans, programs and arrangements, provided that the Executive qualifies for participation in such plans, programs and arrangements pursuant to the terms thereof and only if such plans or programs are put in place. The Executive shall be informed by the Company when and if any of these apply.

(f) *Employee Benefits*. During the Executive's employment with the Company, the Executive shall continue to be eligible to participate in all of the Company benefit plans and programs in effect for similarly-situated employees. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

(g) *Expense Reimbursement*. The Company shall pay or reimburse the Executive (or, in the Company's sole discretion shall pay directly), upon a proper accounting as the Company may reasonably require, for reasonable business related expenses and disbursements incurred by the Executive in the course of the performance of the Executive's duties under this Agreement, provided that the incurring of such expenses shall have been approved in accordance with the Company's regular reimbursement procedures and policies of the Company Group in effect from time to time. This section shall apply to Executive's one-time relocation-related expenses not to exceed USD $87,000, comprised of up to USD $52,000 in lease termination-related payments and up to USD $35,000 in relocation expenses.

(h) *Clawback and Recoupment*. All compensation and benefits provided to the Executive under this Agreement or otherwise in respect of her employment are subject to clawback and recoupment pursuant to the policies of the Company Group, as in effect and amended from time to time.

(i) *Withholding*. Payment of all amounts to the Executive shall be net of any withholding. The Company may withhold from the Executive's compensation all applicable amounts (including, withholding and payroll taxes) required by law.

4. Vacation. The Executive shall be entitled to paid vacation in accordance with the Company's vacation policy, with the timing and duration of specific vacations mutually and reasonably agreed to by the parties hereto.

5. Place of Performance. In connection with her employment by the Company, the Executive shall render her services wherever the Company requires it. The Company's current expectation is that the Executive will primarily provide services from an office in Wilmington, North Carolina, although the Executive will be required to travel to perform her job duties and, in particular, will also provide services from the Company's headquarters in Costa Rica.

6. Facilities Available to Executive. The Company shall furnish Executive with facilities and technical services as may be reasonably appropriate for the performance of her duties in the Company's industry.

7. Equity Acceleration Upon a Change in Control. Upon a Change in Control that occurs before the termination of the Executive's employment with the Company, the Executive

will receive accelerated vesting as to one hundred percent (100%) of the then-unvested portions of all of Executive's outstanding equity awards that were granted on or after the Effective Date, and with respect to such equity awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met.

8. Payments Due Upon Termination of Employment.

(a) *Non-CIC Qualified Termination*. If a Non-CIC Qualified Termination occurs, then, subject to **Sections 8(e)** and 9, the Executive will receive the following severance payment and benefits:

(i) *Salary Severance*. A lump sum severance payment within 75 days of the Executive's termination of employment equal to nine (9) months of the Executive's Base Compensation as in effect immediately prior to such termination of the Executive's employment (or if such termination is the result of Executive's resignation due to a material reduction in the Executive's Base Compensation, as in effect immediately prior to such reduction).

(ii) *Bonus Severance*. A lump sum severance payment equal to (A) the Annual Bonus that the Executive would have earned under **Section 3(b)** for the fiscal year in which the Executive's Non-CIC Qualified Termination occurs had the Executive remained employed with the Company through the date the Executive was required to continue employment with the Company in order to be eligible to receive such bonus multiplied by (B) the fraction obtained by dividing (x) the number of days the Executive has worked during such fiscal year by (y) the total number of days in such fiscal year, which will be paid at the same time as other similarly situated employees of the Company receive bonus payments for the fiscal year but in no event later than March 15 of the year following the year of the Non-CIC Qualified Termination.

(iii) *Health Benefit*. Subject to **Section 8(d)**, the Company will pay the premiums for the Executive and the Executive's eligible dependents to continue healthcare coverage at the rates then in effect for active employees, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "Health Benefit"), until the earlier of (A) a period of nine (9) months from the date of the Executive's termination of employment, (B) the date upon which the Executive and/or the Executive's eligible dependents become covered under similar plans or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA or other applicable law or policy governing such coverage.

(iv) *New Hire Cash Award.* To the extent not already paid, Executive's one-time new hire cash award totaling USD $700,000, payable in two equal installments, with the first payment of USD $350,000 payable as of March 9, 2026 and the second payment of USD $350,000 payable as of January 2, 2027.

(b) *CIC Qualified Termination*. If a CIC Qualified Termination occurs, then, subject to **Sections 8(e)** and **9**, the Executive will receive the following severance payments and benefits from the Company:

(i) *Salary Severance*. A lump sum severance payment within 75 days of the Executive's termination of employment equal to twelve (12) months of the higher of
(x) the Executive's Base Compensation as in effect immediately prior to such termination of Executive's employment (or if such termination is the result of the Executive's resignation due to a material reduction in the Executive's Base Compensation, as in effect immediately prior to such reduction) or (y) the Executive's Base Compensation as of immediately prior to the Change in Control.

(ii) *Bonus Severance*. A lump sum severance payment within 75 days of the Executive's termination of employment equal to one hundred percent (100%) of the Executive's Target Bonus as in effect for the fiscal year in which the Executive's termination of employment occurs.

(iii)*Equity Acceleration*. Accelerated vesting as to one hundred percent (100%) of the then-unvested portions of all of Executive's outstanding equity awards that are granted on or after the Effective Date.

(iv)*Health Benefit*. Subject to **Section 8(d)**, the Company will provide Health Benefit until the earlier of (A) a period of twelve (12) months from the date of the Executive's termination of employment, (B) the date upon which the Executive and/or the Executive's eligible dependents becomes covered under similar plans or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA or other applicable law or policy governing such coverage.

(c) *Voluntary Resignation; Termination for Cause; Death; Disability*. If the Executive's employment with the Company terminates (i) voluntarily by the Executive (other than for Good Reason), (ii) for Cause by the Company, or (iii) as a result of the Executive's death or Disability, then the Executive will not be entitled to receive severance or other benefits (other than Accrued Compensation) except for those (if any) as may then be established under the Company's then existing severance and benefits plans and practices or pursuant to other written agreements with the Company.

(d) *Conditions to Receipt of Health Benefit*. To the extent the Executive is covered under the Company's U.S. health plans as of the time of the Executive's Qualified Termination, the Executive's receipt of the Health Benefit is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents. If the Company determines in its sole discretion that it cannot provide the Health Benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to the Executive a taxable monthly payment payable on the Company's regularly scheduled payroll dates (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue the Executive's group health coverage in effect on the date of the Executive's Qualified

Termination (which amount will be based on the rates then in effect for active employees, subject to any subsequent changes in rates that are generally applicable to the Company's active employees) (each, a "Health Replacement Payment"), which Health Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of Health Replacement Payments equal to the number of months in the applicable Health Benefit period. For the avoidance of doubt, the Health Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings. Notwithstanding anything to the contrary under this Agreement, if at any time the Company determines in its sole discretion that it cannot provide the Health Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the Health Replacement Payments or any further Health Benefit.

(e) *Offset*. The severance payments and benefits the Executive would otherwise be entitled to receive pursuant to **Sections 8(a)** or **(b)** will be reduced by any liability the Company may have to the Executive for any severance payments or benefits required under any applicable statute, law or regulation to the extent permitted by applicable law.

(f) *Accrued Compensation*. For the avoidance of any doubt, in the event of any termination of the Executive's employment with the Company, the Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other vested benefits due to the Executive under the terms of any Company-provided plans, policies, and arrangements, each as in effect from time to time (the "Accrued Compensation").

(g) *Transfer between the Company Group*. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause. If, however, the Company transfers the Executive's employment from Motiva USA, LLC to another member of the Company Group, yet the Executive is precluded from employment at that other member of the Company Group, whether for citizenship or other reasons, and the parties cannot remove the preclusion(s) despite their mutual best efforts, such a transfer would be a termination without Cause.

(h) *Exclusive Remedy*. In the event of a termination of the Executive's employment with the Company, the provisions of this **Section 8** are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive may otherwise be entitled, whether at law, tort or contract, in equity. Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this **Section 8**, subject to applicable law.

9. Conditions to Receipt of Severance/Timing of Severance.

Separation Agreement and Release of Claims. The receipt of any severance payment or benefits pursuant to **Sections 8(a)** or **(b)** will be subject to (i) the Executive resigning from all positions the Executive may hold as an officer or director of a Company Group member and executing all documents the applicable Company Group member determines, in its sole discretion, are necessary to effectuate such resignations prior to the Release Deadline (as defined below) (such

resignation and execution of applicable documents, the "Resignations"), and (ii) the Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "Release") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "Release Deadline"). If the Resignations and the Release do not become effective and irrevocable by the Release Deadline, the Executive will forfeit any rights to severance payments or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Resignations and the Release become effective and irrevocable. If earned and unless otherwise agreed by Company, none of the severance payments and benefits payable upon the Executive's Qualified Termination under **Section 8**, with the exception of the continuation of the Health Benefit, as applicable, will be paid or otherwise provided prior to the sixtieth (60th day) following the Executive's Qualified Termination. Except with respect to the extent that payments are delayed under **Section 9(c)**, on the first regularly scheduled Company payroll date following the 60th day following the Executive's Qualified Termination, the Company will pay or provide the Executive the severance payments and benefits that the Executive would otherwise have received under **Section 8** on or prior to that date, with the balance of the severance payments and benefits being paid or provided as originally scheduled.

(a) *Timing of Severance Payments*. Provided that the Release and Resignations become effective and irrevocable by the Release Deadline, any severance payments or benefits under this Agreement will be paid on, or, in the case of installments, will not commence until, the first regularly scheduled Company payroll date following the date the Release and Resignations become effective and irrevocable, and the remaining payments will be made as provided in the Agreement (including any delay that may be required by **Section 9(c)(ii)**). In no event will the Executive have discretion to determine the taxable year of payment for any Deferred Payments.

(b) *Section 409A*.

(i) Notwithstanding anything to the contrary in this Agreement, no Deferred Payments will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to the Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until the Executive has a "separation from service" within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if the Executive is a "specified employee" within the meaning of Section 409A at the time of the Executive's separation from service (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following the Executive's separation from service, will become payable on the first payroll date that occurs on or after the date that is six (6) months and one (1) day following the date of the Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if the Executive dies following the Executive's separation from service, but prior to the six (6)-month anniversary of the

separation from service, then any payments delayed in accordance with this **Section 9(c)(ii)** will be payable in a lump sum as soon as administratively practicable after the date of the Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii)Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments. Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments.

The foregoing provisions and all compensation and benefits provided for under this Agreement are intended to comply with or be exempt from the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be exempt or so comply. The Company and the Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate, or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to the Executive under Section 409A. In no event will any Company Group member reimburse the Executive for any taxes that may be imposed on the Executive as a result of Section 409A.

(c) *Compliance with Related Agreement*. The Executive's receipt of any payments or benefits under **Section 8(a)** or **(b)** will be subject to the Executive continuing to comply with the terms of the Related Agreement (as defined below) and the provisions of this Agreement.

(d) *No Duty to Mitigate*. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that the Executive may receive from any other source reduce any such payment

10. Limitation on Payments. In the event that the payments and benefits provided for in this Agreement or otherwise payable to the Executive (collectively, the "Payments")
(x) constitute "parachute payments" within the meaning of Section 280G of the Code and (y) but for this **Section 10**, would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payments will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such Payments being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income and employment taxes and the Excise Tax, results in the receipt by the Executive, on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. If a reduction in severance and other benefits constituting "parachute payments" is necessary so that benefits are delivered to a lesser extent, reduction will occur in the following order: (i)

reduction of cash payments, which will occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (ii) cancellation of equity awards that were granted
"contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (iii) reduction of acceleration of vesting of equity awards, which will occur in the reverse order of the date of grant for such equity awards (i.e., the vesting of the most recently granted equity awards will be reduced first); and (iv) reduction of other benefits paid or provided to the Executive, which will occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If more than one equity award was made to the Executive on the same date of grant, all such awards will have their acceleration of vesting reduced pro rata. In no event will the Executive have any discretion with respect to the ordering of payment reductions.

Unless the Company and the Executive otherwise agree in writing, any determination required under this **Section 10** will be made in writing by the Company's legal counsel, a nationally recognized firm of independent public accountants selected by the Company, or such other person or entity to which the parties mutually agree (the "Firm"). For purposes of making the calculations required by this **Section 10**, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Accountants may reasonably request in order to make a determination under this Section 10. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this **Section 10**.

11. Definition of Terms.

(a) "Change in Control" has the meaning given to it in the Company's 2018 Equity Incentive Plan.

(b) "Change in Control Period" means the period beginning on a Change in Control and ending 12 months after the Change in Control.

(c) "Code" means the Internal Revenue Code of 1986, as amended.

(d) "Company Group" means the Company and its parents and subsidiaries.

(e) "Deferred Payment" means any severance pay or benefits to be paid or provided to the Executive (or the Executive's estate or beneficiaries) pursuant to this Agreement and any other severance payments or separation benefits, that in each case, when considered together, are considered deferred compensation under Section 409A.

(f) "Qualified Termination" means a termination of the Executive's employment either (i) by the Company without Cause (excluding by reason of the Executive's death or Disability) or (ii) by the Executive for Good Reason, in either case, during the Change in Control Period (a "CIC Qualified Termination") or outside of the Change in Control Period (a "Non-CIC Qualified Termination").

(g) "Section 409A" means Section 409A of the Code and any final regulations and guidance thereunder and any applicable state law equivalent, as each may be amended or promulgated from time to time.

(h) "Section 409A Limit" will mean 2 times the lesser of: (i) the Executive's annualized compensation based upon the annual rate of pay paid to the Executive during the Executive's taxable year preceding the Executive's taxable year of Executive's separation from service as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which the Executive's separation from service occurred.

12. Representations of Executive. The Executive hereby represents and warrants to the Company that (a) this Agreement is the valid, legal and binding obligation of Executive, and

(b) this Agreement does not, and the Executive's performance of her duties hereunder will not, violate any provision of any agreement, indenture or other instrument, or any fiduciary or other obligation, to which the Executive is a party or by which it is bound. Notwithstanding anything to the contrary in this Section 12, the Executive has informed the Company about the non-competition provision in the employment agreement she has with her current (pre-Company) employer, and the Company has agreed to indemnify the Executive from any liability arising from any allegation her current employer may make that she breached the non-competition provision of that agreement.

13. Confidentiality Agreement. As a material condition of Executive's employment with the Company, the Executive shall execute and comply with the terms of the Motiva USA, LLC Confidentiality, Non-Competition and Non-Solicitation Agreement attached hereto as Exhibit A (the "Related Agreement").

14. Protected Activity. The Executive understands that nothing in this Agreement or the Related Agreement shall in any way limit or prohibit the Executive from engaging in any Protected Activity. For purposes of this Agreement, "Protected Activity" means filing a charge or complaint with, or otherwise communicating or cooperating with or participating in any investigation or proceeding that may be conducted by any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"). The Executive understands that in connection with such Protected Activity, the Executive is permitted to disclose documents or other information as permitted by law and subject to professional rules of conduct applicable to the Executive's role as General Counsel to the Company, and without giving notice to, or receiving authorization from, the Company Group. Notwithstanding, in making any such disclosures or communications, the Executive agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Proprietary Information to any parties other than the Government Agencies. The Executive further understands that "Protected Activity" does not include the disclosure of any Company Group attorney-client privileged communications. In addition, Executive hereby acknowledges that the Company has provided Executive with notice in compliance with the Defend Trade Secrets Act

of 2016 regarding immunity from liability for limited disclosures of trade secrets. The full text of the notice is attached in Exhibit B.

15. Indemnification. The Company hereby agrees to indemnify and hold harmless Executive in accordance with any indemnification agreement entered into by and between any member of the Company Group and the Executive that is currently in effect (each, an "Indemnification Agreement").

16. General Provisions.

(a) *Entire Agreement*. This Agreement, the Indemnification Agreement(s) and the Related Agreement contain the entire understanding between the parties hereto and supersede any prior employment and consulting agreements and understandings between the Executive and the Company (or any member of the Company Group).

(b) *Nonassignability*. Neither this Agreement nor any right or interest hereunder shall be assignable by the Executive, her heirs, beneficiaries or legal representatives without the Company's prior written consent provided, however, that nothing in this **Section 15** shall preclude:

(i) The Executive from designating a beneficiary to receive benefits payable hereunder upon her death; or

(ii) the personal representatives, administrators, or other legal representatives of Executive or her estate from assigning any rights hereunder to the person or persons entitled to such benefits.

The Company may assign this Agreement and its rights and interest hereunder to any entity within the Company Group without notice to or the consent of the Executive.

(c) *No Attachment*. Except as required by law, no right to receive payments under this Agreement shall be subject to anticipation, alienation, sale, assignment, encumbrance, charge, pledge, or hypothecation or to execution, attachment, levy, or similar process or assignment by operation of law, and any attempt, voluntary or involuntary, to effect any such action shall be null, void, and of no effect.

(d) *Notice*. Any notice, consent, approval or other communication given pursuant to the provisions of this Agreement shall be in writing and shall be (i) delivered by hand,
(ii) mailed by certified mail or registered mail, return receipt requested, postage prepaid, or
(iii)delivered by a nationally recognized overnight courier, U.S. Post Office Express Mail, or similar overnight courier which delivers only upon signed receipt of the addressee, and addressed as follows:

If to the Company: ESTABLISHMENT LABS HOLDINGS INC.
11401 Century Oaks Terrace Suite 400
Austin, TX 78758

Attention: Chief Human Resources Officer

If to the Executive: Executive's home address on file with the Company

Any notice shall be effective as of the time of receipt thereof by the addressee or any agent of the addressee, except that in the event the addressee or such agent of the addressee shall refuse to receive any notice given by registered mail or certified mail as above provided or there shall be no person available at the time of the delivery thereof to receive such notice, the time of the giving of such notice shall be the time of such refusal or the time of such delivery, as the case may be. Any party hereto may, by giving five (5) days written notice to the other party hereto in the manner described herein, designate any other address in substitution of the foregoing address to which notice shall be given.

(e) *Modification*. This Agreement may not be modified or amended except by an instrument in writing signed by the party against whom enforcement is sought.

(f) *Waiver*. No term or condition of this Agreement shall be deemed to have been waived, nor shall there be any estoppel against the enforcement of any provision of this Agreement, except by written instrument of the party charged with such waiver or estoppel. No such written waiver shall be deemed a continuing waiver unless specifically stated therein, and each such waiver shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

(g) *Headings*. The section headings used herein are included solely for convenience of reference and shall not control the meaning or interpretation of any of the provisions of this Agreement.

(h) *Binding Agreement*. This Agreement shall be binding upon, and inure to the benefit of, the Executive and the Company, and the Company's successors and assigns. The rights and obligations hereunder are also being granted for the benefit of any Company Group member, and such rights and obligations may be enforced by any Company Group member.

(i) *Additional Acts*. The Executive and the Company each agrees to execute, acknowledge and deliver all further instruments, agreements or documents and do all further acts that are necessary or expedient to carry out this Agreement's intended purposes.

(j) *Construction*. Each of the parties hereto declare that they or their counsel participated in the drafting of this Agreement and that, accordingly, this Agreement shall not be construed more strongly against any party hereto because it drafted this Agreement.

(k) *Severability*. The invalidity or unenforceability of any one or more of the words, phrases, sentences, clauses, or sections contained in this Agreement shall not affect the validity or enforceability of the remaining provisions of this Agreement or any part of any provision, all of which are inserted conditionally on their being valid in law, and in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid or unenforceable, this Agreement shall be construed as if such invalid or unenforceable word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted or shall be enforced as nearly as possible according to their original terms and intent to eliminate any invalidity or unenforceability. If any invalidity or unenforceability is caused by the length of any period of time or the size of any area

set forth in any part of this Agreement, the period of time or area, or both, shall be considered to be reduced to a period or area which would cure the invalidity or unenforceability. A court of competent condition is expressly authorized to modify any unenforceable provision of this Agreement in lieu of severing such unenforceable provision in its entirety, whether by rewriting the offending provision, adding additional language to this Agreement, or making such other modifications as it deems warranted to carry out the intent as embodied herein to the maximum extent permitted by law.

Remedies. Unless otherwise specified herein, no remedy conferred upon either party to this Agreement is intended to be exclusive of any other remedy herein or by law provided or permitted, but each shall be cumulative and shall be in addition to every other remedy given hereunder or now or hereafter existing at law or in equity. Every power or remedy given by this Agreement to any party or to which such party may otherwise be entitled, may be exercised concurrently or independently, from time to time, and as often as may be deemed expedient and inconsistent remedies may be pursued. Because a breach of the provisions of this Agreement, the Indemnification Agreement(s) or the Related Agreement will not adequately be compensated by money damages, either party shall be entitled, in addition to any other right or remedy available, to seek an injunction restraining such breach or a threatened breach by the other party and/or to specific performance by the other party of any such provision of this Agreement, the Indemnification Agreement(s) or the Related Agreement and in any case no bond or other security shall be required in connection therewith, and the parties hereby consent to the issuance of such injunction and to the ordering of specific performance.

(l) *Enforcement*. If any party hereto shall fail to perform any covenant or condition hereof or shall otherwise be in breach of this Agreement, such party shall pay to the non-defaulting party its reasonable attorneys' fees and costs incurred as a result of their efforts to enforce this Agreement (whether or not litigation is commenced, at all trial and appellate levels and in bankruptcy).

(m) *Governing Law and Choice of Forum*. This Agreement shall be construed and enforced in accordance with the laws of the State of Texas, notwithstanding any state's choice-of-law rules to the contrary. The parties further agree that any legal action relating to this Agreement may be commenced and maintained before a state or federal court located in Collin County, Texas. The parties hereby submit to the jurisdiction of such courts and waive any right to challenge or otherwise object to personal jurisdiction or venue, in any action commenced or maintained in such courts.

(n) *Execution in Counterparts*. The parties hereto may execute this Agreement in two or more counterparts, each of which shall be deemed to be an original, but all such counterparts shall constitute one and the same instrument, and all signatures need not appear on any one counterpart.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the day and year first above written.

ESTABLISHMENT LABS HOLDINGS INC.

/s/ Peter Caldini
Peter Caldini
Chief Executive Officer

EXECUTIVE

/s/ Cassandra E. Harris
Cassandra E. Harris

EXHIBIT A

MOTIVA USA, LLC CONFIDENTIALITY,
NON-COMPETITION AND NON-SOLICITATION AGREEMENT

This Confidentiality, Non-Competition and Non-Solicitation Agreement ("***Agreement***") is made by and between **Motiva USA, LLC**, a Delaware limited liability company (the "***Company***") and Cassandra E. Harris, an individual (the "***Employee***"), as of February 23, 2026.

Recitals

A. For purposes of this Agreement, the term "Company" means Motiva USA, LLC, its parent company, Establishment Labs Holdings Inc., and/or any or each of its affiliates, or direct or indirect subsidiaries, as well as any successor-in-interest to Motiva USA, LLC and/or to any of its direct or indirect subsidiaries, affiliates, or parents.

B. Employee is employed or is being employed by Company in a capacity in which Employee has or will have extensive access to Confidential Information and trade secrets of Company, and/or is or may be offered certain equity incentives in consideration for entering this agreement.

C. Company has offered Employee employment and/or other valuable consideration, which may include without limitation such consideration as original employment, job promotion, an increase in compensation and/or a discretionary equity award, and access to Company Confidential Information and trade secrets, contingent upon Employee's entering into this Agreement.

D. This Agreement supersedes and completely replaces any and all prior offers, agreements, understandings, or representations, whether written or oral, between the Employee and the Company regarding the terms and conditions of Employee's employment with and post- employment obligations to the Company.

Agreement

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein, the promises contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Employee agree to be legally bound as follows:

1. **Acknowledgements**. Employee acknowledges that Company is engaged in the highly competitive business of the development, manufacture, distribution, and sale of (a) breast implants and tissue expanders for all indications such as, without limitation: (i) cosmetic surgery and augmentation (primary and revision); (ii) reconstructive surgery (primary and revision) including single or double mastectomy and post-mastectomy settings; (iii) post-lumpectomy; and/or (iv) pectus excavatum; (b) gluteal implants; and (c) specialized tools and components used in breast and gluteal implant surgery (e.g., Keller Funnel) and that Employee serves or will serve in a capacity involving provision of services in support of Company's business. Further, that in the course of Employee's employment with Company, Employee (i) has been and/or will be given access to trade secrets and other Confidential Information (as hereinafter defined); (ii) has

participated and/or will participate in the development, execution, and/or usage of processes, concepts, strategies, methods, and/or technologies related to Company's business; and/or (iii) has been and/or will be given specialized training relating to Company's business and/or processes. Employee further acknowledges that the employment with the Company is at-will employment that can be terminated by Employee or Company at any time with or without cause.

2. **Non-Disclosure and Ownership of Confidential Information**. Employee acknowledges that Confidential Information is a valuable, special, and unique asset of Company, and solely the property of Company, and agrees to the following; provided, however, that this Agreement does not, in any manner, prevent employees from filing a complaint with, providing information to, or participating in an investigation conducted by, the Securities and Exchange Commission, the United States Equal Opportunity Commission or any other governmental or law enforcement agency.

(a) Confidential Information Defined. The term "***Confidential Information***" includes, but is not limited to, any and all of Company's trade secrets, confidential and proprietary information and all other information and data of Company that is not generally known to the public or other third parties who could derive economic value from its use or disclosure. Confidential Information includes, without limitation, technical information such as product specifications, compounds, formulas, improvements, discoveries, developments, designs, inventions, techniques, new products and surgical training methods, and research and development information; confidential business methods and processes; business plans and strategies; marketing plans and strategies; non-public financial information including budgets, sales data, sales forecasts, sales quotas, and information regarding profits or losses; office optimization and logistics information; information pertaining to current and prospective customers; information pertaining to distributors and sales channel structures; pricing information; discount schedules; costing information; personnel information; compensation structure, schedules and plans; and information about current and prospective products or services, whether or not reduced to writing or other tangible medium of expression, including work product created by Employee in rendering services for Company.

(b) Non-Disclosure of Confidential Information. During Employee's employment with Company and thereafter, Employee will not disclose, transfer, or use (or seek to induce others to disclose, transfer, or use) any Confidential Information for any purpose other than (i) disclosure to authorized employees and agents of Company who are bound to maintain the confidentiality of the Confidential Information; (ii) for authorized purposes during the course of Employee's employment in furtherance of Company's business; and/or (iii) as specifically allowed or required under applicable law. Employee's non-disclosure obligations shall continue as long as the Confidential Information remains confidential and shall not apply to information that becomes generally known to the public through no fault or action of Employee. The Federal Defend Trade Secrets Act provides that individuals may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (a) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney if such disclosure is made solely for the purpose of reporting or investigating a suspected violation of law or for pursuing an anti-retaliation lawsuit; or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal and the individual does not disclose the trade secret except pursuant to a court order.

(c) Protection of Confidential Information. Employee will notify Company in writing of any circumstances which may constitute unauthorized disclosure, transfer, or use of Confidential Information. Employee will use Employee's best efforts to protect Confidential Information from unauthorized disclosure, transfer, or use. Employee will implement and abide by all procedures adopted by Company to prevent unauthorized disclosure, transfer, or use of Confidential Information. Notwithstanding the above requirements, nothing in this Agreement shall restrict Employee's right to make disclosures specifically allowed or required under applicable law.

3. **Ownership of Intellectual Property**.

(a) Invention Defined. The term "***Invention***" includes, but is not limited to ideas, programs, processes, systems, intellectual property, discoveries, and/or improvements which Employee discovers, invents, originates, develops, makes, or conceives alone or in conjunction with others which relate to Company's present or future business during Employee's employment with Company and/or within six (6) months after Employee's employment ends. An Invention is covered by this Agreement regardless of whether (i) Employee conceived of the Invention in the scope of Employee's employment; (ii) the Invention is patentable; or (iii) Company takes any action to commercialize or develop the Invention.

(b) Ownership of Inventions. Inventions are solely the property of Company. Employee agrees that by operation of law and/or the effect of this Agreement Employee does not have any rights, title, or interest in any Inventions. Notwithstanding, Employee may be recognized as the inventor of an Invention without retaining any other rights associated therewith.

(c) Disclosure and Assignment of Inventions. Employee hereby assigns to Company all right, title and interest Employee may have in any Inventions. Employee agrees to: (i) promptly disclose all such Inventions in writing to Company; (ii) keep complete and accurate records of all such Inventions, which records shall be Company property and shall be retained on Company premises; and (iii) execute such documents and do such other acts as may be necessary in the opinion of Company to establish and preserve Company's property rights in all such Inventions. This section shall not apply to any Invention for which no equipment, supplies, facility, or Confidential Information of Company was used and which was developed entirely on Employee's own time, and (1) which does not relate (a) directly to the business of Company or (b) to Company's actual or demonstrably anticipated research or development, and (2) which does not result from any work performed by Employee for Company.

(d) Works of Authorship. All written, graphic or recorded material and all other works of authorship fixed in a tangible medium of expression (including but not limited to computer software) made or created by Employee, solely or jointly with others, during Employee's employment with Company and relating to Company's business, actual or contemplated, shall be the exclusive property of Company (collectively "***Works***"). Company will have the exclusive right to copyright such Works. Employee agrees that if any Work created while employed by Company, whether or not created at the direction of Company, is copyrightable, such Work will be a "work made for hire," as that term is defined in the copyright laws of the United States. If, for any reason, any copyrightable Works created by Employee are

excluded from that definition, Employee hereby assigns and conveys to Company all right, title, and interest (including any copyright and renewals) in such Works.

(e) Attribution and Use of Works and Inventions; Waiver of Assertion of "Moral" Rights in Inventions and Works. Employee agrees that Company and its licensees are not required to designate Employee as author, inventor, or developer of any Works or Inventions when distributed or otherwise. Employee hereby waives, and agrees not to assert, any "moral" rights in any Inventions and Works. Employee agrees that Company and its licensees shall have sole discretion with regard to how and for what purposes any Inventions or Works are used or distributed.

(f) Employee Cooperation in Establishment of Company Proprietary Rights. Employee will sign documents of assignment, declarations, and other documents and take all other actions reasonably required by Company, at Company's expense, to perfect and enforce any of its proprietary rights. In the event Company is unable, for any reason whatsoever, to secure Employee's signature to any lawful or necessary documents required to apply for, prosecute, perfect, or assign any United States or foreign application for Letters Patent, trademark, copyright registration, or other filing to protect any Invention or Work, Employee hereby irrevocably designates and appoints Company and its duly authorized officers and agents as Employee's agent and attorney in fact, to act for and on Employee's behalf, to execute and file any such application, registration, or other filing, and to do all other lawfully permitted acts to further the prosecution, issuance, or assignment of Letters Patent or other protections on such Inventions, or registrations for trademark or copyright or other protections on such Works, with the same force and effect as if executed by Employee.

4. **Return of Confidential Information and Company Property**. Immediately upon termination of Employee's employment with Company, Employee shall return to Company all of Company's property relating to Company's business, including without limitation all of Company's property which is in the possession, custody, or control of Employee such as Confidential Information, documents, hard copy files, copies of documents and electronic information/files, and equipment (*e.g.*, computers and mobile phones).

5. **Obligations to Other Entities or Persons**. Employee warrants that Employee is not bound by the terms of a confidentiality agreement or any other legal obligation which would either preclude or limit Employee from disclosing or using any of Employee's ideas, inventions, discoveries, or other information or otherwise fulfilling Employee's obligations to Company. While employed by Company, Employee shall not disclose or use any confidential information belonging to another entity or other person.

6. **Conflict of Interest and Duty of Loyalty**. During Employee's employment with Company, Employee shall not engage, directly or indirectly, in any activity, employment or business venture, whether or not for remuneration, that (i) is competitive with Company's business; (ii) deprives or potentially could deprive Company of any business opportunity; (iii) conflicts or potentially could conflict with Company's business interests; or (iv) is otherwise detrimental to Company, including but not limited to preparations to engage in any of the foregoing activities.

7. **Restrictive Covenants**. Employee agrees to, and covenants to comply with, each of the following separate and divisible restrictions:

(a) Definitions.

(1) "***Competing Product***" is defined as any implant, device, or medical product(s), service(s), instrument(s) or supplies that is the same as, related to, or similar to any product, process or service that Company is researching, developing, manufacturing, distributing, selling and/or providing at the time of Employee's separation from employment with Company. "Competing Products" include but are not limited to the following Company product categories: (a) breast implants and tissue expanders for all indications such as, without limitation, (i) cosmetic surgery and augmentation (primary and revision); (ii) reconstructive surgery (primary and revision) including single or double mastectomy and post-mastectomy settings; (iii) post- lumpectomy; (iv) biological tissue matrix (*i.e.*, supporting slings and meshes); and/or (v) pectus excavatum; (b) gluteal implants; and (c) specialized tools and components used in breast and gluteal implant surgery (e.g., Keller Funnel).

(2) "***Competing Organization***" is defined as any organization that researches, develops, manufactures, markets, distributes and/or sells one or more Competing Products. A "Competing Organization" is diversified if it operates multiple, independently operating business divisions, units, lines, or segments some of which do not research, develop, manufacture, market, distribute and/or sell any Competing Products.

(3) "***Prohibited Capacity***" is defined as (a) any same or similar capacity to that held by Employee at any time during Employee's last two (2) years of employment with Company; (b) any executive or managerial capacity; or (c) any capacity in which Employee's knowledge of Confidential Information and/or Inventions would render Employee's assistance to a Competing Organization a competitive advantage.

(4) "***Restricted Geographic Area***" is defined as all countries, states, parishes or counties, municipalities, and territories, in which Company is doing business or is selling its products at the time of termination of Employee's employment with Company, including but not limited to every parish and municipality in the state of Louisiana. Employee acknowledges that this geographic scope is reasonable given Employee's position with Company, the international scope of Company's business; and the fact that Employee could compete with Company from anywhere Company does business.

(5) "***Restricted Period***" is defined as the date on which Employee executes this Agreement and continuing for twelve (12) months after the Employee's last day of employment with Company unless otherwise extended by Employee's breach of this Agreement. The running time on the Restricted Period shall be suspended during any period in which Employee is in violation of any of the restrictive covenants set forth herein, and all restrictions shall automatically be extended by the period Employee was in violation of any such restrictions.

(6) "***Customer***" is defined as any person or entity (including but not limited to: accounts, distributors, customers, doctors, clinics, surgery centers, hospitals, group purchasing organizations, integrated delivery networks, or clients) to whom, as of the date of Employee's separation from Company employment or at any time during the two (2) years prior

to such separation, Company sold or provided any products and/or services and with whom Employee interacted in the course of employment with the Company or about whom Employee learned Confidential Information during employment with the Company.

(7) "***Active Prospect***" is defined as any person or entity that Company individually and specifically marketed to and/or held discussions with regarding the distribution and/or sale of any of Company's products, processes, or services at any time during the last six (6) months of Employee's employment with Company.

(b) Restrictive Covenants. During the Restricted Period, Employee agrees to be bound by each of the following independent and divisible restrictions:

(1) Covenant Not to Compete.

(A) Employee will not, within the Restricted Geographic Area, be employed by, work for, consult with, provide services to, or lend assistance to any Competing Organization in a Prohibited Capacity. For purposes of this section (A), if Company enforces the Restricted Period for more than 9 months, Company will compensate Employee for any such enforcement at a rate equivalent to Employee's then-applicable annual base salary, with a maximum additional compensation of 3 months' base salary, assuming full enforcement of Restricted Period.

(B) Employee may be employed by, work for, consult with, provide services to, or lend assistance to a Competing Organization provided that: (i) the Competing Organization's business is diversified; (ii) the part of the Competing Organization's business with which Employee will be affiliated would not, evaluated on a stand-alone basis, be a Competing Organization; (iii) Employee's affiliation with the Competing Organization does not involve any Competing Products; (iv) Employee provides Company a written description of Employee's anticipated activities on behalf of the Competing Organization which includes, without limitation, an assurance satisfactory to Company that Employee's affiliation with the Competing Organization does not constitute a Prohibited Capacity; and (v) Employee's affiliation with the Competing Organization does not constitute a competitive disadvantage to Company.

(2) Covenant Not to Solicit Customers, Vendors, or Active Prospects. Employee will not, directly or indirectly, (i) provide, sell, or market; (ii) assist in the provision, selling or marketing of; or (iii) attempt to provide, sell or market any Competing Products to any of Company's Customers or Active Prospects located in the Restricted Geographic Area. Employee will not, directly or indirectly, divert, entice, or otherwise take away from Company the business of any Customer or solicit or induce any vendor, supplier or Customer to terminate or reduce its relationship with Company.

(3) Covenant Not to Solicit Company Employees. Employee will not employ, solicit for employment, or advise any other person or entity to employ or solicit for employment, any individual (1) who is employed by or is a contractor or representative of the Company at the time of Employee's separation from Company and (2) who has access to or possession of any Confidential Information that would give a Competing Organization an unfair

advantage or otherwise directly or indirectly induce or entice any such individual to terminate his/her employment with Company.

(4) Covenant Not to Disparage Company. Employee will not make or publish any disparaging or derogatory statements about Company; about Company's products, processes, or services; or about Company's past, present and future officers, directors, employees, attorneys, and agents. Disparaging or derogatory statements include, but are not limited to, negative statements regarding Company's business, products or other practices; provided, however, nothing herein shall prohibit Employee from providing any information as may be compelled by law or legal process.

8. **Reasonableness of Terms**. Employee acknowledges and agrees that the restrictive covenants contained in this Agreement restrict Employee from engaging in activities for a competitive purpose and are reasonably necessary to protect Company's legitimate interests in Confidential Information, Inventions, and goodwill. Additionally, Employee acknowledges and agrees that the restrictive covenants are reasonable in all respects, including, but not limited to, temporal duration, scope of prohibited activities, and geographic area. Employee further acknowledges and agrees that the restrictive covenants set forth in this Agreement will not pose unreasonable hardship on Employee and that Employee will have a reasonable opportunity to earn an equivalent livelihood without violating any provision of this Agreement.

9. **Severability, Modification of Restrictions**. The covenants and restrictions in this Agreement are separate and divisible, and to the extent any covenant, provision, or clause of this Agreement is determined to be unenforceable or invalid for any reason, Company and Employee acknowledge and agree that such unenforceability or invalidity shall not affect the enforceability or validity of the remainder of the Agreement. If any particular covenant, provision, or clause of this Agreement is determined to be unreasonable or unenforceable for any reason, including, without limitation, temporal duration, scope of prohibited activity, and/or scope of geographic area, Company and Employee acknowledge and agree that such covenant, provision, or clause shall automatically be deemed reformed to have the closest effect permitted by applicable law to the original form and shall be given effect and enforced as so reformed to whatever extent would be reasonable and enforceable under applicable law. The parties agree that any court interpreting the provisions of this Agreement shall have the authority, if necessary, to reform any such provision to make it enforceable under applicable law.

10. **Remedies**. Employee acknowledges that a breach or threatened breach by Employee of this Agreement will give rise to irreparable injury to Company and that money damages will not be adequate relief for such injury. Accordingly, Employee agrees that Company shall be entitled to obtain injunctive relief, including, but not limited to, temporary restraining orders, preliminary injunctions and/or permanent injunctions, without having to post any bond or other security, to restrain or prohibit such breach or threatened breach, in addition to any other legal remedies which may be available. In addition to all other relief to which it shall be entitled, Company shall be entitled to recover from Employee all litigation costs and attorneys' fees incurred by Company in any action or proceeding relating to this Agreement in which Company prevails in any respect, including, but not limited to, any action or proceeding in which Company seeks enforcement of this Agreement or seeks relief from Employee's violation of this Agreement.

11. **Survival of Obligations**. Employee acknowledges and agrees that Employee's obligations under this Agreement, including, without limitation, Employee's non-disclosure and non-competition obligations, shall survive the termination of Employee's employment with Company, whether such termination is with or without cause and whether it is voluntary or involuntary. Employee further acknowledges and agrees that: (a) Employee's non-disclosure, non-disparagement, non-solicitation, and non-competition covenants set forth in Paragraphs 2 and 7 of this Agreement shall be construed as independent covenants and that no breach of any contractual or legal duty by Company shall be held sufficient to excuse or terminate Employee's obligations or to preclude Company from obtaining injunctive relief or other remedies for Employee's violation or threatened violation of such covenants, and (b) the existence of any claim or cause of action by Employee against Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to Company's enforcement of Employee's obligations under Paragraphs 2 and 7 of this Agreement.

12. **Governing Law and Choice of Forum**. This Agreement shall be construed and enforced in accordance with the laws of the State of Texas, notwithstanding any state's choice- of- law rules to the contrary. The parties further agree that any legal action relating to this Agreement may be commenced and maintained before a state or federal court located in Collin County, Texas. The parties hereby submit to the jurisdiction of such courts and waive any right to challenge or otherwise object to personal jurisdiction or venue, in any action commenced or maintained in such courts.

13. **Enforcement**. The parties agree that Motiva USA, LLC, Establishment Labs Holdings Inc., and/or any or each of its affiliates, or direct or indirect subsidiaries, as well as any successor-in-interest to Motiva USA, LLC and/or any of its direct or indirect subsidiaries, affiliates, or parents are express and intended parties to and beneficiaries to this Agreement, with full rights to enforce this Agreement independently or in conjunction with each other.

14. **State Law Modifications for Certain Employees**. Not applicable.

15. **Successors and Assigns**. Company shall have the right to assign this Agreement, and, accordingly, this Agreement shall inure to the benefit of, and may be enforced by, any and all successors and assigns of Company, including without limitation by asset assignment, stock sale, merger, consolidation or other corporate reorganization, and shall be binding on Employee. The services to be provided by Employee to Company are personal to Employee, and Employee shall not have the right to assign Employee's duties under this Agreement.

16. **Modification**. This Agreement may not be amended, supplemented, or modified except by a written document signed by both Employee and a duly authorized officer of Company.

17. **No Waiver**. The failure of Company to insist in any one or more instances upon performance of any provision of this Agreement or to pursue its rights hereunder shall not be construed as a waiver of any such provisions or the relinquishment of any such rights.

18. **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which when taken together will constitute one and the same agreement.

19. **Entire Agreement; Termination of Prior Agreements**. This Agreement, including Recitals, constitutes the entire agreement of the parties with respect to the subjects specifically addressed herein, and supersedes any and all prior offers, agreements, understandings, or representations, whether oral or written, regarding the terms and conditions of Employee's employment with and post-employment obligations to the Company, including but not limited to any Job Offer Letter; Letter of Intent; Employment Agreement and any amendments thereto; and any consulting or professional services agreement, including the one between Company and BCC Ventures LLC and any amendments thereto. Notwithstanding the foregoing, to the extent the employee has an existing non-competition, confidentiality, and/or non-solicitation agreement in favor of Company and has breached or violated the terms thereof, Company may continue to enforce its rights and remedies under and pursuant to such existing agreement.

Employee's signature below indicates that Employee has read the entire Agreement, understands what Employee is signing, and is signing the Agreement voluntarily. Employee has the right to consult with counsel prior to signing this Agreement and agrees that Company advised Employee to consult with an attorney prior to signing the Agreement.

"EMPLOYEE"

/s/ Cassandra E. Harris
Cassandra E. Harris

"COMPANY"

/s/ Peter Caldini
Peter Caldini
CEO

EXHIBIT B

Section 7 of the Defend Trade Secrets Act of 2016

" . . . An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that—(A) is made—(i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual—(A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3ASR (File No. 333-271418) and S-8 (File Nos. 333-226340, 333-230419, 333-237219, 333-254283, 333-263149, 333-270196, 333-277667, and 333-285415) of our report dated February 28, 2025, relating to the consolidated financial statements of Establishment Labs Holdings Inc. (the "Company") as of December 31, 2024 appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Los Angeles, California

February 27, 2026