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, 2023

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.
Building B15 and 25 Coyol Free Zone Alajuela Costa Rica	**Not applicable**
Address of Principal Executive Offices	Zip Code

+506-2434-2400

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 an 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, 2023 was approximately $1,342,497,565. 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 March 1, 2024, the number of the registrant's common shares outstanding was 27,205,003.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2024 annual meeting of shareholders (the "2024 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2024 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, 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, VelvetSurface, ProgressiveGel, TrueMonobloc, BluSeal, Divina, Ergonomix, Ergomonix2, Ergonomix2 Diamond, Mia Femtech, MotivaImagine and Zen, 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 through 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 future operating results, 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 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 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 conditions, including slower growth or recession, inflation or decreases in consumer spending power or confidence, could adversely affect our business, financial condition or results of operations.
- We expect to incur losses for the foreseeable future, 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.
- The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. In addition, safety issues or other challenges may arise during the conduct of a trial. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.
- If the FDA or similar regulatory authority does not approve our products or requires additional clinical trials or preclinical data before any approval or if any approval of our products includes additional restrictions on the label, or requires a characterization of our products, including the description of the product surface (e.g. smooth, texture, other) that differs from ours and/or other regulatory authorities, our business, financial condition, results of operations and growth prospects could be materially adversely affected.
- 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 in recent years.
- In certain large markets, we engage 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.
- 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 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.
- 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.
- 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. If this supplier were to increase prices for this raw material over time 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.
- 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 could be affected by fluctuations in currency rates.
- Negative publicity concerning our products or our competitors' products, including due to product defects, recalls and any resulting litigation, could harm our reputation and reduce demand for silicone breast implants, either of which could adversely impact our financial results and/or share price.

- Recent news coverage has called into question the long-term safety of breast implants and 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 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 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 under a parent holding company in the British Virgin Islands in 2013.

Our line of silicone gel-filled breast implants, branded as Motiva Implants, is the centerpiece of our medical technology platform. Our post-market surveillance data (which was not generated in connection with a United States Food and Drug Administration, or FDA, pre-market approval, or PMA, study collected at defined follow-ups, but was patient or practitioner reported) and published third-party registries and data indicate that Motiva Implants have low rates of adverse events (including rupture, capsular contracture, and safety related reoperations) that we believe compare favorably with those of our competitors. We believe the proprietary technologies that differentiate our Motiva Implants enable improved safety and aesthetic outcomes and drive our revenue growth. We have developed other complementary products and services, which are aimed at further enhancing patient outcomes.

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 86 countries, including, most recently, in China. We currently sell our products via exclusive distributors or our direct sales force and have introduced five generations of Motiva Implants. We currently commercially sell five product families: (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 (a non-invasive, 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

In January 2024, we announced the commercial launch of Motiva Implants in China and the completion of the first procedure with the Motiva Flora SmoothSilk Tissue Expander in the United States.

We also entered into a securities purchase agreement, pursuant to which we sold an aggregate of two million common shares and pre-funded warrants for gross proceeds of approximately $50 million. See Note 15 *“Subsequent Events”* for additional information.

We are in the process of expanding our manufacturing facilities and corporate offices in the Coyol Free Zone, or CFZ, in Costa Rica. Construction of the cold shell structure of the Sulàyöm Innovation Campus was initially funded by the Coyol Free Zone in 2021 until we exercised our option to purchase the title of the land and cold shell building for approximately $12.6 million in 2022. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus, which includes approximately 100,000 square feet of facility space intended to increase our manufacturing capacity by approximately 730,000 units per year. We estimate a total of $51.7 million in costs for this initial phase of our expansion project, of which the majority has been incurred to date. Additional phases of the project may be executed, at our option, to further expand manufacturing capacity at the new facility. We expect to commence manufacturing from the new facility in 2024. See Note 3 *“Balance Sheet Accounts”* for additional information.

In November 2023, we received National Medical Products Administration, or NMPA, approval in China for Motiva Implants, 510(k) clearance from the FDA for the Motiva Flora SmoothSilk Tissue Expander in the United States, and CE mark approval under the European Medical Device Regulation for the Motiva Injector, the Motiva Inflatable Balloon and the Motiva Channel Dissector.

In addition, in October 2023, we completed and announced the results of the two-year 100-patient clinical study for Mia Femtech, our patented technologies that can increase breast shape by 1 to 2 cups in a 15-minute procedure without the need for general anesthesia. The single-center, Institutional Review Board approved study began in December 2020 and involved participation of fifteen board-certified plastic surgeons from Costa Rica, Sweden, England, Brazil, Austria, Italy, Belgium, and the United States. We have launched Mia Femtech globally

through partnerships with clinics in Japan, Spain, Switzerland, Sweden, Germany, France, Costa Rica, Turkey and the Middle East. In October 2023, we also launched, in select geographies, Zen - the newest generation of our passive RFID technology that is now non-ferromagnetic. Zen is available with Motiva Ergonomix2 Round implants in the Joy program.

In April 2023, we issued 1,165,000 common shares in an underwritten public offering for net proceeds of approximately $84.6 million.

In February 2023, we submitted the final module of our clinical trial for Motiva Implants in the United States to the FDA. We received FDA approval to start our clinical trial in 2018. By August 2019, we had completed all surgeries in the aesthetic cohorts and implemented a bifurcated regulatory strategy for data submission. In April 2022, we released preliminary results for the primary augmentation cohort and, by June 2022, we completed enrollment and surgeries for the primary reconstruction cohort. By September 2022, we had completed the three-year follow-up for the aesthetic cohort.

In January 2023, we announced a partnership with Seishin Plastic and Aesthetic Surgery Clinic in Japan for Mia Femtech. Previously, we obtained regulatory approval from the Pharmaceuticals and Medical Devices Agency, as well as reimbursement for post-mastectomy reconstruction under the Japanese National Health System, for Motiva Implants and the Motiva Flora tissue expander in November 2022.

In April 2022, we entered into a credit agreement, or the Credit Agreement, for term loans to the Company in an aggregate principal amount of up to $225 million, with Oaktree Fund Administration, LLC, as administrative agent. The first and second tranche were advanced in the amount of $150 million and $25 million in April and December 2022, respectively. A portion of the proceeds from the first tranche was used to repay in full and terminate the $65 million in aggregate principal amount outstanding under the Company's previous credit agreement with Madryn Health Partners, LP, or the Madryn Credit Agreement, and the $6.5 million early repayment penalty. In February 2024, we amended the Credit Agreement, modifying the access conditions, commitment termination dates and interest rates for the two remaining available tranches. See Note 5 *"Debt"* and Note 15 "*Subsequent Events"* for additional information.

We are focused on investing in manufacturing capacity, marketing, customer service, and sales force in multiple geographies to promote the use of our Motiva Implants. This expansion may result in short-term losses as we grow our organization and invest in research, clinical trials, and other commercialization efforts.

Our Market

Breast Augmentation

Breast augmentation surgery is one of the leading aesthetic surgical procedures by number of procedures globally. Approximately 2.2 million breast augmentations were performed worldwide in 2022, according to International Society of Aesthetic Plastic Surgery, or ISAPS. The following table lists the top markets by country for total breast augmentations in 2022 according to ISAPS.

Total Breast Augmentation Procedures			
Rank[1]	Country	Procedures	Percentage of World-Wide Total
1	United States	255,200	11.7%
2	Brazil	243,923	11.2%
3	Mexico	103,524	4.8%
4	Argentina	77,710	3.6%
5	Germany	76,658	3.5%
6	Colombia	63,204	2.9%
7	Turkey	55,254	2.5%
8	Italy	42,058	1.9%
9	Spain	39,519	1.8%
10	India	29,986	1.4%

(1) Rankings are based solely on those countries from which a sufficient survey response was received and data was considered to be representative.

Breast Reconstruction

The American Society of Plastic Surgeons noted in their *Procedural Statistics Release* that 151,641 breast reconstructions were performed in 2022 in the United States. According to Fairfield Market Research 2023 report, the global breast reconstruction market is expected to grow at a CAGR of 7.2% from 2023 to 2030. The market, currently valued at $0.6 billion in 2022, is projected to exceed $1 billion by 2030. This growth is expected to be driven by factors like technological advancements, increased awareness, 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 primary augmentations

The table below reports key adverse event information from published data from their 10-year prospective Core clinical trials conducted by the only three 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 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 were 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 provides 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 Competitive Strengths

- ***Patient-centric innovative implant technologies.*** We have developed our Motiva Implants by enhancing and creating novel product components for our implants, and then combining these components into products that deliver improved aesthetic outcomes, increased patient satisfaction and favorable safety profiles.
- ***Extensive suite of complementary products and services.*** Our product portfolio includes innovative devices and tools. We believe our designed surgical procedures, such as MotivaHybrid, Motiva MinimalScar and Mia Femtech, will address key unmet needs for both the physician and the patient.
- ***Proprietary internal manufacturing processes and capabilities.*** We manufacture our silicone products in state-of-the-art manufacturing facilities in Costa Rica. In these facilities, we utilize our novel 3D imprinted molding method to create proprietary surface features that, in combination with other proprietary materials and methods, differentiate our products from those of our competitors. We believe our modern facilities, focus on product quality and deep technological expertise have helped us establish and maintain a brand of consistency, quality and safety.
- ***Dynamic worldwide sales platform.*** We sell our products both through exclusive arrangements with leading local distributors who have strong local surgeon relationships and our direct sales force in key markets such as Brazil and primary markets in Europe. Using this market-specific approach, we have built an effective and efficient worldwide sales platform.
- ***Proven management team with expansive industry experience.*** We have a highly experienced management team that is comprised of leaders from the medical aesthetic market.

Our Growth Strategy

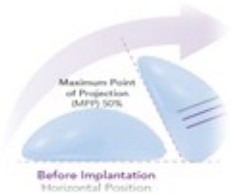
Our goal is to be the global leader in aesthetic surgical implant technology, including breast implants, while improving patient safety through product innovation. The key elements of our strategy include:

- ***Expand revenues in existing markets.*** We believe we can continue to grow market share in our existing markets due to the favorable safety profile and improved aesthetic outcomes of our Motiva Implants.
- ***Launch Motiva Implants in additional markets outside the United States.*** We expect that continued geographic expansion will be a key driver of growth in the near term. In recent years, we started sales through distributors in Australia, Israel, Peru, Russia, Saudi Arabia, Taiwan, Thailand and South Korea, as well as starting direct sales in Brazil, the second largest market for breast augmentation procedures. Expansion into China commenced in January 2024.
- ***Obtain FDA approval and enter the U.S. market.*** We are conducting our IDE clinical trial in the United States, with the goal of obtaining FDA PMA and commercializing our Motiva Implants in the United States. The Motiva IDE clinical trial enrolled 827 patients at 32 centers in the U.S., Germany, and Sweden. All enrollment surgeries in the IDE U.S. clinical trial were completed by June 2022. In February 2023, we submitted the final module of our clinical trial for Motiva Implants in the United States to the FDA. In April 2023, we presented the results of the clinical trial for 451 primary augmentation patients enrolled in the study through the three-year follow-up visit. We are awaiting FDA PMA approval of our Motiva Implants. We received 510(k) clearance for the Motiva Flora SmoothSilk Tissue Expander in October 2023 and announced the completion of the first commercial procedure in January 2024.
- ***Optimize patient conversion through sales and marketing programs.*** We employ a multi-faceted marketing strategy that includes social media engagement, conference presence, online advertising and patient and physician education. This approach enables us to engage with and educate patients on the Motiva brand and the benefits of our products, as well as increase clinical efficiency for our physician collaborators. In the future, we expect our social media and online patient and physician education to have important strategic synergies with our designed surgeries, which are promoted globally.

- ***Seek out and pursue strategic acquisitions.*** We intend to seek out other innovative products, services and procedures that satisfy unmet needs in the aesthetics space and complement our existing product portfolio as we believe this can be additive to future revenue growth. We have purchased distributor networks in strategic markets and may acquire other third-party sales organizations in the future. While we have no specific acquisitions or planned licensing agreements currently ongoing, we may engage in these, or other strategic transactions, with the goal of augmenting our existing product portfolio and global footprint.
- ***Continue a high level of engagement with key opinion leaders.*** We promote Motiva Implants, in part, via an extensive and robust calendar of physician education events led by key opinion leaders in the field of aesthetic and reconstructive surgery. In 2023 and 2022, we conducted 192 and 201 events, respectively, through our medical educational platform. We also collaborate actively with respected and influential key opinion leader surgeons to identify and develop new clinical applications for our existing products, as well as new product and strategic opportunities.

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 • Qid Safety Technology 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	86 countries			

Motiva Implants

The Motiva breast implants are a Class III Medical Device 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, and to date we have sold approximately 3.3 million units in various countries outside the United States. 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 visco-elastic 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, two different surfaces, SmoothSilk and

VelvetSurface, 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 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: SilkSurface/SmoothSilk

The surface topography of the breast implant shell surface varies between commercially available breast implants. Our SmoothSilk surface was designed to improve biocompatibility and to provide for the same surface topography around the entire implant for the benefit of the patients. The International Standard Organization, or ISO, through the new April 2018 standard (ISO 14607:2018), created a classification of implant surface textures according to roughness. This standard includes an objective method of defining the difference between smooth, micro and macro surfaces based on surface roughness average. The topology of SilkSurface/SmoothSilk is categorized in the smooth category, having a low roughness value of approximately 3.09 microns with thousands of contact features per square centimeter, which is significantly lower than the higher limit of the smooth surface clarification defined by ISO (< 10 microns). The Company and the FDA are in discussions on the product's labeling, including surface description terminology.

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 are smoother and have more regular 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.

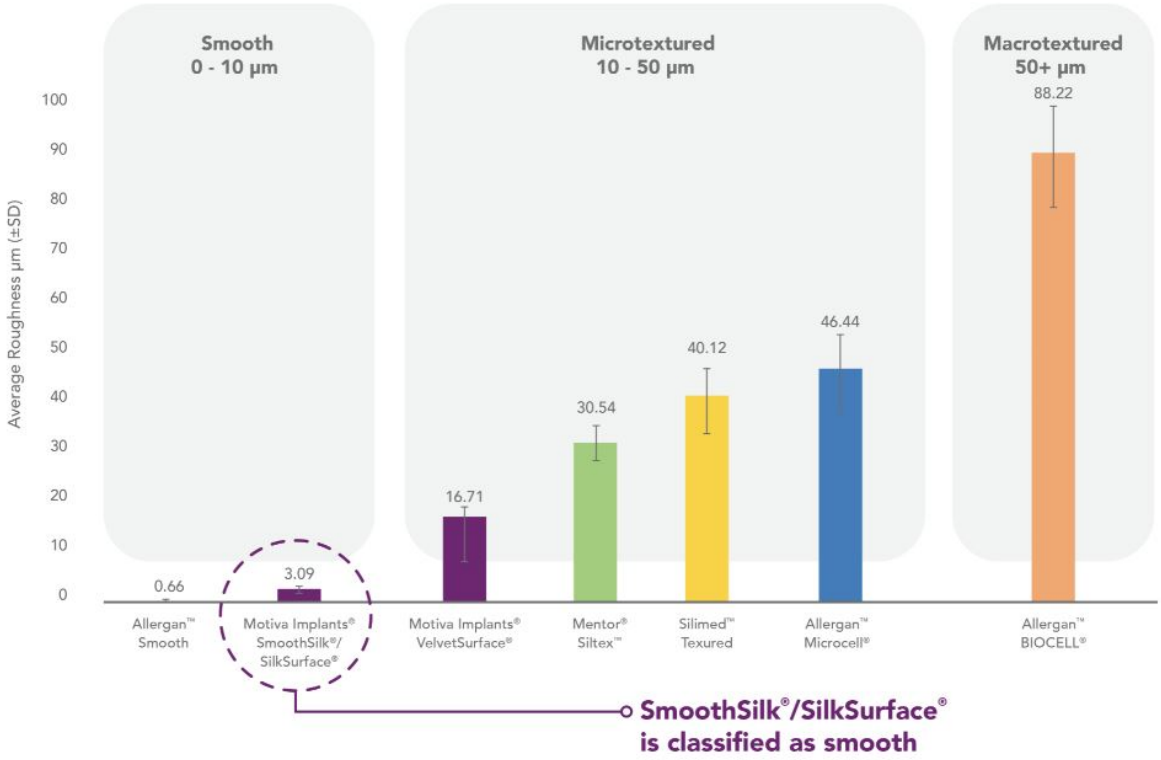
An abstract presented in 2017 by researchers at Montana State University showed less accumulation of both bacteria and biofilm on SmoothSilk in vitro when compared to smoother and textured surfaces. Biofilm formed on implant surfaces increases the risk of bacteria accumulation and capsule formation.

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 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 UC, 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.

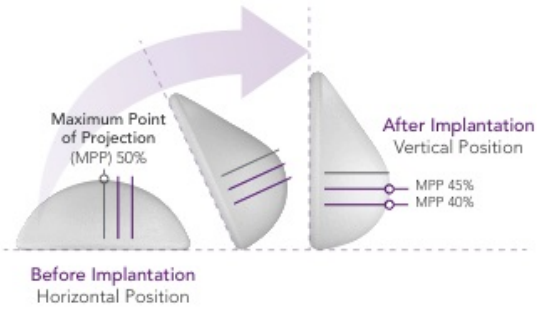
The graph below shows how our surface features compares with those of our competitors.

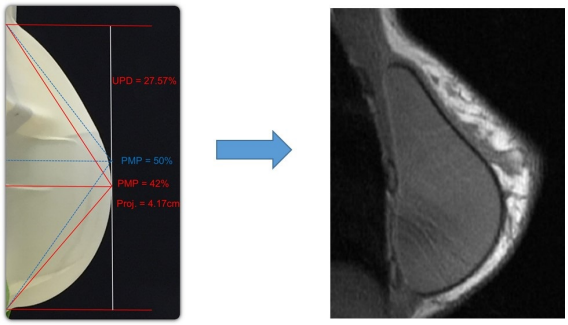


ProgressiveGel Family

The proprietary silicone chemistries that comprise our ProgressiveGel family allow for a high degree of cohesiveness and strength but add 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.

RFID Technology

We offer a Radio-Frequency Identification Device microtransponder (also referred to as Qid) 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.

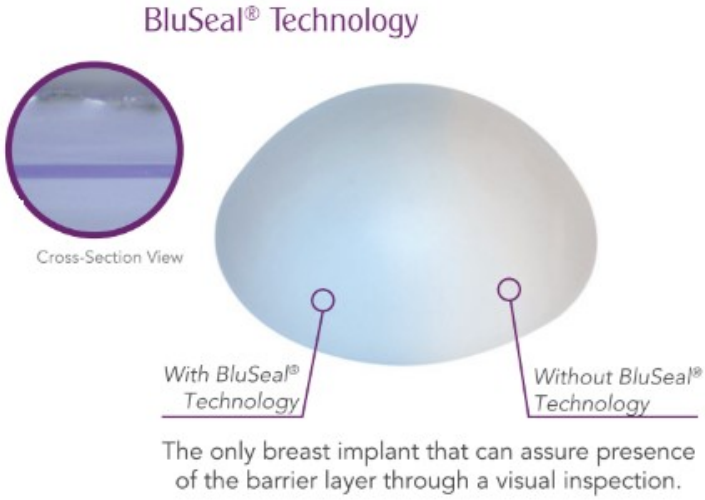
Each implant's unique electronic serial number is encoded into the RFID circuitry as part of a three-point authentication system: the microtransponder, the reader and the database. This authentication system prevents unauthorized access to any personal information of the patient and is compliant with 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. Motiva Ergonomix2 Diamond implants used in the Mia Femtech system feature Zen, and are available in select geographies with Motiva Ergonomix2 Round Implants in 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 has been registered in 57 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. The Motiva Flora received 510(k) clearance from the FDA in October 2023.

Mia Femtech System for Minimally Invasive Aesthetics

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. The IRB approach study began in December 2020 and one year follow up was completed in early 2022 and the two-year follow up started in December 2022 and was presented in October 2023. The study, which had a two-year follow-up compliance rate of 90%, 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.

This premium and personalized breast harmonization experience is currently available at partner clinics in Japan, Spain, Switzerland, Sweden, Germany, France, and Costa Rica. We have also partnered with our distributors in Turkey and the Middle East to begin opening sites in those regions in 2024.

Our Clinical Data

13-Year Safety Post-Market Surveillance Data

Dating from the commercial launch of Motiva Implants in October 2010 through December 2023, we have sold approximately 3.3 million breast implants in various countries outside the United States and Canada. We maintain a Quality Management System database to track and report complaints received from patients or physicians. From October 2010 through December 2023, a total of 4,457 complaints have been reported, investigated and processed, representing approximately 0.1% of the total Motiva Implants sold through December 2023. There were no reported cases of double capsule formation or breast-implant associated anaplastic large-cell lymphoma, or BIA- ALCL, in this data set, and there were 48 cases of early seroma and 4 case of late seroma. 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 2023. In contrast to the above competitor data, our data is self-reported rather than collected at mandatory follow-ups and was generated solely for our post-market surveillance instead of in connection with an FDA PMA study. All of these patients were located outside the United States.

	Motiva Implants
Number of Implants Sold	N= 3,277,844 Implants[1]
Rupture	< 0.1%
Capsular Contracture	< 0.1%
Reoperation for Adverse Events	< 0.1%
Reoperation (All Causes)	N/A[2]

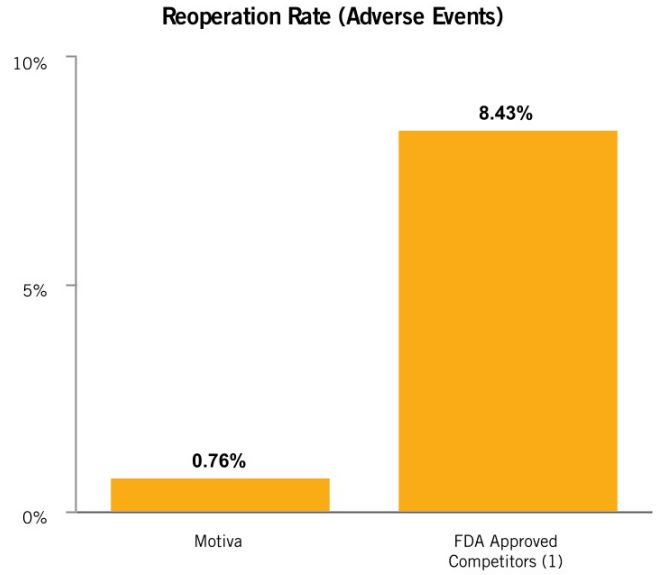
(1) Data is internally tracked on an individual implant basis rather than by patient.

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

Independent Clinical Experience

An independent study by Sforza et al., published in the peer-reviewed *Aesthetic Surgery Journal* in 2017, conducted at a single center, the Hospital Group Ltd.'s Dolan Park Clinic, or Dolan Park, in Bromsgrove, England,

between April 2013 and April 2016, reported 5,813 consecutive cases of breast augmentation with Motiva Implants. This independent study was commissioned by Dolan Park's medical director, Dr. Sforza, who is also a member of our medical advisory board and receives compensation from us in such capacity. The study, conducted by a group of 16 plastic surgeons at Dolan Park, reported overall rates of complication and reoperation of 0.76% over an interval of three years. Beginning in March of 2014, we started supplying our products to Dolan Park under a series of long-term supply agreements with Dolan Park's affiliated companies. The last supply agreement expired in July of 2019. There were no serious adverse events and no cases of implant rupture for device failure, capsular contracture (Baker III/IV) in primary cases, double capsules, or late seromas. The authors presented consistent real-world data and believe that their free, three-year aftercare system is a strong method for patient retention and follow-up by eliminating any financial limitations for patients to return for follow-up consultations if any issues occur. Anecdotally, the same group of surgeons utilizing the same aftercare system for the last seven years reported substantially different results utilizing other types of silicone breast implants (i.e., non-Motiva Implants). The overall revision rate for this group from 2010 to 2013 utilizing a different, macro-textured, FDA approved implant (N > 10,000) was 8.43%, which is more than 10 times higher than the rate for Motiva Implants reported in this analysis.



(1) Names of FDA approved competitors have not been published.

Study to Support a 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, the Company released preliminary results of the two-year patient follow-up data for the primary augmentation cohort of its 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.

In May 2023, we presented the results of the Motiva US IDE Study of data for 451 primary augmentation patients enrolled in the study through the three-year follow-up visit. The three-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	3-year (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5%
Rupture, suspected or confirmed; MRI cohort[(1)]	0.6%
Breast pain	0.7%
Infection	0.9%
Implant removal, with or without replacement	1.6%
Any reoperation[(2)]	6.1%
Any complication[(3)]	8.4%

Kaplan-Meier risk rates were the primary method of analysis for the above data. This table represents preliminary data available as of April 2023 and does not necessarily reflect final clinical results nor demonstrate the investigational device's safety and effectiveness for the United States 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

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 86 countries through exclusive distributors, except in Brazil, Argentina and several European countries where we sell through our direct sales force. As of December 31, 2023, our sales organization included 133 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 post-implantation. We also offer an extended warranty at additional cost outside the JOY program, which provides financial assistance of up to $2,500 to cover surgical costs resulting from rupture or capsular contracture.

We employ a multi-faceted marketing strategy that includes social media engagement, 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, provides us with a strong market position. As of December 31, 2023, we own or have rights to 30 issued, two allowed and 14 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, and our Qid Safety Technology radio frequency identification devices). In addition, we own or have rights to 126 issued, one allowed and 93 pending foreign

applications and one pending Patent Cooperation Treaty, or PCT, applications. Our owned and licensed patents are expected to expire at various times between February 2025 and February 2039. Our owned and licensed pending applications, if granted, likely would expire between September 2033 and December 2043.

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
- John Hopkins Department of Biomedical Engineering
- Plastic and Reconstructive Research Center at the University of Manchester
- Center for Biofilm Engineering of Montana State University
- College of Engineering at UC Santa Barbara
- 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. Our R&D expenses increased $6.1 million, or 30.0%, to $26.4 million for the year ended December 31, 2023, compared to $20.3 million for the year ended December 31, 2022. 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, the next, now non-ferromagnetic, generation of passive RFID technology, in 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 for adapting 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 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 largest manufacturing facility opened at the end of 2016 and we began shipping manufactured product from this facility in March 2017. This 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 oil 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. Our initial facility was established in 2009 and has about 3,000 square feet of production areas, capable of producing over 100,000 implants a year.

We continue to look for ways to improve manufacturing processes and facility organization to increase capacity in these two current facilities. We completed an internal assessment and identified the potential additional manufacturing capacity of approximately 250,000 implants per year, which we added during fiscal 2021, thereby increasing the efficiencies in our process flow.

In July 2017, both facilities 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.

In May 2019, both of our facilities in Coyol Free Zone received the Carbon Neutral certification from 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.

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 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.

We are in the process of expanding our manufacturing facilities and corporate offices in the Coyol Free Zone, or CFZ, in Costa Rica. Construction of the cold shell structure of the Sulàyöm Innovation Campus was initially funded by the Coyol Free Zone in 2021 until we exercised our option to purchase the title of the land and cold shell building for approximately $12.6 million in 2022. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus, which includes approximately 100,000 square feet of facility space to increase our manufacturing capacity by approximately 730,000 units per year. We currently expect to commence manufacturing from the new facility in fiscal 2024. See Note 3 "Balance Sheet Accounts" for additional information regarding this construction project.

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 (previously NuSil Technology LLC), 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. The agreement superseded and replaced the previous master supply agreement originally executed in 2016, as amended, that expired on May 13, 2022.

Other critical materials are the silicone patches and other silicone components used for the assembly of our breast implants. All 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 integrity of the product throughout its shelf-life and all these suppliers must be qualified and materials must be validated prior to being approved for manufacturing activities. Most suppliers are evaluated annually, and we carry second source supplier activities to ensure business continuity and quality and costs improvement.

Competition

The market for silicone breast implants is relatively concentrated, within Allergan Aesthetics, a division of AbbVie, and Mentor Worldwide LLC, a division of Johnson & Johnson. In the United States, Sientra, Inc. is the only other company with an approved silicone implant product. Internationally, the market is more fragmented, with 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 health care 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, notably the United States. 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.

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 postmarket surveillance of medical devices in order to ensure that devices distributed in the U.S. 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 System Regulation (QSR), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. 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 already on the market; a predicate device is a legally marketed device that is not subject to PMA approval. The FDA's 510(k) clearance process usually takes from six 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 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 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 QSR.

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 Quality System Regulation or QSR. 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, conduct 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.

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;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling 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 QSR and other regulatory requirements. The QSR, 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 QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. These requirements impose certain 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 scheduled or unscheduled inspections by the FDA. Following these inspections, the FDA may assert noncompliance with QSR 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 QSR or other FDA requirements. Our failure to maintain compliance with the QSR 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, or HIPAA, established comprehensive U.S. federal protection for the privacy and security of protected health information. HIPAA standards apply to "Covered Entities," which are health plans, health care clearing houses, and certain health care providers which conduct certain health care 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.

Additionally, the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009 amended HIPAA by increasing the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with other applicable privacy laws, including the EU General Data Protection Regulation, including as implemented in the UK, or collectively, the GDPR. There are also additional national, state, and provincial 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. 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 national and local health care programs, we may be 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
- prohibitions in defrauding private sector health insurers.

Numerous national and local agencies enforce the anti-fraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers 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 are approved in the United States and become eligible for federal government reimbursement, our business activities could be subject to scrutiny and enforcement under one or more U.S. federal or state health care 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, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care 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 the Health Insurance Portability and Accountability Act of 1996 (“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 health care programs, additional reporting and government oversight, and the curtailment or restructuring of our operations. As we expand the geographic market for our products, we may be subject to similar national or local laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to health care professionals. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance plan. 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 are approved in the United States and become eligible for federal government reimbursement, 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, teaching hospitals and other "covered recipients", along with physician ownership information. Various states have also implemented regulations prohibiting certain financial interactions with health care 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 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.

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 is 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. 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.

As of May 2021, medical device products that are marketed in the European Union must comply with the requirements of the Medical Device Regulation, or the MDR. The MDR essentially operates in the same way as the Medical Device Directive (described below) to ensure a harmonized approach in the European Union to ensuring the safety and performance of medical devices, and failure to comply with the MDR could affect our ability to market and sell our products in the European Union member states. The European Commission is the legislative body responsible for regulation on the safely of medical devices, including Regulation (EU) 2017/745. Following the transition time, the manufacturers selling medical products in the EU and the European Economic Area, or EEA, will need to comply with the new regulatory framework. All our legacy devices, as well as our Quality Management System, already obtained the certification under the MDR. The EU includes most of the major countries in Europe, while other countries, such as Norway, are part of the EEA and European Free Trade Area, or EFTA, respectively, and have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. The EU regulation addresses regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the General Safety and Performance Requirements, or GSPRs, and, accordingly, can be marketed throughout the EU and EEA. In December 2022, the MDR published two Commission Implementing Regulations, which expanded its authority over products without intended medical purpose, and provided more specific risk management and safety requirements, including conformity assessments and clinical evaluations. In March 2023, the MDR published an additional regulation that provided a staggered extension of the transitional period based on the risk classification of medical devices.

Prior to May 2021, medical device products that were marketed in the European Union were required to comply with the requirements of Medical Device Directive, or the MDD, as implemented in the national legislation of the European Union member states. The MDD, as implemented, provided for a regulatory regime with respect to the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices to ensure that medical devices marketed in the European Union are safe and effective for their intended uses. Medical devices that complied with the MDD, as implemented, are entitled to bear a Conformité Européenne, or CE, marking evidencing such compliance and may be marketed in the European Union. Failure to comply with these domestic and international regulatory requirements could affect our ability to market and sell our products in these countries.

Outside of the EU, 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 U.K. 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, 2023, we had 908 employees. None of our employees are represented by a labor union or covered by collective bargaining agreements except for 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 stockholder 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 diverse 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 towards a more sustainable future by reducing our environmental footprint is important to us. In July 2019, we have been 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 the 2022 Annual Review, which is available at establishmentlabs.com/wp-content/uploads/2023/07/ESTA-Annual-review-2022-1.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/.

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.

Our Motiva Implants have been marketed solely in countries outside of the United States since October 2010, and as such, we have a limited operating history upon which to evaluate our business and forecast our future net sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our direct sales force, distributors and marketing programs to grow sales of our products;
- increase awareness of our brands and build loyalty among plastic surgeons and patients;
- manage expanding operations;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;
- maintain and obtain regulatory clearance or approval of our existing products and commercialize new products;
- respond to changing regulations associated with medical devices across all geographies;
- perform clinical trials with respect to our existing products and any new products;
- attract, retain and motivate qualified personnel in various areas of our business; and
- obtain and maintain coverage and adequate levels of reimbursement for our products.

Due to our limited operating history in the United States, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that we may face. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these 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 development of Motiva Implants, the Mia Femtech technology, and other products and services. We expect our research and development expenses to increase significantly as we continue with our IDE clinical trial in the United States. We have been incurring significant expenses to expand our sales and marketing organization to support sales of Motiva Implants,

including but not limited to a direct sales force in Brazil and several European countries, as well as in preparation of the future commercialization in the United States if we receive FDA approval.

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, including the United States. 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.

The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. In addition, safety issues or other challenges may arise during the conduct of a trial. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

We have obtained a CE Mark for Motiva Implants and certain of our other products and are therefore authorized to sell in the EU. We have received regulatory approval for Motiva Implants and the Motiva Flora tissue expander in Japan by the PMDA. Additionally, the FDA has granted 501(k) clearance for the Motiva Flora tissue expander in the United States. However, in order to market in other regions or jurisdictions, such as the Asia Pacific region, we must obtain separate regulatory approvals. Neither we, nor any future collaboration partner, can commercialize Motiva Implants in the United States without first obtaining regulatory approval for the product from the FDA.

Before obtaining regulatory approval for the sale of a planned product, we may be required to conduct extensive preclinical and clinical studies to demonstrate the safety and effectiveness of our planned products in human patients. Clinical studies can be expensive, difficult to design and implement, can take many years to complete, and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approvals may differ from that required to obtain the CE Mark, PMDA approval, FDA or other regulatory approval.

Investigators for our clinical trials and other health care 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. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future product candidates.

In the United States, FDA guidance on silicone breast implants mandates approval via the PMA process. Extensive preclinical and clinical testing is required to support the PMA and at least one well-controlled clinical trial is required for approval. In connection with the initiation of a clinical study for our Motiva Implants, we filed an IDE application in 2017, which was approved in March 2018. In August 2019, we completed all patient surgeries for the IDE aesthetic cohorts, which include primary augmentation and revision. In June 2022, we completed the enrollment of all subjects in the remaining reconstruction cohort, and all surgeries were completed. Our ongoing U.S. IDE trial may be stopped for unforeseen safety issues or may not be successful in meeting its endpoints, in which case our U.S. regulatory pathway would require subsequent additional clinical trials.

Additionally, we will be required to commit to significant and costly post-approval requirements, which will include follow-up of our clinical trial patients for up to ten years, creation of a patient registry or large post approval study, and/or other studies, and implementation of training programs for physicians. We may be unable to fund, enroll, or complete such trials in a timely fashion, or at all, and we may have an insufficient number of enrolled patients

follow up as instructed. The results of clinical studies may not be favorable enough to support marketing approval in the United States, or may raise other questions (pertaining, for example, to product safety or effectiveness) that jeopardizes our current approvals for sale in other territories. We must also demonstrate that our manufacturing facilities, processes and controls are adequate to support FDA approval and that our clinical investigators complied with good clinical practices in the conduct of the clinical trial for our Motiva Implants.

In general, numerous unforeseen events during, or as a result of, preclinical and clinical studies could occur, which would delay or prevent our ability to receive regulatory approval or commercialize Motiva Implants or any of our planned products, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies may be greater than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might suspend or terminate clinical studies of our planned products for various reasons, including a finding that our planned products have unanticipated serious side effects or other unexpected characteristics, or that the study subjects are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or independent institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or IRBs may require that we, or our investigators, suspend or terminate clinical studies for various reasons, including noncompliance with regulatory requirements;
- regulators may determine that the clinical data submitted to support our request for approval is unreliable or incomplete as a result of any number of factors, including potential financial bias associated with equity holdings in the Company by study investigators, or significant payments by the Company to study investigators for consulting work, which may result in regulators requesting further data analysis or other confirmatory studies to be performed, or determining the data does not support regulatory approval;
- regulators in countries where Motiva Implants are currently marketed may require that we suspend commercial distribution if there is noncompliance with regulatory requirements or safety concerns;
- regulators in countries where Motiva Implants are currently marketed may suspend commercial distribution of silicone breast implants due to safety or other concerns generally applicable to the product category;
- the supply or quality of our planned products or other materials necessary to conduct clinical studies of our planned products may be insufficient or inadequate; and/or
- the enactment of new regulatory requirements in Europe under the new Medical Device Regulation may make approval times longer and standards more difficult to pass.

If we, or any future collaboration partner, are required to conduct additional clinical trials or other testing of Motiva Implants or any planned products, those clinical studies or other testing may not be successfully completed. Additionally, if the results of these studies or tests are not positive, or if they raise safety concerns, we may:

- be delayed in obtaining marketing approvals for Motiva Implants or our planned products;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have a product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; and/or
- be subject to restrictions on how the product is distributed or used.

FDA regulatory approval in the United States is not a guarantee upon successful completion of preclinical and clinical studies, and the filing and approval process itself is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure may occur at any

stage, and we could encounter problems that cause us to abandon or repeat clinical studies, including our ongoing IDE clinical trial that commenced in April 2018 and for which we have submitted all four modules to the FDA, and we not obtain FDA approval on the timeline we anticipate or at all. The FDA can delay, limit, or deny approval of a product candidate for many reasons, including, but not limited, to:

- a product candidate may not be deemed to be safe and effective;
- FDA officials may not find the data from clinical and preclinical studies sufficient;
- the FDA may not approve our manufacturing or our third-party suppliers' processes or facilities;
- the FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting and analysis of the studies to minimize bias; or
- the FDA may change its approval policies or adopt new regulations.

Even if we obtain regulatory approvals or clearances in a jurisdiction, our products may be removed from the market due to a variety of factors, including adverse events, recalls, suspension of regulatory clearance to sell, or other factors. For example, during the summer of 2016 while we were transitioning from one notified body to another, our CE Mark for Motiva Implants was temporarily not in force. We expect that the initial U.S. approval will be subject to a lengthy and expensive follow-up period, during which we must monitor patients enrolled in clinical studies and collect data on their safety outcomes. Even if FDA approval is obtained, the FDA has authority to impose post-market approval conditions, which can include (i) restrictions on sale, distribution, or use, (ii) continuing evaluation of the device's safety and effectiveness, (iii) additional warning/hazard labeling requirements, (iv) significant record management, (v) periodic reporting requirements, and (vi) any other requirements the FDA determines necessary to provide reasonable assurance of the device's safety and effectiveness. Completion of the IDE follow-up study, in a manner which results in data sufficient to maintain FDA approval, is subject to multiple risks, many of which are outside of our control. These include, but are not limited to, our ability to fund the ongoing study from our operations or via additional fundraising; study participants' willingness and ability to return for follow-up study visits; and maintenance of a suitable study database over a long period of time. Even if completed and appropriately evaluated, the study follow-up may reveal safety or other issues that impact the approved labeling or may result in withdrawal of Motiva Implants from the marketplace in the United States or elsewhere.

Although we launched Motiva Implants commercially in October 2010 and have sold approximately 3.3 million units to date in various countries outside the United States, we do not have as much post-market surveillance data as our competitors and may not have clearly identified all possible or actual risks of our products. Furthermore, if our clinical trials do not produce patient data that compares favorably with breast implants that are already on the market, physicians and patients may opt to not use our products, and our business would suffer.

Our product development costs will also increase if we experience delays to our clinical trials or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured, or will be completed on schedule, or at all.

Significant clinical study delays could allow our competitors to bring products to market before we do, which would impair our ability to commercialize our planned products and harm our business and results of operations.

Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. 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 Motiva Implants, or our future 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 the FDA or similar regulatory authority does not approve our products or requires additional clinical trials or preclinical data before any approval or if any approval of* our *products includes additional restrictions on the label, or requires a characterization of our products, including the description of the product surface (e.g. smooth, texture, other*) *that differs from ours and/or other regulatory authorities, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

It is possible that the FDA or similar regulatory authorities may not consider the results of our clinical trials to be sufficient for approval of Motiva Implants for our desired indications for use. Guidance issued by the FDA in 2006 suggests that a single well-controlled study is required for approval of a new silicone breast implant. The FDA may nonetheless require that we conduct additional clinical studies, possibly using a different clinical study design.

Moreover, even if the FDA or other regulatory authorities approve the marketing of Motiva Implants and our other products, the approvals may include additional restrictions on the label or require a characterization of our products that differ from ours and/or other regulatory authorities and result in additional descriptions or other information on the label. Any of these events could make Motiva Implants or our other products less attractive to physicians and patients compared to other approved products, which could limit potential sales of Motiva Implants or our other products.

If we fail to obtain FDA or other regulatory approval of Motiva Implants or our other products, or if the approval is narrower than or otherwise differs from what we seek, it could impair our ability to realize value from those products, and therefore may have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise 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. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, during various times in the recent 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. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign manufacturing facilities and routine surveillance inspections of domestic manufacturing facilities in 2020. If a prolonged government shutdown occurs, or if other events, including global health concerns, prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, it 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 or delays in annual appropriations 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 implant 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 192 and 201 medical training sessions worldwide during 2023 and 2022, 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 and manufacture sufficient quantities of product in the implant sizes that patients and physicians request, and to 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 of 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. Until 2017, we had one manufacturing facility in Costa Rica, and we experienced inventory shortages from time-to-time that impaired our ability to meet market demand. In March 2017, our second manufacturing facility, also located in Costa Rica, became operational, and we received certification under the multi-country MDSAP protocol and began shipping saleable product. 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. We began construction of the third facility in Costa Rica during the third quarter of 2021. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus. We currently expect to commence manufacturing from the new facility in fiscal 2024. If this expansion is not completed in a timely manner, or if we are not able to get required regulatory

approvals for the new facility, our ability to fill incoming orders may be adversely impacted. In addition, if we obtain FDA approval, we will likely need to obtain additional manufacturing capacity prior to any commercialization of our Motiva Implants in the United States. 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 expect to incur losses for the foreseeable future, 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 95% and 98% of our revenues for each of the years ended December 31, 2023 and December 31, 2022, and we expect our revenues to continue to be driven primarily by sales of these products. In order to achieve and sustain profitability, our revenues from these 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.

Our ability to successfully market Motiva Implants and our other current and future offerings depends on numerous factors, including but not limited to:

- the outcomes of current and future clinical studies of Motiva Implants to demonstrate our products' value in improving safety outcomes and/or patient satisfaction;
- acceptance of Motiva Implants as safe and effective by patients, caregivers and the medical community;
- an acceptable safety profile of Motiva Implants in the global market;
- whether key thought leaders in the medical community accept that such clinical studies are sufficiently meaningful to influence their or their patients' choices of product;
- maintenance of our existing regulatory approvals and expansion of the geographies in which we have regulatory approvals;
- designing commercially viable processes at a scale sufficient to meet anticipated demand at an adequate cost of manufacturing, and that are compliant with ISO 13485 Quality Management System requirements and/or good manufacturing practice, or GMP, requirements, as set forth in the FDA's Quality System Regulation, Brazilian and other international regulations;
- our success in educating physicians and patients about the benefits, administration and use of Motiva Implants;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the willingness of patients to pay out-of-pocket for breast augmentation and reconstruction procedures in the absence of coverage and reimbursement for such procedures;
- the success of our internal sales and marketing organization and the sales forces of our distributors; and
- continued demand for breast augmentation and reconstruction procedures using silicone implants, which may be adversely affected by events involving either our products or those of our competitors, including FDA warnings to patients regarding Breast Implant-Associated Anaplastic Large Cell Lymphoma, or BIA-ALCL and other lymphomas or cancers, including squamous cell carcinoma.

Some of these factors are beyond our control. If we are unable to continue to commercialize Motiva Implants and our other products, or 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.

Unfavorable global economic conditions, including slower growth or recession, inflation or decreases in consumer spending power or confidence, could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, such as slower growth or recession, continued inflation or decreases in consumer spending or confidence. 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 those 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 current inflationary pressures, higher interest rates, geopolitical conflicts, including the Russia-Ukraine war and the Hamas-Israel conflict, or macroeconomic fallout from a potential U.S. government default on its debt, may cause consumers to reassess their spending choices and reduce demand for elective aesthetic procedures, which could have an adverse effect on our net sales and profitability. A weak or declining global economy 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.

We have incurred net operating losses in the past and expect to incur net operating losses for the foreseeable future.

We have incurred net operating losses since our inception, and we continue to incur significant research and development and general and administrative expenses related to our operations. We do not expect to be profitable in 2024, and in future years we expect to incur significant research and development expenses related to, among other things, the IDE clinical study 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, 2023, we had an accumulated deficit of $360.1 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting Motiva Implants and other products that are part of our product platform. This will require us to be successful in a range of activities, including manufacturing, marketing, and selling Motiva Implants. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, 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.

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, strategic collaborations or partnership, 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 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. Three of these companies, Sientra, Inc., Mentor Worldwide LLC (a division of Johnson & Johnson), and Allergan plc (recently 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 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 international markets is price sensitive. In these markets, or in the United States if we are successful in obtaining the required regulatory approval to sell in the U.S. market, 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, 2023, we had 908 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 prepare our operations in the anticipation 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 large markets, we engage 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 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 are also working on creating a direct sales structure and strategy in certain markets. We are working to put in place the correct legal and business structures to comply with taxation and operational requirements. These structures may not ultimately be implemented or, if implemented, be successful or effective and may not be able to increase our revenues or improve our gross margins. In addition, our expenses or tax related costs may increase 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 any planned products in clinical studies. The marketing, sale and use of Motiva Implants and our planned 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. If we cannot successfully defend ourselves against claims that Motiva Implants or our planned products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for 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, recalls and any resulting litigation, 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.

Recent news coverage has called into question the long-term safety of breast implants and 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 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 Mark licenses 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 health care 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, health care 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 with 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, expose us to product liability claims, as well as to class actions and other lawsuits. These impacts may occur in the absence of 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, including Juan José Chacón Quirós, our Chief Executive Officer, Roberto de Mezerville, our Chief Technology Officer, Rajbir Denhoy, our Chief Financial Officer, and Ross Mansbach, our General Counsel and Chief Human Resources Officer. The collective efforts of each of these persons, and others working with them as a team, 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 General Counsel and Chief Operating Officer 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.

We do not know whether we will be able to successfully integrate any acquired business, product or technology. The success of any given acquisition may depend on our ability to retain any key employees related thereto, and we may not be successful at retaining or integrating such key personnel. 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. 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 U.S. 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 could be 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, 2023, 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, 2023, the majority of our expenses are denominated in U.S. dollars or in Costa Rican colones, which are 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, Costa Rican colones and the Brazilian real 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 would 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. For example, the weakening of the euro for the majority of fiscal 2022 had a negative effect on our European revenue. 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 and economic risks associated with doing business internationally.

Our products are commercially available in 86 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 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 or social instability. Doing business in Costa Rica and other countries outside the United States involves a number of other risks, including:

- compliance with the free zone regime regulations under which the manufacturing sites operate;
- different regulatory requirements for device approvals in international markets;
- multiple, conflicting and changing laws and regulations such as tariffs and tax laws, export and import restrictions, employment laws, environmental laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure by us or our distributors to obtain and/or maintain regulatory approvals for the sale or use of our products in various countries;
- difficulties in managing global operations;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- governmental price controls, differing reimbursement regimes and other market regulations;
- 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, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- the British exit from the EU, including with respect to its effect on the value of the British pound relative to other currencies;
- 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;
- compliance with tax, employment, immigration and labor laws;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business and shipping interruptions resulting from natural or other disasters including earthquakes, volcanic activity, hurricanes, floods and fires.

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.

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

Our headquarters are located in Costa Rica, and all of our main manufacturing activities are conducted in two ISO-13485 and GMP compliant manufacturing facilities in Costa Rica through Establishment Labs, S.A. A third facility in Costa Rica is under construction and is currently expected to commence manufacturing in 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.

Fluctuations in insurance costs and 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. If this supplier were to increase prices for this raw material over time 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 Inc. (formerly NuSil Technology, LLC), or 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, we may not be able to replace this supply source quickly, or at all. Similarly, they may become unable or unwilling to manufacture our needed raw materials in compliance with regulatory requirements, or their 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 our 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 Coyol, 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 requires 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.

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 silicone, which is the primary raw material used in these products. If this supplier were to increase prices for these raw materials over time or experience interruptions in their 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, or 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 changes could also result in increased costs associated with qualifying the new materials and in increased operating costs. 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.

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.

As referenced above in this risk factor, some of the components used in our Motiva Implants and our other products are currently single-sourced, and substitutes for these components might not be obtained easily or may require substantial redesign or manufacturing modifications related to our specifications or due to regulatory requirements. Any significant problem experienced by one of our single-source suppliers may result in a delay or interruption in the supply of components or products to us because the number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited and certification of a new supplier may be complex and time consuming. Any delay or interruption would likely lead to a delay or interruption in our manufacturing or distribution operations and/or adversely affect our ability to sell Motiva Implants. The inclusion of substitute components or products must meet our specifications and could require us to qualify 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.

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 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.

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 in recent years.

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 in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

The patent position of medical device and diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, 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. 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 U.S. 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.

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.

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

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. Many companies have encountered significant problems in protecting and defending intellectual property rights in international jurisdictions. 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.

We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time consuming, or unsuccessful.

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. In addition, 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. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. 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.

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 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 determination in any such 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. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. 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.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical or management personnel from their normal responsibilities. 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.

The medical device industry is characterized by patent litigation and we could become subject to litigation 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.

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends in part upon our ability and that of our distributors, contract manufacturers, and suppliers to manufacture, market and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property 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. A finding of infringement could prevent us from commercializing our planned products in commercially important territories, or force us to cease some of our business operations, which could harm our business. 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.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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 price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material 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 breaches 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 breaches, 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.

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 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 security breaches 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. For example, the loss of data from completed, ongoing or future studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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.

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. These 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. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's protected health information by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as covered entities, that involve the creation, use, maintenance or transmission of protected health information. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that perform a function or provide specified services to health care providers and other covered entities, collectively referred to as business associates. Most recently, on December 10, 2020, HHS issued a Notice of Proposed Rulemaking, which if finalized, would make changes to some of HIPAA's regulatory requirements, which would impact us, to the extent we are a business associate. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's protected health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose protected health information has been inappropriately accessed or disclosed, notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and 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. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes 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 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. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

Many foreign countries and governmental bodies, including the EU, 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 European Commission recently adopted the General Data Protection Regulation, including as implemented in the UK, or the GDPR, effective on May 25, 2018, that supersedes current EU data protection legislation, imposes more stringent EU data protection requirements and provides for greater penalties for noncompliance. The GDPR 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 US, 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 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 GDPR's requirements requires time, resources and a review of the technology and systems currently in use against the GDPR's requirements.

We may be at risk of enforcement actions taken by certain EU data protection authorities while we continue to build our business practices to ensure that all transfers of personal data to us from the European Economic Area, including the EU, 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.

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.

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 will authorize the commercialization of Motiva Implants or our planned products on a timely basis, if at all, and 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 registered to be sold in 86 countries. In the United States, we have received clearance from the FDA to sell our Intraoperative Sizers and Flora Tissue Expanders, but we are not permitted to market other planned products until we receive the requisite FDA approval or clearance.

The two primary types of FDA marketing authorization in the United States applicable to a device are a premarket approval (by filing a PMA) or a premarket notification clearance (by filing a 510(k) notice). Breast implants are currently classified as Class III Medical Devices requiring an approved PMA for commercial distribution. Certain of our other products or modifications to those products are currently eligible for 510(k) clearance or approval of a PMA supplement. We have not received marketing approval for Motiva Implants in the United States. We have received 501(k) clearance for the Intraoperative Sizers and Flora Tissue Expanders, which are now commercially available in the United States.

Obtaining approval for sale of a medical device from the FDA can be a lengthy, expensive and uncertain process. The PMA approval process generally takes from one to three years and the 510(k) clearance process usually takes from three to twelve months, although each could take longer.

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. Results from preclinical studies and clinical studies can be interpreted in different ways. 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 approval from the FDA is not guaranteed, and the approval process is expensive and may take several years, particularly where a PMA is required. The FDA also has 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 FDA approval varies depending on 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 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. 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 FDA's 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.

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 FDA's 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 may require new regulatory approvals or clearances, including 510(k) clearances or approval of PMA supplements, or 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.

For example, if a manufacturer determines that a modification to a PMA approved device could affect its safety or effectiveness or would constitute a major change in its intended use, then the manufacturer must file for a new a new PMA or approval of a PMA supplement. Where we determine that modifications to our products require a new PMA approval, 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 assurance systems affecting those products. Obtaining certification 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, which 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. 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. 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 System Regulation, or QSR, 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 QSR 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 US 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 U.S. 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 applicable medical device directives (including the Medical Devices Directive and the European Medical Device Regulation) and obtain CE Mark certification in order to market medical devices. 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 European Union regulatory bodies finalized a new Medical Device Regulation (MDR) in 2017, which replaced the existing directives and provided three years for transition and compliance. After a one-year delay, the MDR became effective on May 26, 2021. The MDR changes several aspects of the existing regulatory framework, such as updating clinical data requirements and introducing new ones, such as Unique Device Identification, or UDI.

We and the Notified Bodies who will oversee compliance to the new MDR face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas, including the CE Marking process and data transparency, in the upcoming years. 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. 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 of 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.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of Motiva Implants or our other products.

We have obtained 501(k) clearance to sell Intraoperative Sizers and SmoothSilk Tissue Expanders in the United States. We are not permitted to promote or market other investigational products. After approval, our promotional

materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, 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, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. 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 that event, our reputation could be damaged and adoption of the products could be impaired. 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.

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

Our future arrangements with third-party payors and health care providers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or the financial relationships and engagement we enter into to market, sell, promote and distribute our products for which we obtain clearance in the U.S. Efforts to ensure that our business arrangements with these third parties will comply with applicable health care 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 health care 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.

Health care 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. For example, In January of 2024, FDA issued a final rule to replace the QSR with the adoption of ISO 13485. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the health care 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 health care system, some of which are intended to contain or reduce the costs of medical products and services.

For example, one of the most significant health care reform measures in decades, the Patient Protection and Affordable Care Act, or PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal health care programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government health care programs and will result in the development of new programs. There have been judicial and Congressional challenges to certain aspects of the PPACA. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision repealing the PPACA's individual mandate penalty, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Congress may consider other legislation to repeal or replace elements of the PPACA on a provision-by-provision basis. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to health care reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031.

We cannot predict the impact that ongoing health care 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 the type of products we intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. 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 health care services to contain or reduce costs of health care 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.

The political situation in the United States can affect the ability of our company to conduct business in certain areas or countries if new trade conditions are imposed or enforced by the U.S. government.

There could be negative consequences to our company's revenue if the U.S. government unexpectedly changes its trade policies towards determined geographies or countries. These policy changes can include such things as trade barriers, which serve to limit or prevent international trade. The U.S. government may request additional funds or tariffs in exchange for the right to export items into the country. Tariffs or quotas may be used to protect domestic producers from foreign competition. Changes may include the modification or withdrawal of free trade agreements already in place. This also can have a large effect on the profits of our company because it either cuts revenues as a result of a tax on imports/exports or restricts the amount of revenues that can be earned.

The global economic instability caused by the ongoing military conflicts in Ukraine and Israel may adversely affect our business in Europe and the Middle East.

The conflicts in Ukraine and Israel have resulted in worldwide geopolitical and macroeconomic uncertainty and have caused, and will likely continue to cause, disruption and instability in affected markets. It is not possible at this time to predict the ultimate consequences of the conflicts or the responses of governments or others to the conflicts, which could include, among other things, additional sanctions, greater regional instability or expansion of the conflict, embargoes, geopolitical shifts, litigation, and impacts on macroeconomic conditions, commodities, currency exchange rates, supply chains, and financial markets, which could adversely impact our business and results of operations.

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.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could 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. In October 2023, the EU Council announced that three jurisdictions have been removed from the list of non-cooperative tax jurisdiction, one of which was Costa Rica. This follows the reforms made to the 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 2023 and 2022, 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 your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. Although our common shares are listed on Nasdaq, if we fail to satisfy the continued listing standards, we could be delisted, which would negatively impact the price of our common shares. 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 health care payment systems;
- negative shifts in the economy effecting 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, 2022, and 2021, 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. Prior to the completion of our IPO, we were a private company with limited accounting and compliance personnel and other resources to address our internal control over financial reporting.

On December 31, 2021, it was determined that our primary user access controls (i.e. provisioning, de-provisioning, and quarterly user access review) to ensure appropriate segregation of duties that would adequately restrict user and privileged access to the financially relevant systems and data to appropriate Company personnel were not operating effectively. These user access control deficiencies resulted in a lack of segregation of duties with respect to certain user roles. Automated process-level controls and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. During the fourth quarter of 2023, we completed our testing of the operating effectiveness of the

implemented controls and found them to be effective. As a result, we have concluded the material weakness identified as of December 31, 2021 has been remediated as of December, 31 2023.

It was determined that as of December 31, 2023, our primary change management controls for direct database changes were not designed and implemented effectively for specific localities. Other Information Technology General Controls, automated process-level controls, and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. We have made significant progress remediating change management controls as of December 31, 2023. We improved policies and procedures and designed and documented more effective change management monitoring controls, through the use of systematic audit logging, that addresses the relevant risks in order to remediate the identified material weakness. The material weakness persists and will not be considered remediated until the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the control objective is achieved, and the controls are operating effectively. We expect that the remediation of this material weakness will be completed during 2024.

We also expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. If additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and impact investor confidence in our Company.

The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. The identification and remediation of additional material weaknesses in the future, could adversely affect our ability to report financial information, including our filing of quarterly or annual reports with the SEC on a timely and accurate basis and prohibit us from producing timely and accurate consolidated financial statements, which may adversely affect our share price and we may be unable to maintain compliance with Nasdaq listing requirements.

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 depressing 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 acquiror from conducting a solicitation of proxies to elect the acquiror'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 have 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, 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 measures to protect our information systems, including firewalls, network access controls, intrusion detection systems, phishing campaigns, security awareness training and monitoring, network operation center, security operation center, and data encryption, and to monitor our information systems to detect potential cybersecurity incidents, including through the use of automated detection software. 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 principal executive offices are located in Alajuela, Costa Rica, where we occupy approximately 36,000 square feet of office, laboratory and manufacturing space. I

We are in the process of expanding our manufacturing facilities and corporate offices in the Coyol Free Zone in Costa Rica. Construction began in 2021 and we exercised the option to purchase the land and cold shell building in 2022. The project includes approximately 170,000 square feet of facility space. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus. We currently expect to commence manufacturing from the new facility in fiscal 2024.

We also have office or warehouse space in Wommelgem, Belgium; Sao Paulo and Rio de Janeiro, Brazil; Stockholm, Sweden; Barcelona, Spain; Rome, Italy; Addison, Texas, USA; Santa Barbara, CA, USA; London, England; Haar, Germany, Cavaillon, France and Buenos Aires, Argentina pursuant to a variety of leases that expire in 2024 through 2029.

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 31 shareholders of record of our common shares as of March 1, 2024. 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.

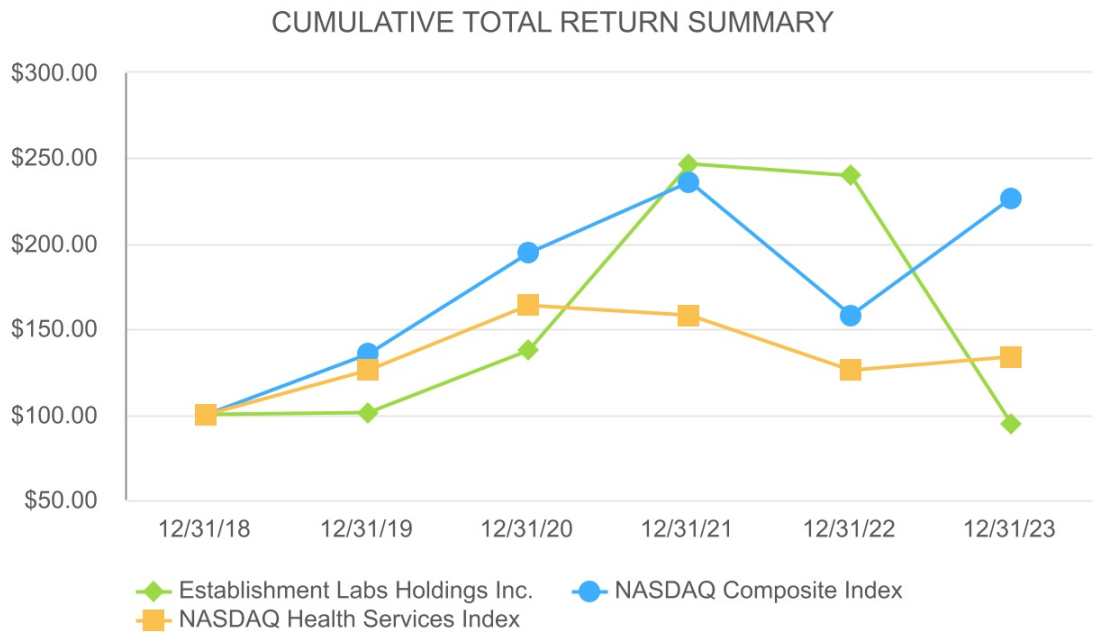
Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common shares made during the three months ended December 31, 2023.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock from December 31, 2018 through 2023, 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 on December 31, 2018 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 post-market surveillance data (which was not generated in connection with a United States Food and Drug Administration, or FDA, pre-market approval, or PMA, study collected at defined follow-ups, but was patient or practitioner reported) and published third-party registries and data indicate that Motiva Implants have low rates of adverse events (including rupture, capsular contracture, and safety related reoperations) that we believe compare favorably with those of our competitors. We believe the proprietary technologies that differentiate

our Motiva Implants enable improved safety and aesthetic outcomes and drive our revenue growth. We have developed other complementary products and services, which are aimed at further enhancing patient outcomes.

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.

Financial Highlights

Our revenue for the years ended December 31, 2023 and 2022 was $165.2 million and $161.7 million, respectively, an increase of $3.5 million, or 2.2%. Net losses were $78.5 million for the year ended December 31, 2023 as compared to $75.2 million for the year ended December 31, 2022. As of December 31, 2023, we had an accumulated deficit of $360.1 million.

Our cash balance as of December 31, 2023 was $40.0 million.

Recent Developments

In January 2024, we announced the commercial launch of Motiva Implants in China and the completion of the first procedure with the Motiva Flora SmoothSilk Tissue Expander in the United States.

We also entered into a securities purchase agreement, pursuant to which we sold an aggregate of two million common shares and pre-funded warrants for gross proceeds of approximately $50 million. See Note 15 *"Subsequent Events"* for additional information.

We are in the process of expanding our manufacturing facilities and corporate offices in the Coyol Free Zone, or CFZ, in Costa Rica. Construction of the cold shell structure of the Sulàyöm Innovation Campus was initially funded by the Coyol Free Zone in 2021 until we exercised our option to purchase the title of the land and cold shell building for approximately $12.6 million in 2022. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus, which includes approximately 100,000 square feet of facility space intended to increase our manufacturing capacity by approximately 730,000 units per year. We estimate a total of $51.7 million in costs for this initial phase of our expansion project, of which the majority has been incurred to date. Additional phases of the project may be executed, at our option, to further expand manufacturing capacity at the new facility. We expect to commence manufacturing from the new facility in 2024. See Note 3 *"Balance Sheet Accounts"* for additional information.

In November 2023, we received National Medical Products Administration, or NMPA, approval in China for Motiva Implants, 510(k) clearance from the FDA for the Motiva Flora SmoothSilk Tissue Expander in the United States, and CE mark approval under the European Medical Device Regulation for the Motiva Injector, the Motiva Inflatable Balloon and the Motiva Channel Dissector.

In addition, in October 2023, we completed and announced the results of the two-year 100-patient clinical study for Mia Femtech, our patented technologies that can increase breast shape by 1 to 2 cups in a 15-minute procedure without the need for general anesthesia. The single-center, Institutional Review Board approved study began in December 2020 and involved participation of fifteen board-certified plastic surgeons from Costa Rica, Sweden, England, Brazil, Austria, Italy, Belgium, and the United States. We have launched Mia Femtech globally through partnerships with clinics in Japan, Spain, Switzerland, Sweden, Germany, France, Costa Rica, Turkey and the Middle East. In October 2023, we also launched, in select geographies, Zen - the newest generation of our passive RFID technology that is now non-ferromagnetic. Zen is available with Motiva Ergonomix2 Round implants in the Joy program.

In April 2023, we issued 1,165,000 common shares in an underwritten public offering for net proceeds of approximately $84.6 million.

In February 2023, we submitted the final module of our clinical trial for Motiva Implants in the United States to the FDA. We received FDA approval to start our clinical trial in 2018. By August 2019, we had completed all surgeries in the aesthetic cohorts and implemented a bifurcated regulatory strategy for data submission. In April 2022, we released preliminary results for the primary augmentation cohort and, by June 2022, we completed enrollment and surgeries for the primary reconstruction cohort. By September 2022, we had completed the three-year follow-up for the aesthetic cohort.

In January 2023, we announced a partnership with Seishin Plastic and Aesthetic Surgery Clinic in Japan for Mia Femtech. Previously, we obtained regulatory approval from the Pharmaceuticals and Medical Devices Agency, as

well as reimbursement for post-mastectomy reconstruction under the Japanese National Health System, for Motiva Implants and the Motiva Flora tissue expander in November 2022.

In April 2022, we entered into a credit agreement, or the Credit Agreement, for term loans to the Company in an aggregate principal amount of up to $225 million, with Oaktree Fund Administration, LLC, as administrative agent. The first and second tranche were advanced in the amount of $150 million and $25 million in April and December 2022, respectively. A portion of the proceeds from the first tranche was used to repay in full and terminate the $65 million in aggregate principal amount outstanding under the Company's previous credit agreement with Madryn Health Partners, LP, or the Madryn Credit Agreement, and the $6.5 million early repayment penalty. In February 2024, we amended the Credit Agreement, modifying the access conditions, commitment termination dates and interest rates for the two remaining available tranches. See Note 5 *"Debt"* and Note 15 "*Subsequent Events"* for additional information.

We are focused on investing in manufacturing capacity, marketing, customer service, and sales force in multiple geographies to promote the use of our Motiva Implants. This expansion may result in short-term losses as we grow our organization and invest in research, clinical trials, and other commercialization efforts.

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 95% of our revenues for the year ended December 31, 2023, 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 direct 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 increase as we enter new markets, expand awareness of our products in existing markets, and grow our distributor network and direct sales force. We also expect our revenue to fluctuate from quarter to quarter due to a variety of factors, including seasonal fluctuations in demand for Motiva Implants. We are also affected by foreign currency fluctuations.

Cost of Revenue and Gross Margin

Our implants are manufactured at our two facilities in Costa Rica. A third facility in Costa Rica is under construction and is currently expected to commence manufacturing in fiscal 2024. 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, 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 continue to increase in absolute dollars for the foreseeable future as our business grows and we continue to invest in our sales, marketing, medical education, training and general

administration resources to build our corporate infrastructure. However, we expect our SG&A expenses to decrease as a percentage of our revenue over the long term, although our SG&A expenses may fluctuate from period to period due to the timing of expenses related to our sales and marketing campaigns.

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 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 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. In August 2019, we completed all patient surgeries for the IDE aesthetic cohorts, which include primary augmentation and revision augmentation, and have now completed the three-year study subject follow-up for the aesthetic cohort. In June 2022, full enrollment of the IDE clinical trial was complete, and all surgeries in the primary reconstruction cohort were performed. As of September 30, 2022, we also completed the three-year study subject follow-up for the aesthetic cohort. In the fourth quarter of 2021, we initiated a modular PMA submission process with the FDA and submitted the first of four modules. The second, third and fourth modules were submitted to the FDA in May 2022, August 2022 and February 2023, respectively. The IDE clinical trial is expected to cost between $30.0 million and $40.0 million over ten years. As of December 31, 2023, around $30 million has been spent on the trial. 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, 2023, we had $192.6 million in outstanding principal under our term loan, including interest accrued into the principal balance. See Note 5 “Debt” for additional information.

Other Expense, Net

Other expense, net primarily consists of foreign currency gains/losses and interest income.

Loss on Extinguishment of Debt

On April 26, 2022, we repaid in full the $65.0 million in aggregate principal amount outstanding under the Madryn Credit Agreement and the agreement was terminated. We recorded a loss on the extinguishment of debt in the amount of $19.0 million, which represents the difference between the carrying value of debt and the cash outflows to extinguish the debt including $6.5 million of the early repayment penalty.

Income Tax Expense

Income tax expense consists primarily of income taxes in foreign jurisdictions in which we conduct business. Due to our history of losses, with the exception of Belgium and JAMM Technologies, Inc., we maintain a full valuation allowance for deferred tax assets including net operating loss carry-forwards, R&D tax credits and other book versus tax differences.

Business Update Regarding Macroeconomic Conditions

- *2023 Results:* The first and second quarters of 2023 resulted in record quarterly revenue, primarily due to share gains in global markets, especially in our EMEA and in Asia-Pacific regions, and the launch of new products and technologies. The second half of 2023 showed a slowing in revenue growth, primarily in distributor markets, in our Asia-Pacific and, to a lesser degree, in Latin American regions, compared to the first half of 2023. We believe the slower growth is a result of an overall slowdown in demand for aesthetic procedures, primarily as a result of general uncertainty about macroeconomic and geopolitical conditions and seasonality. The overall increase in revenue year-to-date as compared to 2022 was driven by an increase in demand during the first half of the year, and our efforts to expand direct sales in multiple geographies.
- *Outlook:* Demand for our products is dependent on the relative strength of the global and regional medical device markets, which are sensitive to general macroeconomic conditions. The current global

macroeconomic environment remains complex, with elevated inflation and interest rates contributing to fear of potential recessionary conditions thus driving limitations on available discretionary spending in the markets we operate. These macroeconomic challenges, combined with geopolitical upheaval, have led to ongoing volatility within global markets. This negatively impacted demand for our products during the second half of 2023 and we expect for this to continue in 2024.

In response to the decrease in demand, we continue downsizing our global workforce, reducing operational expenditures, and effectively managing inventory levels. Our focus will be on investing in our primary growth initiatives, which include the launch of our product in the U.S., development of the Chinese market and promoting Mia Femtech.

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.

Business Update Regarding Russia-Ukraine and Hamas-Israel Conflicts

In February 2022, Russia invaded Ukraine and is still engaged in active armed conflict against the country. In October 2023, Hamas-led Palestinian militant groups started a military offensive against Israel. To date, the impact of these conflicts on our business operations and financial performance in Europe and the Middle East has not been and is not expected to be material. However, the full impact of these conflicts on our business operations and financial performance remains uncertain and will depend on future developments, including the severity and duration of the conflicts and their impact on regional and global economic conditions.

Consolidated Results of Operations

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

	2023	2022
	(in thousands)	
Revenue	$ 165,151	$ 161,700
Cost of revenue	58,174	55,105
Gross profit	106,977	106,595
Operating expenses:		
Sales, general and administrative	145,575	125,984
Research and development	26,428	20,269
Total operating expenses	172,003	146,253
Loss from operations	(65,026)	(39,658)
Interest expense	(15,393)	(11,760)
Change in fair value of derivative instruments	—	703
Loss on extinguishment of debt	—	(19,019)
Other income (expense), net	1,836	(3,090)
Loss before income taxes	(78,583)	(72,824)
Provision for income taxes	81	(2,385)
Net loss	$ (78,502)	$ (75,209)

Comparison of the Year Ended December 31, 2023 and 2022

	2023	2022
	(in thousands)	
Revenue	$ 165,151	$ 161,700
Cost of revenue	58,174	55,105
Gross profit	$ 106,977	$ 106,595
Gross margin	64.8 %	65.9 %

Revenue

Revenue increased $3.5 million, or 2.2%, to $165.2 million for the year ended December 31, 2023, as compared to $161.7 million for the year ended December 31, 2022. The increase was primarily due to share gains in global markets and the launch of new products and technologies. The first half of 2023 resulted in record quarterly revenue, primarily due to strong demand in our EMEA and in Asia-Pacific regions. The third and fourth quarters of 2023 showed a slowing in revenue growth, primarily in distributor markets in our Asia-Pacific and, to a lesser degree, in Latin American regions, compared to the first half of 2023. We believe the slower growth is a result of an overall slowdown in demand for aesthetic procedures primarily as a result of general uncertainty about macroeconomic and geopolitical conditions and seasonality.

Cost of Revenue and Gross Margin

Cost of revenue increased $3.1 million, or 5.6%, to $58.2 million for the year ended December 31, 2023, compared to $55.1 million for the year ended December 31, 2022. The increase in cost of revenue is in line with the increase in revenue except as described below.

Gross margin decreased to 64.8% for the year ended December 31, 2023, compared to 65.9% for the year ended December 31, 2022, due to an increase in the reserve for inventory obsolescence and higher manufacturing costs, primarily driven by a higher cost of labor and overhead, due, in part, to the revaluation of the Costa Rica colón, partially offset by the positive impact of new product initiatives.

Operating Expenses

	2023	2022
	(in thousands)	
Operating expenses:		
Sales, general and administrative	$ 145,575	$ 125,984
Research and development	26,428	20,269
Total operating expenses	$ 172,003	$ 146,253

Sales, General and Administrative Expense

SG&A expense increased $19.6 million, or 15.6%, to $145.6 million for the year ended December 31, 2023, compared to $126.0 million for the year ended December 31, 2022. The increase was primarily due to a $8.2 million increase in sales and marketing expenses, a $4.3 million increase in personnel and related costs due to increased headcount during the first three quarters of the year, a $3.0 million increase in freight associated with higher revenues, a $2.1 million increase in costs in facilities from our expanding operations, a $2.0 million increase in software implementation costs, a $0.9 million increase in consulting fees in part due to added costs for compliance with Section 404(b) of the Sarbanes-Oxley Act and a $0.3 million increase in depreciation and amortization costs, partially offset by a $1.8 million decrease in sales commissions. In the fourth quarter of 2023, we implemented measures targeting a decrease in operating expenses, including headcount reduction to lower global personnel costs.

Research and Development Expense

R&D expense increased $6.1 million, or 30.0%, to $26.4 million for the year ended December 31, 2023, compared to $20.3 million for the year ended December 31, 2022. The increase in R&D expense was primarily due to a $6.9 million increase in personnel cost, partially offset by a $0.6 million decrease in regulatory affairs costs and a $0.1 million decrease in expenditures related to our IDE clinical trial in the United States.

Interest Expense

Interest expense increased $3.6 million, or 30.5%, to $15.4 million for the year ended December 31, 2023, as compared to $11.8 million for the year ended December 31, 2022. The increase was primarily due to the new Credit Agreement entered into in April 2022 and the second tranche advanced pursuant to the Credit Agreement in December 2022.

Change in Fair Value of Derivative Instruments

Change in fair value of derivative instruments for the year ended December 31, 2022 resulted in a gain of $0.7 million due to changes in the fair value of Madryn derivatives embedded in the Madryn Credit Agreement we entered into in August 2017. The loan was repaid in June 2022.

Provision for Income Taxes

Provision for income taxes decreased $2.5 million to a benefit of $0.1 million for the year ended December 31, 2023, compared to a provision of $2.4 million for the year ended December 31, 2022. The change in income tax provision is mainly due to the release of a valuation allowance on deferred tax assets in Brazil. This was based on positive evidence that these assets will be realized in the near future.

Other Income (Expense), Net

Other income (expense), net, increased $4.0 million to a gain of $0.8 million for the year ended December 31, 2023, compared to a loss of $3.2 million for the year ended December 31, 2022. The increase was primarily due 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 $1.8 million, for the year ended December 31, 2023, compared to a loss of $3.0 million for the year ended December 31, 2022.

Loss on Extinguishment of Debt

Loss on extinguishment of debt was $19.0 million for the year ended December 31, 2022 due to the extinguishment of the Madryn Credit Agreement. The $19.0 million loss on the extinguishment of debt represents the difference between the carrying value of the debt under the Madryn Credit Agreement and the cash outflows to extinguish the debt, including $6.5 million of the early repayment penalty. There was no extinguishment of debt in 2023.

Comparison of the Year Ended December 31, 2022 and 2021

The discussion related to our results of operations and changes in financial condition for 2022 compared to 2021 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, 2022, which was filed with the SEC on March 1, 2023.

Liquidity and Capital Resources

As of December 31, 2023, we had an accumulated deficit of $360.1 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, 2023 and 2022, we had cash of $40.0 million and $66.4 million, respectively.

On April 27, 2023, we issued 1,100,000 common shares in an underwritten public offering, at a price to the public of $71.50 per share. The underwriters purchased the shares from the Company at a price of $67.21 per share and exercised the option to purchase additional 165,000 common shares, at the public offering price per share. Net

proceeds to us after deducting underwriting discounts and offering expenses were approximately $84.6 million. See Note 7 “Shareholders’ Equity (Deficit)” for additional information.

On January 9, 2024, we entered into a securities purchase agreement with select institutional accredited investors to sell, at price of $25.00 per share, 1,101,565 common shares and pre-funded warrants for purchase of 898,435 common shares. The pre-funded warrants may be exercisable immediately at a price of $0.001 per share. The aggregate gross proceeds from the offering, before deducting offering expenses, were approximately $50.0 million.

Our short-term liquidity requirements consist primarily of operating expenses and interest payments on the Credit Agreement. 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 IDE clinical trial, 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, especially the IDE clinical trial, and the timing of regulatory approval for our Motiva Implants in the United States;
- 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 2022 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, 2022, which was filed with the SEC on March 1, 2023.

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

	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (88,513)	$ (52,166)
Investing activities	(24,547)	(34,791)
Financing activities	86,227	100,255
Effect of exchange rate changes on cash	513	(358)
Net (decrease) increase in cash	$ (26,320)	$ 12,940

Net Cash Used in Operating Activities

Net cash used in operating activities of $88.5 million for the year ended December 31, 2023 was primarily comprised of a net loss of $78.5 million, changes in operating assets and liabilities of $34.1 million, $4.2 million of unrealized foreign currency gain and $3.6 million of interest capitalized for construction in progress, partially offset by $14.4 million of share-based compensation expense, $13.3 million of non-cash interest expense due to accretion of debt discounts, $4.2 million of non-cash depreciation and amortization expense, a $1.4 million change in provision for inventory obsolescence, a $1.2 million change in allowance for doubtful accounts and $0.7 million of non-cash amortization expense of right-to-use assets.

Net cash used in operating activities of $52.2 million for the year ended December 31, 2022 was primarily comprised of a net loss of $75.2 million, a $19.0 million loss on extinguishment of debt, $13.4 million of share-based compensation expense, $8.1 million of non-cash interest expense due to accretion of debt discounts and interest subsumed into the principal of the new Credit Agreement, $3.9 million of non-cash depreciation expense, $1.7 million of unrealized foreign currency loss, and a $1.6 million change in provision for inventory obsolescence, partially offset by a $1.9 million gain from write-off of liability and a $0.7 million change in fair value of derivatives, as well as changes in operating assets and liabilities of $21.5 million.

Net Cash Used in Investing Activities

Net cash used in investing activities of $24.5 million for the year ended December 31, 2023 primarily consisted of $15.3 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, $7.9 million in purchases of property and equipment related to the new manufacturing facility and $1.3 million in purchases of intangibles.

Net cash used in investing activities of $34.8 million for the year ended December 31, 2022 primarily consisted of $29.9 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, $2.9 million in purchases of property and equipment, $1.5 million of purchases of intangibles and $0.5 million of cash paid for past asset acquisition.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $86.2 million for the year ended December 31, 2023 primarily consisted of $84.5 million of proceeds received for the issuance of common shares, net of underwriters' discount and issuance costs, from our public offering in April 2023 and $2.2 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.

Net cash provided by financing activities of $100.3 million for the year ended December 31, 2022 primarily consisted of $168.1 million of borrowings under the new Credit Agreement, net of discount and issuance costs,

and $3.9 million in proceeds received for stock option exercises, partially offset by $71.7 million used to repay borrowings under the Madryn Credit Agreement.

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, 2023:

	2024	2025	2026	2027	2028	Thereafter	Total
				(in thousands)			
Debt obligations - principal [1]	$ —	$ —	$ —	$ 196,399	$ —	$ —	$ 196,399
Debt obligations - Interest payments [1]	14,142	17,921	17,921	5,696	—	—	55,680
Future minimum lease payments [2]	998	912	833	724	506	295	4,268
License and software commitments [3]	2,363	1,999	1,501	1,031	601	—	7,495
Short-term borrowing [4]	1,100	—	—	—	—	—	1,100
	$ 18,603	$ 20,832	$ 20,255	$ 203,850	$ 1,107	$ 295	$ 264,942

(1) Contractual obligations related to the Credit Agreement. The interest payments were projected as of December 31, 2023 assuming we will choose to PIK interest into principal though April 2024. See below under "Indebtedness" and Note 5 "Debt" for additional details.

(2) Contractual obligations related to the minimum lease payments and interest on our operating leases. See Note 6 "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.

In August 2021, we entered into a contract with the Zona Franca Coyol, S.A., or CFZ, to begin construction of a new manufacturing facility in Costa Rica. In 2022, we exercised our option to purchase the title of the land and cold shell building for approximately $12.6 million. We also have the option to buy an adjacent lot of land for approximately $2.8 million and engage CFZ to construct an additional manufacturing facility. In July 2023, we announced the grand opening of the first phase of the Sulàyöm Innovation Campus. We currently expect to commence manufacturing from the new facility in fiscal 2024.

In September 2023, the Company signed a lease for an office space in Irving, Texas that commenced on January 1, 2024 upon completion of tenant improvements. No right-of-use assets or lease liabilities have been recorded as of December 31, 2023. See Note 6.

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 to the Company 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 the Madryn Credit Agreement in full, including the early repayment penalty of $6.5 million. In December 2022, $25 million was advanced under the second 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. As of December 31, 2023, $192.6 million was outstanding under the Credit Agreement representing the initial principal of $150 million for the Tranche A Term Loan and $25 million for the Tranche B Term Loan and $17.6 million of interest accrued into the principal balance. In February 2024, we amended the Credit Agreement where funding milestones, commitment termination dates and interest rates for the two remaining available tranches were modified. See Note 5 and Note 15.

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

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, 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.

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 product from direct customers in certain regions in limited instances within fifteen 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, 2023 an allowance of $0.3 million was recorded for product returns. As of December 31, 2022, the allowance for product returns was de minimis.

A portion of the Company's 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 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.

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 deferred 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.

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.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable is stated at invoice value less estimated allowances for returns and doubtful accounts. 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.

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 considering actual losses, projected future demand, and remaining shelf life to record a provision for excess and slow-moving inventory.

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, 2023 and 2022.

Income Taxes

The Company records income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or income tax returns. In estimating future tax consequences, expected future events, enactments or changes in the tax law or rates are considered. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company operates in various tax jurisdictions and is subject to audit by various tax authorities.

The Company records uncertain tax positions based on a two-step process whereby (1) a determination is made as to whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold the Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. Significant judgment is required in the identification of uncertain tax positions and in the estimation of penalties and interest on uncertain tax positions.

There were no material uncertain tax positions as of December 31, 2023 and 2022.

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, stockholders' 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, 2023, foreign currency transaction gain amounted to $1.8 million as compared to a foreign currency transaction loss of $3.0 million for the year ended December 31, 2022.

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 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 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.

See Note 9 “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 $40.0 million and $66.4 million as of December 31, 2023 and 2022, 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, 2023, foreign currency transaction gain amounted to $1.8 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, 2023, the effect of an immediate 10% adverse change in foreign exchange rates on foreign-denominated accounts as of December 31, 2023 would have had an impact of approximately 1.9% 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, 2023, 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 not 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, 2023 using the criteria established in "Internal Control—Integrated Framework" (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. 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 the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on that assessment and due to the material weakness described below, our management has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2023.

Material Weaknesses in Internal Control and Plan for Remediation

It was determined that as of December 31, 2023, our primary change management controls for direct database changes were not designed and implemented effectively for specific localities. Other Information Technology General Controls, automated process-level controls, and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. We have made significant progress remediating change management controls as of December 31, 2023. We improved policies and procedures and designed and documented more effective change management monitoring controls, through the use of systematic audit logging, that addresses the relevant risks in order to remediate the identified material weakness. The material weakness persists and will not be considered remediated until the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the control objective is achieved, and the controls are operating effectively. We expect that the remediation of this material weakness will be completed during 2024.

Remediation of Previously Reported Material Weakness in Internal Control over Financial Reporting

On December 31, 2021, it was determined that our primary user access controls (i.e. provisioning, de-provisioning, and quarterly user access review) to ensure appropriate segregation of duties that would adequately restrict user and privileged access to the financially relevant systems and data to appropriate Company personnel were not operating effectively. These user access control deficiencies resulted in a lack of segregation of duties with respect to certain user roles. Automated process-level controls and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. We implemented a number of measures to address the material weakness identified as of December 31, 2021. We improved policies and procedures and designed and documented more effective controls that addressed the relevant risks in order to remediate the previously identified material weakness in addition to engaging both internal and external resources to review and remediate the deficient controls around sensitive access and segregation of duties, including identifying any specific areas within our information technology systems that require additional resources. During the fourth quarter of 2023, we completed our testing of the operating effectiveness of the implemented controls and found them to be effective. As a result we have concluded the material weakness identified as of December 31, 2021 has been remediated as of December, 31 2023.

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation effort discussed above, there was no change in our internal control over financial reporting that occurred during the three months ended December 31, 2023 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, 2023 has been audited by Marcum LLP, 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 Shareholders and Board of Directors of
Establishment Labs Holdings Inc.

Adverse 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, 2023, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness described in the following paragraph on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness have been identified and included in "Management's Annual Report on Internal Control Over Financial Reporting":

It was determined that as of December 31, 2023, the Company's primary change management controls for direct database changes were not designed and implemented effectively for specific localities. Other Information Technology General Controls, automated process-level controls, and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency.

This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the fiscal 2023 consolidated financial statements, and this report does not affect our report dated March 4, 2024 on those financial statements.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets as of December 31, 2023 and the related consolidated statements of operations, comprehensive loss, shareholders' (deficit) equity, and cash flows for the three years ended December 31, 2023 of the Company and our report dated March 4, 2024 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 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/ Marcum LLP

Marcum LLP
Los Angeles, California
March 4, 2024

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

During the three months ended December 31, 2023, no director or Section 16 officer of the Company adopted or terminated any contract, instruction or written plan for the purchase or sale of securities of the Company intended to satisfy the affirmative defense condition of Rule 10b5-1(c) of the Exchange Act or any "non-Rule 10b5-1 trading arrangement" (as defined in the Exchange Act).

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.

The remaining information required by this Item is incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, 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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, 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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, 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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, 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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, 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 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.
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 Juan José Chacón-Quirós dated effective as of December 26, 2018.	Incorporated by reference from Registrant's Current Report on Form 8-K filed December 28, 2018.
10.9	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.
10.10	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
10.11	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.	Filed herewith.
10.12	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
10.13	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
10.14+	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.

Exhibit Number	Description of Exhibit	Incorporation by Reference
10.15+	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.
10.16+	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.
10.17+	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.
10.18+	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.
21.1	List of Subsidiaries of the Registrant.	Filed herewith.
23.1	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.
97.1	Policy Regarding the Recoupment of Certain Compensation Payments	Filed herewith.
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)	

'+ Indicates management contract or compensatory plan or arrangement.

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

** The certifications furnished in Exhibit 32.1 hereto is 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.*

ITEM 16. FORM 10-K SUMMARY

None.

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 sheets of Establishment Labs Holdings Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, shareholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 March 4, 2024, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of a material weakness.

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.

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/ Marcum LLP
Marcum LLP (688)

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

Los Angeles, California
March 4, 2024

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Balance Sheets

(In thousands, except share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 40,035	$ 66,355
Accounts receivable, net of allowance for doubtful accounts of $1,841 and $741 at December 31, 2023 and 2022, respectively	46,918	35,423
Inventory, net	79,471	36,583
Prepaid expenses and other current assets	8,477	11,543
Total current assets	174,901	149,904
Long-term assets:		
Property and equipment, net of accumulated depreciation	77,205	51,092
Goodwill	465	465
Intangible assets, net of accumulated amortization	7,987	4,608
Right-of-use operating lease assets, net	3,381	3,702
Other non-current assets	4,702	1,290
Total assets	$ 268,641	$ 211,061
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 41,624	$ 20,034
Accrued liabilities	13,690	17,237
Other liabilities, short-term	1,836	1,688
Total current liabilities	57,150	38,959
Long-term liabilities:		
Note payable, Oaktree, net of debt discount and issuance costs	188,739	175,461
Operating lease liabilities, non-current	2,712	3,200
Other liabilities, long-term	1,645	1,626
Total liabilities	250,246	219,246
Commitments and contingencies (Note 14)		
Shareholders' equity (deficit):		
Common shares – zero par value, unlimited amount of shares authorized at December 31, 2023 and 2022; 26,495,250 and 24,815,908 shares issued at December 31, 2023 and 2022, respectively; 26,087,180 and 24,407,838 shares outstanding at December 31, 2023 and 2022, respectively	315,634	223,637
Additional paid-in-capital	63,748	49,911
Treasury shares, at cost, 408,070 shares held at December 31, 2023 and 2022	(2,854)	(2,854)
Accumulated deficit	(360,096)	(281,594)
Accumulated other comprehensive income	1,963	2,715
Total shareholders' equity (deficit)	18,395	(8,185)
Total liabilities and shareholders' equity (deficit)	$ 268,641	$ 211,061

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,		
	2023	**2022**	**2021**
Revenue	$ 165,151	$ 161,700	$ 126,682
Cost of revenue	58,174	55,105	41,278
Gross profit	106,977	106,595	85,404
Operating expenses:			
Sales, general and administrative	145,575	125,984	92,229
Research and development	26,428	20,269	18,315
Total operating expenses	172,003	146,253	110,544
Loss from operations	(65,026)	(39,658)	(25,140)
Interest income	1,020	87	23
Interest expense	(15,393)	(11,760)	(9,062)
Change in fair value of derivative instruments	—	703	737
Loss on extinguishment of debt	—	(19,019)	—
Other income (expense), net	816	(3,177)	(6,270)
Loss before income taxes	(78,583)	(72,824)	(39,712)
Benefit (provision) for income taxes	81	(2,385)	(1,427)
Net loss	$ (78,502)	$ (75,209)	$ (41,139)
Basic and diluted net loss per share	$ (3.07)	$ (3.08)	$ (1.72)
Weighted average outstanding shares used for basic and diluted net loss per share	25,600,029	24,457,793	23,972,722

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,		
	2023	**2022**	**2021**
Net loss	$ (78,502)	$ (75,209)	$ (41,139)
Other comprehensive income:			
Foreign currency translation gain (loss)	(752)	(942)	784
Other comprehensive income (loss)	(752)	(942)	784
Comprehensive loss	$ (79,254)	$ (76,151)	$ (40,355)

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

ESTABLISHMENT LABS HOLDINGS INC.

Consolidated Statements of Shareholders' (Deficit) 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, 2021	**23,925,789**	**$ 213,471**	**(408,070)**	**$ (2,854)**	**$ 26,717**	**$ (165,246)**	**$ 2,873**	**$ 74,961**
Stock option exercises	521,316	6,226	—	—	(141)	—	—	6,085
Shares withheld to cover strike price upon cashless option exercise	(1,879)	(3)	—	—	—	—	—	(3)
Share-based compensation	48,124	48	—	—	10,359	—	—	10,407
Shares withheld to cover income tax obligation upon vesting of restricted stock	(5,015)	(5)	—	—	(351)	—	—	(356)
Foreign currency translation gain (loss)	—	—	—	—	—	—	784	784
Net loss	—	—	—	—	—	(41,139)	—	(41,139)
Balance at December 31, 2021	**24,488,335**	**219,737**	**(408,070)**	**(2,854)**	**36,584**	**(206,385)**	**3,657**	**50,739**
Warrant exercises	4,703	5	—	—	(5)	—	—	—
Stock option exercises	301,412	3,873	—	—	—	—	—	3,873
Share-based compensation	21,537	22	—	—	13,336	—	—	13,358
Shares withheld to cover income tax obligation upon vesting of restricted stock	(79)	—	—	—	(4)	—	—	(4)
Foreign currency translation gain (loss)	—	—	—	—	—	—	(942)	(942)
Net loss	—	—	—	—	—	(75,209)	—	(75,209)
Balance at December 31, 2022	**24,815,908**	**223,637**	**(408,070)**	**(2,854)**	**49,911**	**(281,594)**	**2,715**	**(8,185)**
Issuance of common stock, net of underwriters' discount and issuance costs	1,265,000	84,538	—	—	—	—	—	84,538
Issuance of common shares, post-IPO	14,676	490	—	—	—	—	—	490
Issuance of common stock in lieu of cash compensation	8,365	255	—	—	—	—	—	255
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 gain (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**

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,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (78,502)	$ (75,209)	$ (41,139)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,166	3,870	3,718
Provision for doubtful accounts	1,223	111	200
Provision for inventory obsolescence	1,392	1,577	338
Change in reserve for PP&E impairment	(341)	341	—
Provision for deferred income taxes	(3,706)	86	7
Share-based compensation	14,362	13,358	10,407
Loss from disposal of property and equipment	280	229	170
Unrealized foreign currency (gain)/loss, net	(4,181)	1,732	4,200
Loss on extinguishment of debt	—	19,019	—
Amortization of right-to-use asset	717	469	406
Gain from write-off of liability	—	(1,866)	(736)
Change in fair value of derivative instruments	—	(703)	(737)
Stock compensation in lieu of cash fees	495	—	—
Interest capitalized for construction in progress	(3,567)	(1,762)	—
Non-cash interest expense and amortization of debt discount	13,278	8,124	2,074
Changes in operating assets and liabilities:			
Accounts receivable	(11,557)	(12,333)	(6,695)
Inventory	(42,230)	(10,900)	(7,644)
Prepaid expenses and other current assets	2,637	(4,489)	(1,611)
Other assets	318	(750)	90
Accounts payable	18,957	4,376	4,959
Accrued liabilities	(1,662)	2,815	4,726
Operating lease liabilities	(689)	(378)	(408)
Other liabilities	97	117	143
Net cash used in operating activities	(88,513)	(52,166)	(27,532)
Cash flows from investing activities:			
Purchases of property and equipment	(7,908)	(2,851)	(2,425)
Cash used in asset acquisitions	—	(525)	(434)
Cost incurred for intangible assets	(1,328)	(1,491)	(1,447)
Capital expenditures on construction in progress	(15,311)	(29,924)	(2,857)
Net cash used in investing activities	(24,547)	(34,791)	(7,163)
Cash flows from financing activities:			
Issuance of common stock, net of underwriters' discount and issuance costs	84,538	—	—
Borrowings under Oaktree credit agreement, net of debt discount and issuance costs	—	168,093	—
Repayment of Madryn debt agreement	—	(71,681)	—
Repayments on finance leases	—	(26)	(175)

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,		
	2023	**2022**	**2021**
Proceeds from stock option exercises	2,173	3,873	4,583
Tax payments related to shares withheld upon vesting of restricted stock	(484)	(4)	(356)
Net cash provided by financing activities	86,227	100,255	4,052
Effect of exchange rate changes on cash and cash equivalents	513	(358)	(465)
Net (decrease)/increase in cash and cash equivalents	(26,320)	12,940	(31,108)
Cash at beginning of period	66,355	53,415	84,523
Cash and cash equivalents at end of period	$ 40,035	$ 66,355	$ 53,415
Supplemental disclosures:			
Cash paid for interest	$ 5,689	$ 5,363	$ 6,927
Cash paid for income taxes	$ 2,165	$ 2,125	$ 652
Supplemental disclosures of non-cash investing and financing activities:			
Unpaid balance for property and equipment	$ 2,847	$ 1,129	$ 22
Unpaid balance for intangible assets	$ 2,907	$ —	$ —
Equity consideration in an asset acquisition	$ 250	$ —	$ —
Consideration payable related to asset acquisition	$ —	$ —	$ 546
Cashless option exercises	$ 4,500	$ —	$ 1,640

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, 2023, 2022 and 2021

1. Formation and Business of the Company

Formation and Business of the Company

Establishment Labs Holdings Inc. and 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, 2023, 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), 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 two manufacturing facilities in Costa Rica. The Company is in the process of finishing the construction for a third facility in Costa Rica and currently expects to commence manufacturing from the new facility in fiscal 2024. 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, and Asia, and the Company's Motiva Flora SmoothSilk Tissue Expander is also approved for sale in the United States. The Company sells its products internationally through a combination of distributors and direct sales to customers.

The Company is pursuing regulatory approval to commercialize its Motiva Implant products in the United States. The Company received approval for an investigational device exemption, or IDE, from the United States Food and Drug Administration, or FDA, in March 2018 to initiate a clinical trial in the United States for its Motiva Implants. In August 2019, the Company completed all patient surgeries for the IDE aesthetic cohorts, which include primary augmentation and revision. In 2021, the Company initiated a modular pre-market approval, or PMA, submission process with FDA and submitted the first of four modules. In April 2022, the Company released preliminary results of the two-year patient follow-up data for the primary augmentation cohort of its 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. By June 30, 2022, the Company completed the three-year study subject follow-up for the aesthetic cohort. The final fourth module was submitted to the FDA in February 2023. The Company presented three-year patient follow-up data for the primary augmentation cohort of the IDE clinical trial at The Aesthetic Meeting in April 2023. In October 2023, the FDA granted 510(k) clearance for the Motiva Flora SmoothSilk Tissue Expander. In January 2024, the Company announced completion of the first commercial procedure of the Motiva Flora SmoothSilk Tissue Expander in the United States and the commercial launch of Motiva Implants in China.

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, 2023, 2022 and 2021

The consolidated financial statements include the Company's accounts and those of its wholly owned subsidiaries as of December 31, 2023 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

All intercompany accounts and transactions have been eliminated in consolidation.

Segments

The chief operating decision maker 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 a 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.

Geographic Concentrations

The Company derives substantially all its revenues from sales to customers in Europe, the Middle East, Latin America, and Asia, and has not yet received approval to sell its products in the United States other than the Motiva Flora SmoothSilk Tissue Expander.

For the years ended December 31, 2023, 2022 and 2021, Brazil accounted for 13.3%, 16.6% and 11.6%, 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 80% and 88% of the total long-lived assets as of December 31, 2023 and 2022, 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 derivatives 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, 2023, 2022 and 2021, no customer accounted for more than 10% of the Company's revenue. Two customers accounted for 12.7% and 11.6% of the Company's trade accounts receivable balance as of December 31, 2023, respectively. One customer accounted for 11.5% of the Company's trade accounts receivable balance as of December 31, 2022.

The Company relies on Avantor, Inc. (formerly NuSil Technology, LLC) as the sole supplier of medical-grade silicone used in Motiva Implants. During the years ended December 31, 2023, 2022 and 2021, the Company had purchases of $53.7 million, or 68.4% of total purchases, $32.1 million, or 38.2% of total purchases, and $23.1 million or 51.4% of total purchases, respectively, from Avantor Inc. As of December 31, 2023 and 2022, the Company had an outstanding balance owed to this vendor of $5.3 million and $5.6 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 regulatory approval of 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 clearances 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 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 $2.8 million and zero cash equivalents as of December 31, 2023 and 2022, respectively.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable is stated at invoice value less estimated allowances for returns and doubtful accounts. 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 doubtful accounts is as follows:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Beginning balance	$ 741	$ 1,221	$ 1,143
Provision for doubtful accounts	1,223	111	200
Write-offs	(123)	(591)	(122)
Ending balance	$ 1,841	$ 741	$ 1,221

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 considering actual losses and remaining shelf life to record a provision for obsolete or damaged inventory.

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

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Beginning balance	$ 2,649	$ 1,167	$ 1,625
Provision for inventory obsolescence	1,392	1,577	338
Write-offs	(111)	(95)	(796)
Ending balance	$ 3,930	$ 2,649	$ 1,167

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, 2023, 2022 and 2021, shipping and handling costs were $11.8 million, $9.0 million and $5.3 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 since each product unit represents a single performance obligation. 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 product from direct customers in certain regions in limited instances within fifteen 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, 2023, an allowance of $0.3 million was recorded for product returns. As of December 31, 2022 and 2021, allowance for product returns was de minimis. 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,		
	2023	2022	2021
	(in thousands)		
EMEA (Europe / Middle East / Africa)	$ 80,150	$ 62,419	$ 57,913
Latin America	48,891	52,442	38,226
Asia-Pacific	33,953	45,844	29,677
Other	2,157	995	866
Total revenue	$ 165,151	$ 161,700	$ 126,682

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 deferred 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 two to fifteen 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, 2023, 2022 and 2021, 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, 2023, 2022 and 2021.

Debt and Embedded Derivatives

The Company applies the accounting standards for derivatives and for distinguishing liabilities from equity when accounting for hybrid contracts. The Company accounts for convertible debt instruments when the Company has determined that the embedded conversion options should not be bifurcated from their host instruments in accordance with ASC 470-20 *Debt with Conversion and Other Options* (see Note 5).

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 records income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or income tax returns. In estimating future tax consequences, expected future events, enactments or changes in the tax law or rates are considered. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company operates in various tax jurisdictions and is subject to audits by various tax authorities.

The Company records uncertain tax positions based on a two-step process whereby (1) a determination is made as to whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold the Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. Significant judgment is required in the identification of uncertain tax positions and in the estimation of penalties and interest on uncertain tax positions.

There were no material uncertain tax positions in the years ended December 31, 2023, 2022 and 2021.

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, stockholders' 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 expense, net" in the consolidated statement of operations. For the years ended December 31, 2023, 2022 and 2021, foreign currency transaction gain/loss amounted to a gain of $1.8 million, and loss of $3.0 million and $5.6 million, respectively.

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 RSUs and RSAs granted 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.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. These reclassifications had no material impact on the Company's financial position as of December 31, 2023 or results of operations for year ended December 31, 2023.

Recent Accounting Standards

Periodically, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies 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 August 2020, the FASB issued Accounting Standards Update, or ASU, No. 2020-06, *Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*. The new guidance eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The Company adopted ASU No. 2020-06 as of January 1, 2022 and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

Recently Issued Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280):Improvements to Reportable Segment Disclosures*, which expands annual and interim disclosure requirements for reportable segments, especially significant segment expenses, and provides new disclosure requirements for entities with a single reportable segment. The new guidance is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025. The Company is currently evaluating the potential impact of the updated requirements, but based on current understanding, does not expect a material impact on its consolidated financial statements and related disclosures.

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. The guidance is effective for annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on the financial statement disclosures.

3. Balance Sheet Accounts

Inventory, Net

	December 31,	
	2023	2022
	(in thousands)	
Raw materials	$ 40,663	$ 12,549
Work in process	1,727	1,666
Finished goods	37,081	22,368
Total inventory, net	$ 79,471	$ 36,583

As of December 31, 2023 and 2022, $7.1 million and $2.0 million of inventory was on consignment, respectively.

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Prepaid Expenses and Other Current Assets

	December 31, 2023	2022
	(in thousands)	
Prepaid insurance	$ 2,747	$ 2,598
Prepaid construction in process	13	2,240
Prepaid services	420	685
Prepaid taxes	1,073	1,400
Prepaid assets	394	991
Prepaid raw materials and accessories	468	433
Prepaid U.S. clinical trial costs	176	300
Prepaid warranty and distribution rights	275	238
Prepaid software	506	1,090
Other	2,405	1,568
Total prepaid expenses	$ 8,477	$ 11,543

Property and Equipment, Net

	December 31, 2023	2022
	(in thousands)	
Machinery and equipment	$ 20,510	$ 11,118
Building improvements	10,626	7,006
Furniture and fixtures	9,224	5,645
Building	16,109	2,472
Leasehold improvements	2,600	2,233
Land	3,694	802
Vehicles	176	176
Construction in process	30,593	35,261
Total	93,532	64,713
Less: Accumulated depreciation and amortization	(16,327)	(13,621)
Total property and equipment, net	$ 77,205	$ 51,092

For the years ended December 31, 2023, 2022 and 2021, depreciation and amortization expense related to property and equipment was $2.8 million, $2.5 million and $2.5 million, respectively.

In August 2021, the Company entered into a contract with the Zona Franca Coyol, S.A., or CFZ, to begin construction of a new manufacturing facility in Costa Rica. The costs for improvement of the land and construction of a cold shell building were being paid for by CFZ while the Company was paying for internal improvements and customization. In 2022, the Company exercised it's option to purchase the title to the land and cold shell building for approximately $12.6 million. The Company has the option to buy an adjacent lot of land for approximately

$2.8 million and engage CFZ to construct an additional manufacturing facility. In July 2023, the Company announced the grand opening of the first phase of the Sulàyöm Innovation Campus. The Company currently expects to complete construction and commence manufacturing from the new facility in fiscal 2024.

Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Performance bonus	$ 4,451	$ 5,245
Payroll and related expenses	5,223	4,097
Bonus feature of stock option grants	—	4,500
Operating lease liabilities - current	773	688
Commissions	344	712
Professional and legal services	1,269	1,203
Warranty reserve	119	171
Taxes	109	130
Other	1,402	491
Total accrued liabilities	$ 13,690	$ 17,237

Other Liabilities, Short-Term

Other liabilities, short-term consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Deferred revenue	1,836	1,688

Other Liabilities, Long-Term

Other liabilities, long-term consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Deferred revenue	$ 1,498	$ 1,670
Other	147	(44)
Total other liabilties, long-term	$ 1,645	$ 1,626

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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, 2023 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.

There were no changes in the carrying amount of goodwill during the year ended December 31, 2023:

	Balance as of January 1, 2023	Additions	Accumulated Impairment Losses	Balance as of December 31, 2023
	(in thousands)			
Goodwill	$ 465	$ —	$ —	$ 465

The carrying amounts of these intangible assets other than goodwill as of December 31, 2023 were as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Estimated Useful Lives
	(in thousands)			(in years)
Patents and license rights	$ 2,007	$ (1,414)	$ 593	7-12
Customer relationships	2,033	(1,987)	46	4-10
510(k) authorization	567	(307)	260	15
Developed technology	62	(62)	—	10
Capitalized software development costs	5,293	(2,653)	2,640	2-5
Other	183	(41)	142	2-5
Capitalized software development costs not yet amortized	3,865	—	3,865	
Patents and license rights not yet amortized	441	—	441	
Total intangibles other than goodwill	$ 14,451	$ (6,464)	$ 7,987	

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The carrying amounts of intangible assets other than goodwill as of December 31, 2022 were as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Estimated Useful Lives
		(in thousands)		(in years)
Patents and license rights	$ 1,757	$ (1,321)	$ 436	7-12
Customer relationships	2,033	(1,967)	66	4-10
510(k) authorization	567	(269)	298	15
Developed technology	62	(58)	4	10
Capitalized software development costs	5,001	(1,630)	3,371	2-5
Other	183	(41)	142	2-5
Capitalized patents and license rights not yet amortized	291	—	291	
Total intangibles other than goodwill	$ 9,894	$ (5,286)	$ 4,608	

The amortization expense associated with intangible assets was $1.2 million for the years ended December 31, 2023, 2022 and 2021. Non-product related amortization is recorded in SG&A while product related amortization is recorded in cost of revenue.

As of December 31, 2023, 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)
2024	$ 1,155
2025	1,024
2026	561
2027	329
2028	185
Thereafter	427
Total expected future amortization expense	$ 3,681

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. As of December 31, 2023, there has been no impairment of goodwill or intangible assets based on the qualitative assessments performed by the Company. As of December 31, 2023, no triggering events have occurred which would indicate that the acquired intangible asset values may not be recoverable.

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5. 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.

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 will be advanced at the Company's election prior to March 31, 2024, subject to the Administrative Agent having received either (a) evidence that specified FDA approvals have been issued or (b) evidence that specified gross sales thresholds have been met, and subject to the other terms and conditions of the Credit Agreement.
- The fourth tranche, or the Tranche D Term Loan, of $25 million will be advanced at the Company's election prior to December 31, 2024, subject to the Administrative Agent having received both (a) evidence that specified FDA approvals have been issued and (b) evidence that specified gross sales thresholds have been met, or the Tranche D Funding Milestone, and subject to the other terms and conditions of the Credit Agreement.

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 or, at any time following the Tranche D Funding Milestone, 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 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 Term Loans prior to the second anniversary of the Closing 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 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.

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 10.4%, and the weighted average interest rate is 9.0%. 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 3.00%. The Company incurred $16.9 million and $9.4 million in interest expense in connection with the Credit Agreement during the years ended December 31, 2023 and 2022, respectively. No principal payments are due on the Term Loans until the final maturity date on April 26, 2027.

As of December 31, 2023, $192.6 million was outstanding under the Credit Agreement representing the initial principal of $150 million for the Tranche A Term Loan and $25 million for the Tranche B Term Loan and $17.6 million of interest accrued into the principal balance.

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

	December 31, 2023	2022
	(in thousands)	
Principal	$ 192,566	$ 181,314
Net unamortized debt discount and issuance costs	(3,827)	(5,853)
Net carrying value of Oaktree debt	$ 188,739	$ 175,461

As of December 31, 2023, the Company was in compliance with all financial debt covenants.

Madryn Debt

In August 2017, the Company entered into the Madryn Credit Agreement with Madryn and a syndicate of lenders that was scheduled to mature on September 30, 2025. After an amendment in August 2020, the Madryn Credit Agreement provided for term loans in a maximum aggregate principal amount of $65.0 million.

In connection with the Madryn Credit Agreement, the Company and certain of its subsidiaries granted a security interest in substantially all of their respective assets, including, without limitation, intellectual property, and pledges of certain shares of the Company’s subsidiaries, subject to certain excluded collateral exceptions.

Borrowings under the Madryn Credit Agreement bore interest at a rate equal to 3-month LIBOR plus 8.0% per annum provided that no default had occurred. The effective interest rate under the amended Madryn Credit

Agreement was 18.4%, and the weighted average interest rate was approximately 10.6% until extinguishment. The Company incurred $2.2 million and $6.9 million in interest expense in connection with Madryn Credit Agreement during the years ended December 31, 2022 and 2021, respectively. No principal payments were due on the term loans until the final maturity date on September 30, 2025.

The Company also determined that the Madryn Credit Agreement contained put options which were mandatory repayment provisions related to liquidity events or an event of default and a call option related to voluntary repayment option. The Company allocated a fair value of $15.1 million for these embedded derivatives as a debt discount on the original commitment date in August 2017. An additional $5.0 million and $1.6 million debt discount was recorded on respective borrowing dates when the Company met the required milestones and borrowed an additional $10.0 million in the fourth quarter of fiscal 2017 and $25.0 million in August 2019. The Company revalued the embedded derivatives as of each reporting period and recorded the change in the fair value in the consolidated statement of operations.

On April 26, 2022 the Company repaid in full the $65.0 million in aggregate principal amount outstanding under the Madryn Credit Agreement and the agreement was terminated. The Company recorded a loss on the extinguishment of debt in the amount of $19.0 million, which represents the difference between the carrying value of debt and the cash outflows to extinguish the debt including $6.5 million of the early repayment penalty.

As of December 31, 2023 and 2022, the Company did not have any Madryn debt recorded on the balance sheet.

6. 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 7 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 year ended December 31, 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.

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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.

Total lease cost includes the following components for the years ended December 31, 2023 and 2022:

	December 31,	
	2023	2022
	(in thousands)	
Operating lease expense cost	$ 1,079	$ 740
Sublease income	$ (233)	$ —
Total lease cost, net of sublease income	$ 846	$ 740

	December 31,	
	2023	2022
Supplemental balance sheet information	(in thousands)	
Operating lease right-of-use assets	$ 3,381	$ 3,702
Operating lease liabilities - short-term	773	688
Operating lease liabilities - long-term	2,712	3,200
Total operating lease liabilities	$ 3,485	$ 3,888
Weighted-average remaining lease term (years)		
Operating leases	4.6	5.4
Weighted-average discount rate (%)		
Operating leases	9.3 %	9.5 %

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	December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities	(in thousands)	
Operating cash outflows from operating leases	$ 1,052	$ 648
Operating cash inflows from subleases	$ (214)	$ —
Operating cash outflows from operating leases, net of sublease income	$ 838	$ 648
ROU assets obtained in exchange for new lease liabilities		
Operating leases	$ 478	$ 1,962

Maturities of lease liabilities as of December 31, 2023 were as follows:

Years Ending December 31,	Operating Leases
	(in thousands)
2024	$ 998
2025	912
2026	833
2027	724
2028	506
Thereafter	295
Total future minimum lease payments	4,268
Less: Amount of lease payments representing interest	(783)
Present value of future minimum lease payments	$ 3,485

The undiscounted future cash receipts from the Company's sublease as of December 31, 2023 were as follows:

Years Ending December 31,	Sublease
	(in thousands)
2024	$ 321
2025	332
2026	343
2027	355
2028	368
Thereafter	315
Total undiscounted future sublease cash receipts	$ 2,034

In September 2023, the Company signed a lease for an office space in Irving, Texas that commenced on January 1, 2024 upon completion of tenant improvements. No right-of-use assets or lease liabilities have been recorded as of December 31, 2023. The lease term is for 5.25 years with an option to renew, and the monthly rent will start at $21,800 and increase annually until it reaches $24,500 in the last year. The first three months of rent are waived.

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7. Shareholders' Equity (Deficit)

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, 2023 and 2022, 26,495,250 and 24,815,908 common shares, respectively, were issued and 26,087,180 and 24,407,838 common shares, respectively, were outstanding.

During the year ended December 31, 2023, the Company granted stock options and restricted stock to employees and contractors (see Note 9).

On April 27, 2023, the Company issued 1,100,000 common shares in an underwritten public offering, at a price to the public of $71.50 per share. The underwriters purchased the shares from the Company at a price of $67.21 per share and exercised the option to purchase additional 165,000 common shares, at the public offering price per share. Net proceeds to the Company after deducting underwriting discounts and offering expenses were approximately $84.6 million.

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

	2023	2022
Options to purchase common shares	1,487,387	1,873,165
Remaining shares available under the 2018 Equity Incentive Plan	2,953,884	2,271,999
Shares issuable on vesting of grants of RSUs	196,177	164,643
Remaining shares available under the 2018 ESPP	1,035,000	848,000
Total reserved common shares for future issuances	5,672,448	5,157,807

8. Warrants

In March 2017, the Company issued warrants for the purchase of 145,000 Class B ordinary shares to parties related to Rockport Ventures, with a fixed exercise price of $3.80 per share.

During the year ended December 31, 2022, warrants to purchase 5,000 shares were net exercised to obtain 4,703 shares. As of December 31, 2023 and 2022, no warrants were outstanding and exercisable.

9. 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 2023 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 5,250,000 as of December 31, 2023.

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

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Sales, general and administrative	$ 12,101	$ 11,154	$ 7,908
Research and development	2,261	2,204	2,499
Total stock compensation expense	$ 14,362	$ 13,358	$ 10,407

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, 2022	1,873,165	$ 42.73	7.06	$ 47,273
Granted (weighted-average fair value of $41.17 per share)	139,916	64.77		
Exercised	(349,967)	19.06		
Forfeited/canceled	(175,727)	67.35		
Balance at December 31, 2023	1,487,387	$ 47.47	6.27	$ 4,308

As of December 31, 2023, 931,798 options were vested and exercisable with weighted-average exercise price of $39.57 per share and a total aggregate intrinsic value of $4.0 million.

During the year ended December 31, 2023, 349,967 options were exercised at a weighted-average price of $19.06 per share. The intrinsic value of the options exercised during the years ended December 31, 2023, 2022, and 2021 was $5.1 million, $15.0 million, and $28.7 million, respectively. Upon the exercise of stock options, the Company issued new shares from its authorized shares.

At December 31, 2023, unrecognized compensation expense was $12.7 million related to stock options granted to employees and members of the Board of Directors and $1.0 million related to stock options granted to consultants. The weighted-average period over which such compensation expense will be recognized is 1.9 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, 2023, 2022 and 2021, the Company recognized $8.7 million, $9.9 million and $8.2 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 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,		
	2023	2022	2021
Volatility	62% - 71%	56% - 62%	60%
Risk-free interest rate	3.4% - 4.4%	1.6% - 3.8%	0.7% - 1.4%
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, 2023, 2022 and 2021, the Company recognized expense of $0.9 million, $0.4 million and $1.8 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,		
	2023	2022	2021
Volatility	60% - 65%	56% - 60%	60%
Risk-free interest rate	4.0% - 4.1%	2.4%- 3.6%	1.6%
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 2023:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Outstanding unvested at December 31, 2022	164,643	$ 69.49
Granted	128,694	52.60
Vested	(49,351)	61.58
Forfeited/canceled	(47,809)	66.69
Outstanding unvested at December 31, 2023	196,177	$ 56.89

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, 2023, 2022 and 2021 was $4.8 million, $3.0 million and $0.4 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, 2023, the Company had unrecognized share-based compensation cost of approximately $10.6 million associated with unvested awards of RSUs. This cost is expected to be recognized over a weighted-average period of approximately 2.5 years.

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2023, 2022 and 2021

10. Income Taxes

For the year ended December 31, loss before income tax consisted of the following:

	2023	2022	2021
		(in thousands)	
Costa Rica operations	$ (13,556)	$ (9,721)	$ 4,027
Non-Costa Rica operations	(65,027)	(63,103)	(43,739)
Total loss before income taxes	$ (78,583)	$ (72,824)	$ (39,712)

For the year ended December 31, the income tax (benefit) provision consisted of the following:

	2023	2022	2021
		(in thousands)	
Current:			
Costa Rica	$ 297	$ 114	$ 289
Non-Costa Rica	3,328	2,185	1,131
Total current	3,625	2,299	1,420
Deferred:			
Costa Rica	—	—	—
Non-Costa Rica	(3,706)	86	7
Total deferred	(3,706)	86	7
Total (benefit) provision for income taxes	$ (81)	$ 2,385	$ 1,427

ESTABLISHMENT LABS HOLDINGS, INC.

Notes to Consolidated Financial Statements
For the Years Ended December 31, 2023, 2022 and 2021

The items accounting for the difference between income taxes computed at the Costa Rica statutory income tax rate and the income tax provision (benefit) consisted of the following for the year ended December 31:

	2023		2022		2021	
			(in thousands)			
Tax benefit at Costa Rica statutory rate	$ (23,575)	30.0 %	$ (21,847)	30.0 %	$ (11,914)	30.0 %
Foreign tax rate differential	18,070	(22.9)	15,978	(22.0)	9,430	(24.0)
Tax rate changes	(7)	—	104	—	2	—
Return to provision adjustment	(539)	0.7	2,651	(4.0)	384	(1.0)
Tax credits	—	—	(52)	—	(53)	0.2
Change in valuation allowance	438	(0.6)	3,573	(5.0)	7,043	(18.0)
Tax holiday adjustment (benefit)	4,386	(5.6)	3,030	(4.0)	(918)	2.0
U.S. stock compensation	984	(1.3)	(1,353)	2.0	(2,681)	7.0
Other	162	(0.2)	301	—	134	(0.4)
Total provision (benefit) for income taxes	$ (81)	0.1 %	$ 2,385	(3.0)%	$ 1,427	(4.2)%

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, 2023, 2022 and 2021. The zero percent tax holiday, as extended, is effective for a period of 12 years through the year 2030.

As of December 31, the components of the Company's deferred tax assets and liabilities are as follows:

	2023	2022
	(in thousands)	
Accruals and reserves	$ 567	$ 348
Deferred revenue	4	1,198
Intangibles	125	143
Stock compensation	661	1,404
Net operating loss	25,087	19,933
R&D credits	336	232
Other	293	(144)
Valuation allowance	(23,380)	(22,942)
Total net deferred tax assets (included in "Other non-current assets")	$ 3,693	$ 172

As of December 31, 2023, the Company assessed that it is more-likely-than-not that it will not realize its deferred tax assets based on the absence of sufficient positive objective evidence that it would generate sufficient taxable income in its U.S. tax jurisdiction (Motiva USA, LLC) to realize the deferred tax assets. The Company intends to continue maintaining a full valuation allowance on its deferred tax assets in this jurisdiction until there is sufficient evidence to support the reversal of all or some portion of these allowances. The Company released the valuation allowance on its deferred tax assets in Brazil believing there is enough positive evidence that the deferred tax assets in Brazil will be realized in the following years.

As of December 31, 2023, the Company had U.S. and California tax credit carryforwards of approximately $0.5 million in total. The federal research credits begin to expire in 2037. However, the California research credits can be carried forward indefinitely.

As of December 31, 2023, the Company had U.S. federal, state, U.K. and Brazil net operating losses of approximately $102.6 million, $10.2 million, $0.2 million and $10.9 million, respectively. The U.S. federal net operating losses of $3.3 million generated prior to 2018, and state net operating losses will begin to expire on December 31, 2030. The U.S. federal net operating losses generated in 2018 and future years will be carried forward indefinitely. Brazil net operating losses can be carried forward indefinitely.

The United States federal and California laws impose restrictions on the utilization of net operating loss carryforwards and R&D 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 the Company has experienced an “ownership change” at any time since its formation, it would already be subject to limitations on its ability to utilize its existing net operating losses and other tax attributes. The Company did not experience an ownership change in the past that would materially impact the availability of its net operating losses and tax credits. Nevertheless, future changes in the Company’s share ownership, which may be outside of the Company’s control, may trigger an “ownership change” and, consequently, Section 382 and 383 limitations. The Company has not completed a Section 382 and 383 analysis to determine if an ownership change has occurred. Until such analysis is completed, the Company cannot be sure that the full amount of the existing net operating loss carryforwards will be available, even if the Company does 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.

Discontinuation of preferential tax treatment the Company currently enjoys or other unfavorable changes in tax law could result in additional compliance obligations and costs. The Company is currently the beneficiary of a tax holiday in Costa Rica pursuant to which it is subject to a tax at a 0% rate, with the exception of types pf income that is subject to 30% income tax. 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 the Company will continue to qualify for or receive such favorable tax treatment. If the Company fails to maintain such favorable tax treatment it may be subject to tax in Costa Rica at a significantly higher rate.

A tax authority may disagree with tax positions that the Company has taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge the amounts paid between the Company and its subsidiaries pursuant to the Company’s intercompany arrangements and transfer pricing policies. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by the Company, in which case, the Company expects that it might contest such assessment. Contesting such an assessment may be lengthy and costly and, if the Company is unsuccessful in disputing the assessment, the implications could increase its anticipated effective tax rate, where applicable. In addition, the Company may be subject to additional tax liabilities, which could materially and adversely affect its business, financial condition and results of operations. The application, interpretation and enforcement of the value-added tax, or VAT, and other taxes and related regulations applicable to medical device companies are complex and evolving.

The Company conducts operations in multiple jurisdictions and is subject to certain taxes, including income, sales and use, employment, value added and other taxes, in the United States and other jurisdictions in which the Company does business. A change in the tax laws in the jurisdictions in which the Company does 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 incurred.

The Company’s determination of its tax liability is subject to review by applicable U.S. and foreign tax authorities. Any adverse outcome of such a review could harm the Company’s operating results and financial condition. The determination of the Company’s 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, the Company has 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 the Company operates may challenge the Company's methodologies, which could impact its financial position and operating results. Historically, the Company has allocated some of its employees' and contractors' time across multiple business entities in the international jurisdictions in which the Company operates. If the Company determined that it had misclassified the employees' or contractors' employment status or certain of its expenditures under local laws, the Company may be subjected to penalties or be required to pay withholding taxes for, extend employee benefits to, provide compensation for unpaid overtime to, 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 the Company's operating results and financial condition.

The Company is periodically reviewed and audited by tax authorities with respect to income and non-income taxes. Tax authorities may disagree with certain positions the Company has taken, and the Company may have exposure to additional income and non-income tax liabilities which could have an adverse effect on the Company's operating results and financial condition. Such authorities could impose additional taxes, interest and penalties, claim that various withholding requirements apply to the Company or its subsidiaries or assert that benefits of tax treaties are not available to the Company or its subsidiaries. In addition, the Company's future effective tax rates could be favorably or unfavorably affected by changes in tax rates, changes in the valuation of the Company's deferred tax assets or liabilities, the effectiveness of its tax planning strategies, or changes in tax laws or their interpretation. Such changes could have an adverse impact on the Company's financial condition.

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

A non-U.S. corporation is 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 the Company's income and valuation of its assets, the Company does not believe it is a PFIC and does not expect to be a PFIC for the current taxable year or to become one in the future. However, because the PFIC status is subject to a number of uncertainties, neither the Company nor its tax advisors can provide any assurances regarding the PFIC status. If the Company is a PFIC for any taxable year during which a U.S. holder holds the Company's common shares, the U.S. holder may be subject to adverse tax consequences.

The Company records income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or income tax returns. In estimating future tax consequences, expected future events, enactments or changes in the tax law or rates are considered. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount expected to be realized.

Accounting for Uncertainty in Income Taxes

The Company records uncertain tax positions based on a two-step process whereby (1) a determination is made as to whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold the Company recognizes the largest amount of tax benefit that is greater than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. Significant judgment is required in the identification of uncertain tax positions and in the estimation of penalties and interest on uncertain tax positions.

The Company has adopted ASC 740-10 *Accounting for Uncertainty in Income Taxes*. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

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Notes to Consolidated Financial Statements
For the Years Ended December 31, 2023, 2022 and 2021

For the years ended December 31, 2023 and 2022 the Company has no material uncertain tax positions. The Company has R&D credits in the United States and has recorded reserves of $0.1 million which offsets R&D credit deferred tax assets. The Company does not expect any significant increases or decreases to its unrecognized tax benefits within the next 12 months. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

As of December 31, 2023, the Company is subject to taxation in Costa Rica, Belgium, France, Brazil, the United Kingdom, Sweden, Italy, Germany, Austria, Spain, Argentina, Switzerland and the United States and the Company's fiscal tax years 2018 through 2023 are subject to examination by the tax authorities.

11. 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,		
	2023	2022	2021
	(in thousands, except share and per share data)		
Numerator:			
Net loss	$ (78,502)	$ (75,209)	$ (41,139)
Denominator:			
Weighted average common shares used for basic and diluted earnings per share	25,600,029	24,457,793	23,972,722
Net loss per share:			
Basic and diluted	$ (3.07)	$ (3.08)	$ (1.72)

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,		
	2023	2022	2021
Options to purchase common shares	1,487,387	1,623,165	1,848,087
Shares issuable on vesting of grants of RSUs	196,177	164,643	3,982
Warrants to purchase common shares	—	—	5,500
Total potentially dilutive shares outstanding	1,683,564	1,787,808	1,857,569

12. Related Party Transactions

During the years ended December 31, 2023, 2022 and 2021, the Company recorded revenue of $1.2 million, $1.2 million and $1.4 million, respectively, for product sales to Herramientas Medicas, S.A., a distribution company owned by a family member of the Chief Executive Officer of the Company. Accounts receivable owed to the Company from this distribution company amounted to approximately $0.6 million and $0.4 million as of December 31, 2023 and 2022, respectively.

In 2016, the Company also entered into a separate agreement with Dr. Chacón Quirós, the brother of the Company's 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, 2023, 2022 and 2021, the Company paid Dr. Chacón Quirós approximately $0.4 million, $0.2 million and $0.4 million, respectively, for services rendered.

On December 12, 2022, the Company granted to Nicholas Lewin, a member of the board of directors, a stock option award for 7,829 options with a grant date fair value of $0.4 million as a compensation for consulting services he performs for the Company in addition to his services as a non-employee director. In addition, on May 28, 2023, the Company awarded Mr. Lewin a performance-based grant for 27,756 restricted stock units with a grant date fair value of $1.8 million as compensation for consulting services he performs for the Company.

On April 1, 2022, the Company entered into a consulting agreement with Lisa Gersh, who served on our Board of Directors until March 31, 2022. Pursuant to the consulting agreement, Ms. Gersh will perform consulting services as requested by the Company, with the expectation that she will advise our Board on elements of corporate leadership and governance. As payment for Ms. Gersh's consulting services, the Company paid Ms. Gersh a consulting fee of $0.1 million during the year ended December 31, 2023 and 2022. In addition, her outstanding equity awards granted during her term as a member of the Board of Directors will continue to vest in accordance with their terms. The consulting agreement terminates on March 31, 2024.

13. 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, 2023, the Company has 44 employees in Brazil and 3 employees in Argentina who were represented by a labor union.

14. 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, 2023 and 2022, contingent liabilities were not material, individually or in the 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.

15. Subsequent Events

On January 9, 2024. the Company entered into a securities purchase agreement with select institutional accredited investors to sell 1,101,565 common shares and pre-funded warrants to purchase 898,435 common shares at a price of $25.00 per share. The pre-funded warrants may be exercised immediately at a price of $0.001 per share. The aggregate gross proceeds from the offering, before deducting offering expenses, were approximately $50.0 million.

On February 21, 2024, the Company entered into a Second Amendment to the Credit Agreement, or the Amendment. The Amendment extended the Commitment Termination Date (i) with respect to the commitments applicable to the Tranche C Term Loans, from March 31, 2024 to December 31, 2024, and (ii) with respect to the commitments applicable to the Tranche D Term Loans, from December 31, 2024 to June 30, 2025. The Amendment also increased the interest rate applicable to Tranche C Term Loans and Tranche D Term Loans from 9.0% per annum to 10.0% per annum. The Yield Protection Premium applicable to the Tranche C Term Loans and Tranche D Term Loans was 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, and the existing prepayment premium schedule was otherwise preserved. Finally, the milestones triggering the availability of the Tranche C Term Loans and Tranche D Term Loans were modified by the Amendment to (i) provide for availability of the Tranche C Term Loans upon FDA approval of Motiva Implants for augmentation use in the U.S. and removed the alternative to trigger availability of Tranche C Term Loans upon achieving trailing twelve month gross sales of $185 million, and (ii) provided for availability of the Tranche D Term Loans upon achieving trailing twelve month gross sales of $195 million, which was reduced from $225 million. The terms of the Tranche A Term Loans and Tranche B Term Loans were not modified.

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: March 4, 2024

By: */s/ Juan José Chacón Quirós*
Name: Juan José Chacón Quirós
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/ Juan José Chacón Quirós Juan José Chacón Quirós	Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2024
/s/ Rajbir S. Denhoy Rajbir S. Denhoy	Chief Financial Officer (Principal Financial and Accounting Officer) (Authorized Representative in the United States)	March 4, 2024
/s/ Nicholas Lewin Nicholas Lewin	Chairman of the Board of Directors	March 4, 2024
/s/ Dennis Condon Dennis Condon	Director	March 4, 2024
/s/ Ann Custin Ann Custin	Director	March 4, 2024
/s/ Leslie Gillin Leslie Gillin	Director	March 4, 2024
/s/ Edward Schutter Edward Schutter	Director	March 4, 2024
/s/ Bryan Slotkin Bryan Slotkin	Director	March 4, 2024

EXECUTION VERSION
CONFIDENTIAL

FIRST AMENDMENT TO CREDIT AGREEMENT AND GUARANTY

This First Amendment to the Credit Agreement and Guaranty (this "**Amendment**") is made as of January 12, 2023, by and among **ESTABLISHMENT LABS HOLDINGS INC.**, a BVI business company limited by shares incorporated under the BVI Business Companies Act, 2004 (as amended) with company number 1794254 and with its registered office address at Commerce House, Wickhams Cay 1, P.O. Box 3140, Road Town, Tortola, VG1110, British Virgin Islands (the "***Borrower***"), each Subsidiary Guarantor party hereto, each Lender party hereto and **OAKTREE FUND ADMINISTRATION, LLC**, as administrative agent on behalf of the Lenders (in such capacity, the "***Administrative Agent***").

WHEREAS, the Borrower, the Subsidiary Guarantors party thereto, the Lenders party thereto and the Administrative Agent previously entered into that certain Credit Agreement and Guaranty, dated as of April 26, 2022 (as amended, amended and restated, restated, supplemented, modified or otherwise in effect from time to time prior to the date hereof, the "**Existing Credit Agreement**", and as further amended by this Amendment, the "**Credit Agreement**"); and

WHEREAS, the Borrower and the Lenders have agreed to amend the Existing Credit Agreement as set forth in this Amendment.

NOW, THEREFORE, for and in consideration of the above premises and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, each of the Borrower, the Subsidiary Guarantors, the Lenders and the Administrative Agent party hereto hereby covenants and agrees as follows:

1. Definitions. Capitalized terms used herein and not otherwise defined herein shall have the meanings assigned to such terms in the Credit Agreement.

2. Amendments. The Existing Credit Agreement is hereby amended by: (a) deleting the stricken text (indicated textually in the same manner as the following example: ~~stricken text~~) and adding the double-underlined text (indicated textually in the same manner as the following example: double-underlined text) as reflected in the modifications identified in the document attached as Annex A to this Amendment and (b) adding Schedule 8.11(a) attached as Annex B to this Amendment.

3. Reaffirmation of Financing Documents. Except as otherwise expressly provided herein, the parties hereto agree that all terms and conditions of the Credit Agreement and the other Loan Documents remain in full force and effect. The Borrower and each Subsidiary Guarantor party hereto hereby acknowledges, confirms and agrees that the Collateral shall continue to secure all applicable Obligations of such Obligor at any time and from time to time outstanding under the Credit Agreement and the other Loan Documents, as such Obligations may have been amended pursuant to this Amendment.

4. Conditions Precedent to Effectiveness. This Amendment shall not be effective unless and until each of the following conditions precedent has been fulfilled to the satisfaction

of or waived by the Administrative Agent (the date of such fulfillment or waiver, the "**Amendment Effective Date**"):

(a) This Amendment shall have been duly executed and delivered to the Administrative Agent by the Borrower, each Subsidiary Guarantor party hereto, the Lenders and the Administrative Agent;

(b) As determined in the Administrative Agent's reasonable discretion, there has not been any Material Adverse Change;

(c) The representations and warranties in Section 5 of this Amendment, Section 7 of the Credit Agreement and elsewhere in the Loan Documents shall be true, correct and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof, and provided further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(d) No Default shall have occurred and be continuing; and

(e) The Administrative Agent shall have received such other documents, instruments and agreements as are reasonably requested by the Administrative Agent.

5. Representations and Warranties. The Borrower and each Subsidiary Guarantor party hereto hereby represents and warrants:

(a) The execution, delivery and performance by such Obligor of this Amendment and the documents, instruments and agreements executed in connection herewith (collectively, the "**Amendment Documents**"), such Obligor's consummation of the transactions contemplated by the Amendment Documents and performance under the Amendment Documents do not and will not (i) conflict with any of its organizational, constitutional or constituent documents; (ii) contravene, conflict with, constitute a default under or violate any Law except as would not reasonably be expected to have a Material Adverse Change; (iii) contravene, conflict with or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which it or any of its property or assets may be bound or affected except as would not reasonably be expected to have a Material Adverse Change; (iv) require any action by, filing, registration, or qualification with, or permit from, any Governmental Authority (except such permits which have already been obtained and are in full force and effect, or the filing of any UCC financing statement) except where the failure to do so would not reasonably be expected to have a Material Adverse Change; or (v) constitute a default under or conflict with any Material Agreement.

(b) This Amendment and the other Amendment Documents have been duly authorized, executed and delivered by such Obligor and constitute legal, valid and binding agreements of such Obligor, enforceable in accordance with their terms

(subject, as to enforcement, to (x) the effect of applicable bankruptcy, insolvency, examinership or similar laws affecting the enforcement or creditors' rights and (y) general principles of equity).

(c) The execution, delivery and performance by such Obligor of the Amendment and the other Amendment Documents executed or to be executed by it is in each case within such Obligor's powers.

6. Waiver of Claims. The Borrower and each Subsidiary Guarantor party hereto hereby acknowledges and agrees that it has no offsets, defenses, claims or counterclaims against the Administrative Agent or the Lenders or any of the Administrative Agent's or the Lenders' affiliates, or any of their respective officers, directors, employees, attorneys, representatives, agents, predecessors, parents, subsidiaries, shareholders, affiliates, successors and assigns (collectively, the "**Lender Parties**") with respect to the Obligations and that if such Obligor now has, or ever did have, any offsets, defenses, claims or counterclaims against the Lender Parties, or any one of them, with respect thereto whether known or unknown, at law or in equity, from the beginning of the world through this date and through the time of execution of this Amendment, all of them are hereby expressly **WAIVED**, and the Borrower hereby **RELEASES** the Lender Parties from any liability therefor.

7. Miscellaneous.

(a) Except as otherwise expressly provided herein, all provisions of the Credit Agreement and the other Loan Documents remain in full force and effect. This Amendment shall constitute a Loan Document.

(b) This Amendment may be executed in several counterparts and by each party on a separate counterpart, each of which when so executed and delivered shall be an original, and all of which together shall constitute one instrument. An executed facsimile or electronic copy of this Amendment shall be effective for all purposes as an original hereof.

(c) This Amendment expresses the entire understanding of the parties with respect to the amendments contemplated hereby. No prior negotiations or discussions shall limit, modify or otherwise affect the provisions hereof.

(d) Any determination that any provision of this Amendment or any application hereof is invalid, illegal or unenforceable in any respect and in any instance shall not affect the validity, legality or enforceability of such provision in any other instance, or the validity, legality or enforceability of any other provisions of this Amendment.

(e) The Borrower and each Subsidiary Guarantor party hereto represents and warrants that such Obligor has consulted with independent legal counsel of its selection in connection with this Amendment and is not relying on any representations or warranties of the Administrative Agent.

(f) This Amendment and all rights and obligations hereunder, including matters of construction, validity and performance, shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply.

[*Signature pages follow.*]

IN WITNESS WHEREOF, the parties have hereunto caused this Amendment to be executed as of the date first above written.

BORROWER:

ESTABLISHMENT LABS HOLDINGS INC.,
a BVI business company incorporated under the laws of the British Virgin Islands

DocuSigned by:
By: _____
1B432DF9FA6F4C2...
Name: Juan José Chaćon Quirós
Title: Chief Executive Officer

SUBSIDIARY GUARANTORS:

ESTABLISHMENT LABS SOCIEDAD ANONIMA,
a company incorporated under the laws of Costa Rica

DocuSigned by:
By: _____
1B432DF9FA6F4C2...
Name: Juan José Chaćon Quirós
Title: Secretary

EUROPEAN DISTRIBUTION CENTER MOTIVA BV,
a Belgium *besloten vennootschap*

DocuSigned by:
By: _____
1B432DF9FA6F4C2...
Name: Juan José Chaćon Quirós
Title: Director

ESTABLISHMENT LABS BRASIL PRODUTOS PARA SAUDE LTDA.,
a Brazil limited liability company

DocuSigned by:
By: _____
46F9682DAB4047C...
Name: Mariana De Castro Bonatto
Title: Director

JAMM TECHNOLOGIES, INC.,
a Delaware corporation

By: DocuSigned by:
1B432DF9FA6F4C2...
Name: Juan José Chaćon Quirós
Title: Director

MOTIVA USA LLC,
a Delaware limited liability company

By: DocuSigned by:
1B432DE9EA6E4C2...
Name: Juan José Chaćon Quirós
Title: Director

ADMINISTRATIVE AGENT:

OAKTREE FUND ADMINISTRATION, LLC

By: Oaktree Capital Management, L.P.
Its: Managing Member

By: DocuSigned by: Jessica Dombroff
3688F305AD9F1E9...
Name: Jessica Dombroff
Title: Vice President

By: DocuSigned by: Maria Attaar
129C9A1CE0084D...
Name: Maria Attaar
Title: Vice President

LENDERS:
AL-RAYYAN HOLDING LLC

By: _____
Name: Ahmed Ali Al Hammadi
Title: Director

OAKTREE SPECIALTY LENDING CORPORATION
By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

DocuSigned by:

By: _____
Name: Jessica Dombroff
Title: Vice President

DocuSigned by:

By: _____
Name: Maria Attaar
Title: Vice President

OAKTREE STRATEGIC CREDIT FUND
By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

By: DocuSigned by: Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: DocuSigned by: Maria Altaar
Name: Maria Altaar
Title: Vice President

OAKTREE DIVERSIFIED INCOME FUND INC.
By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

DocuSigned by:
By: _____
Name: Jessica Dombroff
Title: Vice President

DocuSigned by:
By: _____
Name: Maria Attaar
Title: Vice President

OAKTREE LSL HOLDINGS EURRC SARL

By: _____
Name: Martin Eckel
Title: Manager

By: _____
Name:
Title:

OAKTREE GCP HOLDINGS II SARL

By: _____
Name: Martin Eckel
Title: Manager

By: _____
Name:
Title:

OAKTREE HUNTINGTON INVESTMENT FUND II AIF (DEBT ACQUISITION), L.P.

By: Oaktree Fund AIF Series, L.P. – Series X
Its: General Partner

By: Oaktree Fund GP AIF, LLC
Its: General Partner

By: Oaktree Fund GP III, L.P.
Its: Managing Member

DocuSigned by:
By: _____
3599F39BAD0F4E0...
Name: Jessica Dombroff
Title: Authorized Signatory

DocuSigned by:
By: _____
129C801CED0844D...
Name: Maria Attaar
Title: Authorized Signatory

OAKTREE LSL FUND HOLDINGS EURRC S.À R.L.

By: 

Name: Martin Eckel
Title: Manager

BYLSMA 2022-1, LTD.,
by Brookfield Asset Management Reinsurance Advisor LLC, in its capacity as collateral manager

By: _____
Name: Darryl Pinsker
Title: Authorized Signatory

CASALS 2022-1, LTD.,
by Brookfield Asset Management Reinsurance Advisor LLC, in its capacity as collateral manager

By: _____
Name: Darryl Pinsker
Title: Authorized Signatory

DUPRE 2022-1, LTD.,
by Brookfield Asset Management Reinsurance Advisor LLC, in its capacity as collateral manager

By: _____
Name: Darryl Pinsker
Title: Authorized Signatory

Annex A

[*See attached.*]

EXECUTION VERSION
CONFIDENTIAL

CREDIT AGREEMENT AND GUARANTY

dated as of April 26, 2022

by and among

ESTABLISHMENT LABS HOLDINGS INC.,
as the Borrower,

THE SUBSIDIARY GUARANTORS FROM TIME TO TIME PARTY HERETO,
as the Guarantors,

THE LENDERS FROM TIME TO TIME PARTY HERETO,
as the Lenders,

and

OAKTREE FUND ADMINISTRATION, LLC,
as the Administrative Agent

U.S. $225,000,000

~~4875-6208-3346 v.20~~
4895-9011-1037 v.7

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SCHEDULES AND EXHIBITS

CREDIT AGREEMENT AND GUARANTY

CREDIT AGREEMENT AND GUARANTY, dated as of April 26, 2022 (this "***Agreement***"), among **ESTABLISHMENT LABS HOLDINGS INC.**, a BVI business company limited by shares incorporated under the BVI Business Companies Act, 2004 (as amended) with company number 1794254 and with its registered office address at Commerce House, Wickhams Cay 1, P.O. Box 3140, Road Town, Tortola, VG1110, British Virgin Islands (the "***Borrower***"), certain Subsidiaries of the Borrower that may be required to provide Guarantees from time to time hereunder (each a "***Guarantor***" and collectively, the "***Guarantors***"), the lenders from time to time party hereto (each a "***Lender***" and collectively, the "***Lenders***"), and **OAKTREE FUND ADMINISTRATION, LLC**, as administrative agent for the Lenders (in such capacity, the "***Administrative Agent***").

WITNESSETH:

WHEREAS, the Borrower has requested that the Lenders provide a senior secured term loan facility to the Borrower in an aggregate principal amount of $225,000,000, consisting of (a) a $150,000,000 Tranche A Term Loan to be extended on the Closing Date, (b) a $25,000,000 Tranche B Term Loan to be extended on the Applicable Funding Date, (c) a $25,000,000 Tranche C Term Loan to be extended on the Applicable Funding Date, and (d) a $25,000,000 Tranche D Term Loan to be extended on the Applicable Funding Date; and

WHEREAS, the Lenders are willing, on the terms and subject to the conditions set forth herein, to provide such senior secured term loan facility.

NOW, THEREFORE, the parties hereto agree as follows:

SECTION 1.
DEFINITIONS

1.01 Certain Defined Terms. As used herein, the following terms have the following respective meanings:

"***Acquisition***" means any transaction, or any series of related transactions, by which any Person (for purposes of this definition, an "***acquirer***") directly or indirectly, by means of amalgamation, merger, purchase of assets, purchase of Equity Interests, or otherwise, (a) acquires all or substantially all of the assets of any other Person, (b) acquires an entire business line, or an entire product or unit or division of any other Person, (c) with respect to any other Person that is managed or governed by a Board, acquires control of Equity Interests of such other Person representing more than fifty percent (50%) of the ordinary voting power (determined on a fully-diluted basis) for the election of directors of such Person's Board, or (d) acquires control of more than fifty percent (50%) of the Equity Interests in any other Person (determined on a fully-diluted basis) that is not managed by a Board.

"***Administrative Agent***" has the meaning set forth in the preamble hereto.

"***Affected Financial Institution***" means (a) any EEA Financial Institution or (b) any U.K. Financial Institution.

"***Affiliate***" means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified; provided that solely with respect to transfers by, or any other rights afforded to, the QIA Lender or any of its Affiliates, all references to "Affiliate" or "Affiliates" with respect to the QIA Lender shall include (i) Qatar Investment Authority and any individual, corporation, partnership, firm, joint venture, investment fund, association, trust, unincorporated association or organization, governmental body or other entity, which controls, is controlled by or is under common control with, the QIA Lender, and (ii) government entities or instrumentalities of, or entities that are wholly-owned or controlled by, the State of Qatar, the Amiri Diwan of the State of Qatar or any entities that are wholly-owned or controlled by any one or more of the foregoing.

"***Agreement***" has the meaning set forth in the preamble hereto.

"***Allocable Amount***" has the meaning set forth in **Section 13.10(b)**.

"***Anti-Terrorism Laws***" means any laws relating to terrorism or money laundering, including, without limitation, (a) the Money Laundering Control Act of 1986 (*e.g.*, 18 U.S.C. §§ 1956 and 1957), (b) the Bank Secrecy Act of 1970 (*e.g.*, 31 U.S.C. §§ 5311 – 5330), as amended by the Patriot Act, (c) the laws, regulations and Executive Orders administered by the United States Department of the Treasury's Office of Foreign Assets Control ("**OFAC**"), (d) the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 and implementing regulations by the United States Department of the Treasury, (e) the laws, regulations and orders administered by the UK Office of Financial Sanctions Implementation, (f) any law prohibiting or directed against terrorist activities or the financing of terrorist activities (*e.g.*, 18 U.S.C. §§ 2339A and 2339B), (g) the Brazilian Federal Law No. 12,846/2013 and (h) any similar laws enacted in the United States, BVI, Costa Rica, the European Union, Brazil or any other jurisdictions in which the parties to this agreement operate, and all other present and future legal requirements of any Governmental Authority governing, addressing, relating to, or attempting to eliminate, terrorist acts and acts of war.

"***Applicable Availability Period***" means the Tranche B Availability Period, the Tranche C Availability Period or the Tranche D Availability Period, as the context may require.

"***Applicable Commitment***" means the Tranche A Commitment, the Tranche B Commitment, the Tranche C Commitment or the Tranche D Commitment, as the context may require.

"***Applicable Funding Condition***" means the Tranche A Funding Condition, the Tranche B Funding Condition, the Tranche C Funding Condition or the Tranche D Funding Condition, as the context may require.

"***Applicable Funding Date***" means, with respect to each Applicable Commitment, the date on or prior to the expiration of the Applicable Availability Period for such Applicable Commitment

on which all conditions precedent set forth in **Section 6.02** are satisfied or waived in accordance with the terms of this Agreement.

"***Approved Lender***" means any Person designated by Oaktree Capital Management, L.P. by written notice to the Borrower prior to the Closing Date.

"***Arm's Length Transaction***" means, with respect to any transaction, the terms of such transaction shall not be less favorable to the Borrower or any of its Subsidiaries than it would obtain in a comparable arms' length transaction with a Person that is not an Affiliate.

"***Asset Sale***" has the meaning set forth in **Section 9.09**.

"***Assignment and Assumption***" means an assignment and assumption entered into by a Lender and an assignee of such Lender substantially in the form of **Exhibit A**, or such other form as agreed by the Administrative Agent.

"***Bail-In Action***" means the exercise of any Write-Down and Conversion Powers by the applicable EEA Resolution Authority or U.K. Resolution Authority in respect of any liability of an Affected Financial Institution.

"***Bail-In Legislation***" means (a) with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law, regulation, rule or requirement for such EEA Member Country from time to time that is described in the EU Bail-In Legislation Schedule; and (b) with respect to the United Kingdom, Part I of the United Kingdom Banking Act 2009 (as amended from time to time) and any other law, regulation or rule applicable in the United Kingdom relating to the resolution of unsound or failing banks, investment firms or other financial institutions or their Affiliates (other than through liquidation, administration or other insolvency proceedings).

"***Bailee Letter***" means a bailee letter substantially in the form of Exhibit F to the Security Agreement (or such other form as is reasonably acceptable to the Administrative Agent).

"***Bank Levy***" means any amount payable by a Person to any Governmental Authority or taxing authority on the basis of or in relation to its balance sheet or capital base or any part of it or its liabilities or minimum regulatory capital or any combination thereof, in each case in connection with the conducting of banking activities, including any tax in any jurisdiction levied on a similar basis or for a similar purpose or any financial activities tax (including any contribution to the Single Resolution Mechanism levied pursuant to article 67 of EU Regulation n°806/2014 as amended by EU Regulations n°2015/63, n°2015/81, and n°2016/1434).

"***Bankruptcy Code***" means Title 11 of the United States Code entitled "Bankruptcy."

"***Belgian Code of Companies and Associations***" means the Belgian *Wetboek van vennootschappen en verenigingen/Code des sociétés et des associations* dated 23 March 2019, as amended from time to time.

"***Belgian Guarantor***" means European Distribution Center Motiva BV, a private limited liability company (*besloten vennootschap/société à responsabilité limitée*) incorporated and

existing under the laws of Belgium, having its registered office (*zetel/siège*) at Nijverheidsstraat 96, 2160 Wommelgem, Belgium and registered with the Crossroads Bank for Enterprises (*Kruispuntbank van Ondernemingen/Banque-Carrefour des Entreprises*) under number 0881.512.541, RPR/RPM Antwerp, section Antwerp.

"***Belgian Obligor***" means any Obligor that is incorporated and existing under the laws of Belgium.

"***Belgian Security Documents***" means (a) the receivables pledge agreement to be entered into by the Belgian Guarantor and the Administrative Agent, (b) the bank account pledge agreement to be entered into by the Belgian Guarantor and the Administrative Agent, (c) the share pledge agreement in relation to the shares in the Belgian Guarantor to be entered into by the shareholder(s) of the Belgian Guarantor and the Administrative Agent, and (d) the register pledge agreement to be entered into by the Belgian Guarantor and the Administrative Agent.

"***Beneficial Ownership Certification***" means a certification regarding beneficial ownership as required by the Beneficial Ownership Regulation.

"***Beneficial Ownership Regulation***" means 31 C.F.R. § 1010.230.

"***Benefit Plan***" means any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or Subsidiary thereof has any obligation or liability, contingent or otherwise.

"***Board***" means, with respect to any Person, the board of directors or equivalent management or oversight body of such Person or any committee thereof authorized to act on behalf of such board (or equivalent body).

"***Borrower***" has the meaning set forth in the preamble hereto.

"***Borrowing***" means the borrowing of the Loans on each Applicable Funding Date.

"***Borrowing Notice***" means a written notice substantially in the form of **Exhibit B** or such other form approved by the Administrative Agent.

"***Brazil***" means the Federative Republic of Brazil.

"***Brazilian Guarantor***" means any Guarantor that is organized and existing under the Laws of Brazil.

"***Brazilian Securities***" means the Fiduciary Assignment of Receivables and the Fiduciary Transfer of Quotas.

"***Brazilian Security Agreements***" means the Fiduciary Assignment of Receivables Agreement and the Fiduciary Transfer of Quotas Agreement.

"***Bringdown Date***" means each date on which a Loan is advanced pursuant to **Section 2.01** and any other date the representations and warranties under the Loan Documents are required to be made (other than the Closing Date).

"***Business Day***" means a day (other than a Saturday or Sunday) on which commercial banks are not authorized or required to close (i) in New York City, (ii) in Costa Rica, (iii) in the BVI or (iv) exclusively in relation to the perfection of the Brazilian Securities, where the Brazilian Guarantors' headquarters are located; provided, that with respect to any notices to a QIA Lender or any obligation for a QIA Lender to fund any Borrowings, "Business Day" shall not include any day on which commercial banks in Qatar are authorized or required to close.

"***BVI***" means the British Virgin Islands.

"***BVI BCA***" means the BVI Business Companies Act, 2004 (as amended) of the British Virgin Islands.

"**BVI Registrar**" means the Registrar of Corporate Affairs of the BVI appointed under section 229 of the BVI BCA.

"***Capital Lease Obligations***" means, as to any Person, the obligations of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) any property by such Person as lessee, which obligations are required to be classified and accounted for as a capital lease on a balance sheet of such Person under GAAP or IFRS, as applicable, and for the purposes of this Agreement, the amount of such obligations shall be the capitalized amount thereof, determined in accordance with GAAP or IFRS, as applicable.

"***Casualty Event***" means the damage, destruction or condemnation, as the case may be, of property of the Borrower or any of its Subsidiaries in excess of $2,000,000.

"***Change of Control***" means an event or series of events (a) as a result of which any "person" or persons constituting a "group" (as such terms are used in Sections 13(d) and 14(d) of the Securities Act, but excluding any of such person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such Plan) becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Exchange Act, except that a person or group shall be deemed to have "beneficial ownership" of all Equity Interests that such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time (such right, an "***option right***")), directly or indirectly, of Equity Interests representing more than thirty-five percent (35%) of the Equity Interests of the Borrower entitled to vote for members of the Board of the Borrower on a fully-diluted basis (and taking into account all such Equity Interests that such person or group has the right to acquire pursuant to any option right); (b) as a result of which, during any period of twelve (12) consecutive months, a majority of the members of the Board of the Borrower cease to be composed of individuals (x) who were members of such Board on the first day of such period, (y) whose election or nomination to such Board was approved by individuals referred to in **clause (x)** above constituting at the time of such election or nomination at least a majority of such Board or equivalent governing body or (z) whose election or nomination to such Board was approved by individuals referred to in **clauses (x)** and **(y)** above constituting at the time of such election or nomination at least a majority of such Board;

(c) that results in the sale of all or substantially all of the assets or businesses of the Borrower and its Subsidiaries, taken as a whole; or (d) that results in the Borrower's failure to own, directly or indirectly, beneficially and of record, one hundred percent (100%) of all issued and outstanding Equity Interests of each Subsidiary Guarantor.

"***Claims***" means (and includes) any claim, demand, complaint, grievance, action, application, suit, cause of action, order, charge, indictment, prosecution, judgement or other similar process, whether in respect of assessments or reassessments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel, and all costs incurred in investigating or pursuing any of the foregoing or any proceeding relating to any of the foregoing.

"***Closing Date***" means the date on which the conditions precedent specified in **Section 6.01** are satisfied (or waived in accordance with **Section 14.04**).

"***Code***" means the Internal Revenue Code of 1986, as amended from time to time, and the rules and regulations promulgated thereunder from time to time.

"***Collateral***" means any real, personal and mixed property (including Equity Interests), whether tangible or intangible, in which Liens are granted or purported to be granted to the Administrative Agent as security for the Obligations under any Loan Document on or after the Closing Date, including future acquired or created assets or property (or collectively, all such real, personal and mixed property, as the context may require); provided that "Collateral" shall not include any Excluded Assets (as defined in the Security Agreement).

"***Commitment***" means, with respect to each Lender, the obligation of such Lender to make Loans to the Borrower on each Applicable Funding Date in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Applicable Commitment", as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise pursuant to this Agreement. The aggregate amount of Commitments on the Closing Date equals $225,000,000.

"***Commitment Termination Date***" means (a) with respect to the Applicable Commitments of the Tranche A Term Loans, the Closing Date; (b) with respect to the Applicable Commitments of the Tranche B Term Loans, September 30, 2023; (c) with respect to the Applicable Commitments of the Tranche C Term Loans, March 31, 2024; and (d) with respect to the Applicable Commitments of the Tranche D Term Loans, December 31, 2024; provided that if any such date is not a Business Day, then the Commitment Termination Date shall be on the immediately preceding Business Day.

"***Compliance Certificate***" has the meaning set forth in **Section 8.01(c)**.

"***Contracts***" means any contract, license, lease, agreement, obligation, promise, undertaking, understanding, arrangement, document, commitment, entitlement or engagement under which a Person has, or will have, any liability or contingent liability (in each case, whether written or oral, express or implied, and whether in respect of monetary or payment obligations, performance obligations or otherwise).

"***Control***" means, in respect of a particular Person, the possession by one or more other Persons, directly or indirectly, of the power to direct or cause the direction of the management or policies of such particular Person, whether through the ability to exercise voting power, by contract or otherwise. "Controlling" and "Controlled" have meanings correlative thereto.

"***Controlled Account***" has the meaning set forth in **Section 8.16(a)**.

"***Copyright***" means all copyrights (including with respect to published and unpublished works of authorship, software, website and mobile content, data, databases and other compilations of information), copyright registrations and applications for copyright registrations, including all renewals, restorations, reversions and extensions thereof and all other rights whatsoever accruing thereunder or pertaining thereto throughout the world.

"***Costa Rica***" means the Republic of Costa Rica.

"***Costa Rican Conditional Assignment Agreements***" means the agreements, in form and substance reasonably satisfactory to the Administrative Agent, pursuant to which the Costa Rican Guarantor conditionally assigns certain rights under any material project document to the Administrative Agent for the benefit of the Secured Parties, including without limitation, over lease agreements and/or purchase agreements, as requested by the Administrative Agent.

"***Costa Rican Guarantor***" means any Guarantor that is organized under the Laws of Costa Rica.

"***Costa Rican Notes***" has the meaning set forth in **Section 2.04(b)**.

"***Costa Rican Security Documents***" means (a) each CR Moveable Guarantee Agreement; (b) any Mortgage to be executed by the Costa Rican Guarantor in Costa Rica; (c) each Costa Rican Conditional Assignment Agreement; and (d) all other notices, consents, acknowledgements and documents necessary or advisable to perfect any security interest over any asset in Costa Rica in favor of, or for the benefit of, the Administrative Agent for the benefit of the Secured Parties, in form and substance reasonably satisfactory to the Administrative Agent, as each may be amended, modified, supplemented, renewed or restated, including any consent letter with respect to a Costa Rican Conditional Assignment Agreement.

"***CR Assets Moveable Guarantee Agreement***" means the moveable guarantee agreement creating a Lien on all non-registrable assets owned by the Costa Rican Guarantor in favor of, or for the benefit of, the Administrative Agent for the benefit of the Secured Parties, in form and substance reasonably satisfactory to the Administrative Agent, and containing such provisions as shall be advisable under the Laws of Costa Rica, as the same may be amended, amended and restated, supplemented or otherwise modified from time to time.

"***CR Equity Moveable Guarantee Agreement***" means the moveable guarantee agreement creating a Lien on all Equity Interests of the Costa Rican Guarantor owned by the Borrower in favor of, or for the benefit of, the Administrative Agent for the benefit of the Secured Parties, in form and substance reasonably satisfactory to the Administrative Agent, and containing such provisions as shall be advisable under the Laws of Costa Rica, as the same may be amended, amended and restated, supplemented or otherwise modified from time to time.

"***CR Moveable Guarantee Agreements***" means, collectively, the CR Equity Moveable Guarantee Agreement and the CR Assets Moveable Guarantee Agreement, and each individually, a "***CR Moveable Guarantee Agreement***".

"***Cure Expiration Date***" has the meaning set forth in **Section 11.04(a)**.

"***Default***" means any Event of Default and any event that, upon the giving of notice, the lapse of time or both, would constitute an Event of Default.

"***Default Rate***" has the meaning set forth in **Section 3.02(b)**.

"***Defaulting Lender***" means, subject to **Section 2.07(b)**, any Lender, as determined by the Administrative Agent, that (a) has failed to perform any of its funding obligations hereunder, including with respect to any Tranche A Commitments, any Tranche B Commitments, any Tranche C Commitments or any Tranche D Commitments, within three (3) Business Days of the date required to be funded by it hereunder, (b) has notified the Borrower or the Administrative Agent that it does not intend to comply with its funding obligations hereunder or (c) has, or has a direct or indirect parent company that has, (i) become the subject of an Insolvency Proceeding, (ii) had a receiver, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or a custodian appointed for it, (iii) taken any action in furtherance of, or indicated its consent to, approval of or acquiescence in any such proceeding or appointment or (iv) become the subject of a Bail-In Action; provided, that, a Lender shall not be a Defaulting Lender solely by virtue of the ownership or acquisition of any Equity Interests in that Lender or any direct or indirect parent company thereof by a Governmental Authority so long as such ownership interest does not result in or provide such Lender with immunity from the jurisdiction of courts within the United States of America or from the enforcement of judgments or writs of attachment on its assets or permit such Lender (or such Governmental Authority) to reject, repudiate, disavow or disaffirm any contracts or agreements made with such Lender. Any determination by the Administrative Agent that a Lender is a Defaulting Lender under any one or more of **clauses (a)** through **(c)** above, and of the effective date of such status, shall be conclusive and binding absent manifest error, and such Lender shall be deemed to be a Defaulting Lender (subject to **Section 2.07(b)**) as of the date established therefor by the Administrative Agent in a written notice of such determination, which shall be delivered by the Administrative Agent to the Borrower and each Lender promptly following such determination.

"***Deferred Acquisition Consideration***" means any purchase price adjustments, royalty, earn-out, milestone payments, contingent or other deferred payments of a similar nature (including any non-compete payments and consulting payments) made in connection with any Permitted Acquisition or other acquisition or investment permitted under this Agreement.

"***Designated Jurisdiction***" means any country or territory to the extent that such country or territory is the subject of country- or territory-wide Sanctions.

"***Disqualified Equity Interests***" means, with respect to any Person, any Equity Interest of such Person that, by its terms (or by the terms of any security or other Equity Interest into which it is convertible or for which it is exchangeable), or upon the happening of any event or condition

(a) matures (excluding any maturity as the result of an optional redemption by the issuer thereof) or is mandatorily redeemable (other than solely for (x) Qualified Equity Interests and (y) cash in lieu of fractional shares), including pursuant to a sinking fund obligation or otherwise, (b) is redeemable at the option of the holder thereof (other than solely for (x) Qualified Equity Interests and (y) cash in lieu of fractional shares), in whole or in part, (c) provides for the scheduled payments of dividends or other distributions in cash (other than the payment of cash in lieu of redemption of fractional shares) or other securities that would constitute Disqualified Equity Interests, or (d) is or becomes convertible into or exchangeable for (unless at the sole option of the issuer thereof) Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is 91 days after the Maturity Date; provided, that, any Disqualified Equity Interests that would not constitute Disqualified Equity Interests but for provisions thereof giving holders thereof (or the holders of any security into or for which such Equity Interests are convertible, exchangeable or exercisable) the right to require the issuer thereof to redeem or repurchase such Equity Interests upon the occurrence of a change in control shall not constitute Disqualified Equity Interests if such Equity Interests provide, to the reasonable satisfaction of the Administrative Agent, that the issuer thereof will not redeem or repurchase any such Equity Interests pursuant to such provisions prior to the payment in full of all Obligations (other than any inchoate indemnification and expense reimbursement obligations for which no claim has been made) under the Loan Documents; provided, further, that, if such Equity Interests are issued pursuant to a plan for the benefit of employees of the Borrower or any Subsidiary or by any such plan to such employees, such Equity Interests shall not constitute Disqualified Equity Interests solely because the Borrower or its Subsidiaries may be required to repurchase such Equity Interests in order to satisfy applicable statutory or regulatory obligations or as a result of such employee's termination, death or disability.

"***Disqualified Lender***" means any Person designated by the Borrower as a "Disqualified Lender" by written notice delivered to the Administrative Agent on or prior to the date of this Agreement. Notwithstanding anything to the contrary contained in this Agreement, (a) the Administrative Agent shall not be responsible or have any liability for, or have any duty to ascertain, inquire into, monitor or enforce, compliance with the provisions hereof relating to Disqualified Lenders and (b) the Borrower, the Guarantors and the Lenders acknowledge and agree that the Administrative Agent shall have no responsibility or obligation to determine whether any Lender or potential Lender is a Disqualified Lender and that the Administrative Agent shall have no liability with respect to any assignment or participation made to a Disqualified Lender.

"***Division***" has the meaning set forth in **Section 1.04**.

"***Dollars***" and "***$***" means lawful money of the United States of America.

"***EEA Financial Institution***" means (a) any credit institution or investment firm established in any EEA Member Country which is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country which is a parent of an institution described in **clause (a)** of this definition, or (c) any financial institution established in an EEA Member Country which is a subsidiary of an institution described in **clauses (a)** or **(b)** of this definition and is subject to consolidated supervision with its parent.

"***EEA Member Country***" means any of the member states of the European Union, Iceland, Liechtenstein, and Norway.

"***EEA Resolution Authority***" means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

"***Employee Benefit Plan***" means any of (a) an "employee benefit plan" (as defined in ERISA) that is subject to Title I of ERISA, (b) a "plan" as defined in and subject to Section 4975 of the Code or (c) any Person whose assets include (for purposes of ERISA Section 3(42) or otherwise for purposes of Title I of ERISA or Section 4975 of the Code) the assets of any such "employee benefit plan" or "plan".

"***Environmental Claims***" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, information request, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (a) pursuant to or in connection with any actual or alleged violation of any Environmental Law; (b) in connection with any Hazardous Material or any actual or alleged Hazardous Materials Activity; or (c) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment, arising out of a violation of Environmental Law or any Hazardous Materials Activity.

"***Environmental Law***" means all laws (including common law and any federal, state, provincial or local governmental law), rule, regulation, order, writ, judgment, notice, requirement, binding agreement, injunction or decree, whether U.S. or non-U.S., relating in any way to (a) environmental matters, including those relating to any Hazardous Materials Activity; (b) the generation, use, storage, transportation or disposal of Hazardous Materials; or (c) to the extent related to Hazardous Materials Activity, occupational safety and health, industrial hygiene, land use, natural resources or the protection of human, plant or animal health or welfare, in any manner applicable to the Borrower or any of its Subsidiaries or any Facility.

"***Environmental Liability***" means any liability, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of any Obligor or any of its Subsidiaries directly or indirectly resulting from or based upon (a) violation of any Environmental Law, (b) the generation, use, handling, transportation, storage, treatment or disposal of any Hazardous Materials, (c) exposure to any Hazardous Materials, (d) the release or threatened release of any Hazardous Materials into the environment or (e) any contract, agreement or other consensual arrangement pursuant to which liability is assumed or imposed with respect to any of the foregoing.

"***Equity Interests***" means, with respect to any Person (for purposes of this defined term, an "***issuer***"), all shares of, interests or participations in, or other equivalents in respect of such issuer's capital stock, including all membership interests, partnership interests or equivalent, or shares of such Person, whether now outstanding or issued after the Closing Date, and in each case, however designated and whether voting or non-voting. Notwithstanding the foregoing, in no event shall any Indebtedness convertible or exchangeable into Equity Interests constitute "Equity Interests" hereunder.

"***Equivalent Amount***" means, with respect to an amount denominated in one currency, the amount in another currency that could be purchased by the amount in the first currency determined by reference to the Exchange Rate at the time of determination.

"***ERISA***" means the United States Employee Retirement Income Security Act of 1974, as amended.

"***ERISA Affiliate***" means, collectively, any Obligor, Subsidiary thereof, and any Person under common control, or treated as a single employer, with any Obligor or Subsidiary thereof, within the meaning of Section 414(b) or (c) of the Code.

"***ERISA Event***" means (a) a reportable event as defined in Section 4043 of ERISA with respect to a Title IV Plan, excluding, however, such events as to which the PBGC by regulation has waived the requirement of Section 4043(a) of ERISA that it be notified within thirty (30) days of the occurrence of such event; (b) the requirements of Section 4043(b) of ERISA are met with respect to a contributing sponsor, as defined in Section 4001(a)(13) of ERISA, of any Title IV Plan where an event described in paragraph (9), (10), (11), (12) or (13) of Section 4043(c) of ERISA is reasonably expected to occur with respect to such plan within the following thirty (30) days; (c) a withdrawal by any Obligor or any ERISA Affiliate thereof from a Title IV Plan with two (2) or more contributing sponsors or the termination of any such Title IV Plan resulting in liability to any Obligor or any ERISA Affiliate thereof under Sections 4063 or 4064 of ERISA; (d) the withdrawal of any Obligor or any ERISA Affiliate thereof in a complete or partial withdrawal (within the meaning of Section 4203 and 4205 of ERISA) from any Multiemployer Plan which results in the imposition of liability on such Obligor or any ERISA Affiliate thereof, or the receipt by any Obligor or any ERISA Affiliate thereof of notice from any Multiemployer Plan that it is insolvent pursuant to Section 4245 of ERISA; (e) the filing of a notice of intent to terminate, the treatment of a plan amendment as a termination under Section 4041 or 4041A of ERISA, or the commencement of proceedings by the PBGC to terminate under Section 4042 of ERISA a Title IV Plan or Multiemployer Plan, but in the case of a multiple-employer plan or a Multiemployer Plan, only once notice has been received from the plan administrator; (f) the imposition of liability on any Obligor or any ERISA Affiliate thereof pursuant to Sections 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA; (g) the failure by any Obligor or any ERISA Affiliate thereof to meet the minimum funding standard of Section 412 of the Code with respect to any Title IV Plan (whether or not waived in accordance with Section 412(c) of the Code) or the failure by any Obligor or any ERISA Affiliate thereof to make by its due date a required installment under Section 430 of the Code with respect to any Title IV Plan or the failure by any Obligor or any ERISA Affiliate thereof to make any required contribution to a Multiemployer Plan; (h) the determination that any Title IV Plan is considered an at-risk plan or that any Multiemployer Plan is in endangered to critical status within the meaning of Sections 430, 431 and 432 of the Code or Sections 303, 304 and 305 of ERISA, but in the case of a multiple-employer plan or a Multiemployer Plan, only once notice has been received from the plan administrator; (i) the occurrence an event or condition which constitutes grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Title IV Plan or Multiemployer Plan; (j) the imposition on any Obligor or any ERISA Affiliate thereof of any liability under Title I or Title IV of ERISA, other than PBGC premiums due but not delinquent under Section 4007 of ERISA, upon any Obligor or any ERISA Affiliate thereof; (k) the filing of application for a funding waiver under Section 303 of ERISA or an extension of any amortization

period pursuant to Section 412 of the Code with respect to any Title IV Plan, but in the case of a multiple-employer plan, only once notice has been received from the plan administrator; (l) any Obligor or any Subsidiary thereof engages in a non-exempt prohibited transaction under Sections 406 or 407 of ERISA with respect to any Benefit Plan; (m) the occurrence of an act or omission which results in the imposition on any Obligor or any ERISA Affiliate thereof of fines, penalties, taxes or related charges under Chapter 43 of the Code or under Sections 409, 502(c), (i) or (1) or 4071 of ERISA; (n) receipt from the IRS of notice of the failure of any Qualified Plan to qualify under Section 401(a) of the Code, or the failure of any trust forming part of any Qualified Plan to fail to qualify for exemption from taxation under Section 501(a) of the Code that is not corrected under the IRS's Employee Plans Compliance Resolution System (EPCRS), but in the case of a multiple-employer plan, only once notice has been received from the plan administrator; or (o) the imposition of any lien on any of the rights, properties or assets of any Obligor or any ERISA Affiliate thereof, in either case pursuant to Title I or IV of ERISA, including Section 302(f) or 303(k) of ERISA or to Section 401(a)(29) or 430(k) of the Code.

"***ERISA Funding Rules***" means the rules regarding minimum required contributions (including any installment payment thereof) to Title IV Plans, as set forth in Sections 412, 430, 431, 432 and 436 of the Code and Sections 302, 303, 304 and 305 of ERISA.

"***Erroneous Payment***" has the meaning assigned to it in **Section 12.14(a)**.

"***Erroneous Payment Deficiency Assignment***" has the meaning assigned to it in **Section 12.14(d)**.

"***Erroneous Payment Return Deficiency***" has the meaning assigned to it in **Section 12.14(d)**.

"***EU Bail-In Legislation Schedule***" means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor Person), as in effect from time to time.

"***EU Insolvency Regulation***" means Regulation (EU) 2015/848 of 20 May 2015 on insolvency proceedings (recast).

"***Event of Default***" has the meaning set forth in **Section 11.01**.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"***Exchange Rate***" means, as of any date, the rate at which any currency may be exchanged into another currency, as set forth on the relevant Bloomberg screen at or about 11:00 a.m. (Eastern time) on such date. In the event that such rate does not appear on the Bloomberg screen, the "Exchange Rate" shall be determined by reference to such other publicly available service for displaying exchange rates as may be reasonably designated by the Administrative Agent.

"***Excluded Accounts***" means (a) deposit accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Obligor's employees, (b) zero balance accounts swept no less frequently than weekly to a Controlled Account, (c) accounts (including trust accounts) used exclusively for bona fide escrow purposes,

insurance or fiduciary purposes, (d) cash collateral for Permitted Liens and (e) any other deposit accounts only for so long as, in the case of this **clause (e)**, the amounts of deposit therein do not exceed $1,000,000 in the aggregate.

"***Excluded Taxes***" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient: (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes and branch profits Taxes, in each case, (x) imposed as a result of such Recipient being organized under the Laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivisions thereof) or (y) that are Other Connection Taxes, (b) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Commitment pursuant to a law in effect on the date on which (1) such Lender acquires such interest in the Loan or Commitment or (2) such Lender changes its lending office (in either case, other than pursuant to an assignment request by the Borrower under **Section 5.04)**, except in each case to the extent that, pursuant to **Section 5.03**, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (c) Taxes attributable to such Recipient's failure to comply with **Section 5.03(f)**, ~~and (d)~~ (d) any Taxes that are imposed in France on amounts paid by an Obligor if such Taxes are imposed solely because this payment is made either to (i) a Recipient incorporated, domiciled, established or acting through a lending office situated in a Non-Cooperative Jurisdiction or to (ii) an account opened in the name of or for the benefit of a Recipient in a financial institution situated in a Non-Cooperative Jurisdiction, (e) any Bank Levies, and (f) any withholding Taxes imposed under FATCA.

"***Existing Indebtedness***" means the Indebtedness in the aggregate principal amount of $65,000,000 incurred pursuant to that certain Credit Agreement, dated as of August 24, 2017, by and among the Borrower, the guarantors party thereto, the lenders party thereto and Madryn Health Partners, LP, as administrative agent (as amended by that certain First Amendment to Credit Agreement dated as of October 31, 2017, as further amended by that certain Second Amendment to Credit Agreement and Waiver dated as of June 15, 2018, as further amended by that certain Third Amendment to Credit Agreement and Waiver dated as of June 17, 2019, as further amended by that certain Fourth Amendment to Credit Agreement dated as of August 5, 2020, and as further amended, restated, supplemented, or modified prior to the date hereof).

"***Exit Fee***" has the meaning assigned to such term in **Section 3.05**.

"***Facility***" means any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased or operated by any Obligor or any of its Subsidiaries.

"***FATCA***" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

"***FD&C Act***" means the U.S. Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (or any successor thereto), as amended from time to time, and the rules and regulations issued or promulgated thereunder.

"***FDA***" means the U.S. Food and Drug Administration and any successor thereto.

"***Federal Funds Effective Rate***" means, for any day, the rate calculated by the Federal Reserve Bank of New York based on such day's federal funds transactions by depositary institutions (as determined in such manner as the Federal Reserve Bank of New York shall set forth on its public website from time to time) and published on the next succeeding Business Day by the Federal Reserve Bank of New York as the federal funds effective rate; provided, that (a) if such day is not a Business Day, the Federal Funds Effective Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day, and (b) if no such rate is so published on such next succeeding Business Day, the Federal Funds Effective Rate for such day shall be the average rate charged to three (3) major banks on such day on such transactions as determined by the Administrative Agent; provided, further, that if the Federal Funds Effective Rate as so determined would be less than zero, such rate shall be deemed to be zero for the purposes of this Agreement.

"***Fee Letter***" means the Fee Letter, dated the date of this Agreement, among the Borrower, the Lenders and the Administrative Agent.

"***Fiduciary Assignment of Receivables***" means one of the Brazilian Securities to be granted by the Brazilian Guarantor by means of a fiduciary assignment of receivables as further described in the Fiduciary Assignment of Receivables Agreement.

"***Fiduciary Assignment of Receivables Agreement***" means the "Fiduciary Assignment of Receivables Agreement" to be entered into by and between the Brazilian Guarantor and the Administrative Agent, in which the Brazilian Guarantor will grant the Fiduciary Assignment of Receivables in favor of the Administrative Agent, for the benefit of the Secured Parties.

"***Fiduciary Transfer of Quotas***" means one of the Brazilian Securities to be granted by European Distribution Center Motiva BV by means of a fiduciary transfer of quotas of the Brazilian Guarantor as further described in the Fiduciary Transfer of Quotas Agreement.

"***Fiduciary Transfer of Quotas Agreement***" means the "Fiduciary Transfer of Quotas Agreement" to be entered into by and among European Distribution Center Motiva BV, the Brazilian Guarantor and the Administrative Agent, in which European Distribution Center Motiva BV will grant the Fiduciary Transfer of Quotas in favor of the Administrative Agent, for the benefit of the Secured Parties.

"***Foreign Lender***" means a Lender that is not a U.S. Person.

"***Foreign Plan***" means any employee pension benefit plan, program, policy, arrangement or agreement maintained or contributed to by any Obligor or any Subsidiary thereof primarily for the benefit of employees employed outside the United States (other than any governmental arrangement).

"***French Material Subsidiary***" means Motiva Implants France, a French *société par actions simplifiée*, having its registered office at 143 rue Abel Sarnette, 84300 Cavaillon, France, and registered with the Trade and Companies Registry of Avignon under number 803 117 605.

"***French Guarantor***" means a Guarantor incorporated under the laws of France.

"***French Security Documents***" means the securities account pledge agreement to be entered into between the Administrative Agent, as security agent (*agent des sûretés*), and the Borrower, as pledgor (*constituant*), with respect to the financial securities issued by the French Material Subsidiary and related cash proceeds, as well as all the statements, certificates and other documents required to perfect such pledge.

"***Funding Date Certificate***" means a certificate substantially in the form of **Exhibit C**.

"***GAAP***" means generally accepted accounting principles in the United States of America, as in effect from time to time, set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, in the statements and pronouncements of the Financial Accounting Standards Board and in such other statements by such other entity as may be in general use by significant segments of the accounting profession that are applicable to the circumstances as of the date of determination. All references to "GAAP" shall be to GAAP applied consistently with the principles used in the preparation of the financial statements delivered pursuant to **Section 6.01(f)**.

"***German Guarantor***" means any Guarantor incorporated and established under the laws of the Federal Republic of Germany.

"***Governmental Approval***" means any consent, authorization, approval, order, license, franchise, permit, certification, accreditation, registration, clearance or exemption that is issued or granted by or from (or pursuant to any act of) any Governmental Authority, including any application or submission related to any of the foregoing.

"***Governmental Authority***" means any nation, government, branch of power (whether executive, legislative or judicial), state, province or municipality or other political subdivision thereof and any entity exercising executive, legislative, judicial, monetary, regulatory or administrative functions of or pertaining to government, including without limitation regulatory authorities, governmental departments, agencies, commissions, bureaus, courts, bodies, and other law-, rule- or regulation-making organizations or entities of any state, territory, county, city or other political subdivision of any country, in each case whether U.S. or non-U.S.

"***Gross Sales***" means, for any relevant fiscal period, the consolidated gross sales in arm's length sales by the Borrower and its Subsidiaries or their respective licensees, sublicensees, assignees, transferees or other commercial partners to independent, unrelated third parties for such fiscal period, calculated in accordance with the Borrower's accounting policies, practices and methodologies on a consistent basis as applied in the Borrower's audited consolidated financial statements for the year ended December 31, 2021 provided to the Administrative Agent prior to the Closing Date.

"***Gross Sales Cure Payment***" means, with respect to any fiscal quarter of the Borrower to which **Section 10.02** applies, the greater of (a) the Gross Sales Shortfall Amount and (b) $1,000,000.

"***Gross Sales Shortfall Amount***" means, with respect to any fiscal quarter of the Borrower to which **Section 10.02** applies, the amount between (a) the Gross Sales for such fiscal quarter and (b) the Target Gross Sales for such fiscal quarter.

"***Guarantee***" of or by any Person (the "***guarantor***") means any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation (the "***primary obligations***") of any other Person (the "***primary obligor***") in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (a) to purchase or pay (or advance or supply funds for the purchase or payment of) such primary obligations or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (b) to purchase or lease property, securities or services for the purpose of assuring the owner of such primary obligations of the payment thereof, (c) to maintain working capital, equity capital or any other financial statement condition or liquidity of the primary obligor so as to enable the primary obligor to pay such primary obligations or (d) as an account party in respect of any letter of credit or letter of guaranty (including any bank guarantee) issued to support such primary obligations; provided, that the term Guarantee shall not include (x) endorsements for collection or deposit and (y) guarantees of operating leases, in each case, in the Ordinary Course. The amount of any Guarantee of any guarantor shall be deemed to be equal to the stated or determinable amount of the primary obligation in respect of which such Guarantee is made unless pursuant to the terms of the instrument embodying such Guarantee, the amount of such Guarantee shall be limited under such instrument or applicable Law, in which case the amount of such Guarantee shall be equal to the maximum amount as permitted by such instrument or applicable Law.

"***Guarantee Assumption Agreement***" means a Guarantee Assumption Agreement substantially in the form of **Exhibit D** by an entity that, pursuant to **Section 8.11(a)**, is required to become a "Subsidiary Guarantor."

"***Guaranteed Obligations***" has the meaning set forth in **Section 13.01**.

"***Guarantor***" has the meaning set forth in the preamble hereto and includes each Subsidiary Guarantor.

"***Guarantor Payment***" has the meaning set forth in **Section 13.10(a)**.

"***Guaranty***" means the Guaranty made by the Guarantors under **Section 13** in favor of the Secured Parties (including any Guaranty assumed by an entity that is required to become a "Subsidiary Guarantor" pursuant to a Guarantee Assumption Agreement).

"***Hazardous Material***" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or would reasonably be expected to pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"***Hazardous Materials Activity***" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, release, threatened release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, recycling, disposition or handling of any Hazardous Materials, and any investigation, monitoring, corrective action or response action with respect to any of the foregoing.

"***Healthcare Laws***" means, collectively, all Laws applicable to the business, any Product or the Product Commercialization and Development Activities of any Obligor, whether U.S., Costa Rican, BVI, Belgian, Brazilian, or of any other jurisdiction, regulating the distribution, dispensing, importation, exportation, quality, manufacturing, marketing, labeling, promotion and provision of and payment for drugs, or healthcare products, items and services, including, without limitation, the FD&C Act, the Federal Anti-Kickback Statute, the federal False Claims Act, and all rules and regulations with respect to the coverage of prescription drugs pursuant to the Medicare and Medicaid programs, the TRICARE Program, and federal employee health benefit plans; and all rules and regulations promulgated under or pursuant to any of the foregoing, including any state and non-U.S. equivalents.

"***Hedging Agreement***" means any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement or other interest or currency exchange rate or commodity price hedging arrangement.

"***IFRS***" means international financial reporting standards, as adopted by the European Union, and with respect to any Obligor organized under the Laws of the United Kingdom, as generally accepted in the United Kingdom.

"***Immaterial Subsidiary***" means any Subsidiary of the Borrower that (a) individually constitutes or holds less than five percent (5%) of the Borrower's consolidated total assets and generates less than five percent (5%) of the Borrower's consolidated total revenue and (b) when taken together with all then existing Immaterial Subsidiaries, such Subsidiary and such Immaterial Subsidiaries, in the aggregate, would constitute or hold less than five percent (5%) of the Borrower's consolidated total assets and generate less than five percent (5%) of the Borrower's consolidated total revenue, in each case of the foregoing clauses as of the last day of, or for, the most recently ended fiscal period for which financial statements were required to have been delivered pursuant to **8.01(a)** or **(b)**; provided that no Subsidiary of the Borrower shall be an Immaterial Subsidiary if such Subsidiary holds Material Intellectual Property (other than, for the avoidance of doubt, foreign Product Authorizations).

"***IND***" means an investigational new drug application submitted to the FDA pursuant to 21 C.F.R. § 312 requesting allowance to proceed clinical trials in human subjects, including all supplements or amendments thereto.

"***Indebtedness***" of any Person means, without duplication, (a) all obligations of such Person for borrowed money, (b) all obligations of such Person evidenced by bonds, debentures, notes, loan agreements or similar instruments, (c) all obligations of such Person upon which interest charges are customarily paid (excluding interest penalties for late payments under commercial contracts entered into in the Ordinary Course and, for the avoidance of doubt, which

commercial contracts do not relate to obligations for borrowed money or purchase money indebtedness), (d) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (e) all obligations of such Person in respect of the deferred purchase price of property or services (excluding (A) any royalty payments or similar payments based on a percentage of sales under any such license or other agreement and (B) deferred compensation and accounts payable incurred in the Ordinary Course and not overdue by more than forty-five (45) days or otherwise being disputed in good faith), (f) all Indebtedness of others secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person, whether or not the Indebtedness secured thereby has been assumed, (g) all Guarantees by such Person of Indebtedness of others, (h) all Capital Lease Obligations of such Person, (i) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (j) obligations under any Hedging Agreement, currency swaps, forwards, futures or derivatives transactions, (k) all obligations, contingent or otherwise, of such Person in respect of bankers' acceptances, (l) all milestone or similar payments of such Person under any license or other agreements (but excluding any such payments based on a percentage of sales or revenues under any such license or other agreement), (m) any Disqualified Equity Interests of such Person and (n) all other obligations required to be classified as indebtedness of such Person under GAAP or IFRS, as applicable. The Indebtedness of any Person shall include the Indebtedness of any other entity (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such entity, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor.

"***Indemnified Party***" has the meaning set forth in **Section 14.03(b)**.

"***Indemnified Taxes***" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any Obligation and (b) to the extent not otherwise described in **clause (a)**, Other Taxes.

"***Insolvency Proceeding***" means (a) any case, action or proceeding before any court or other Governmental Authority relating to bankruptcy, reorganization, insolvency, administration, re-arrangement, moratorium, liquidation, receivership, examinership, dissolution, winding-up or relief of debtors, or (b) any general assignment for the benefit of creditors, composition, marshaling of assets for creditors, or other, similar arrangement in respect of any Person's creditors generally or any substantial portion of such Person's creditors, in each case undertaken under U.S. federal or state, or other foreign law, including the Bankruptcy Code.

"***Intellectual Property***" means all intellectual property or proprietary rights anywhere in the world, including all rights in or to Patents, Trademarks, Copyrights, and Technical Information.

"***Intercompany Subordination Agreement***" means a subordination agreement to be executed and delivered by each Obligor and each of its Subsidiaries, pursuant to which all obligations in respect of any Indebtedness owing to any such Person by an Obligor shall be subordinated to the prior payment in full in cash of all Obligations on the terms set forth therein, such agreement to be in substantially the form attached hereto as **Exhibit E**.

"***Interest Rate***" means (a) 9.00% per annum or (b) at any time following the occurrence of the Tranche D Funding Milestone, 8.25% per annum, in each case, as may be increased pursuant to **Section 3.02(b)**.

"***Invention***" means any novel, inventive and useful art, apparatus, method, process, machine (including any article or device), manufacture or composition of matter, or any novel, inventive and useful improvement in any art, method, process, machine (including article or device), manufacture or composition of matter.

"***Investment***" means, for any Person: (a) the acquisition (whether for cash, property, services or securities or otherwise) of any debt or Equity Interests, bonds, notes, debentures, partnership or other ownership interests or other securities of any other Person (including any "short sale" or any sale of any securities at a time when such securities are not owned by the Person entering into such sale); (b) the making of any deposit with, or advance, loan, assumption of debt or other extension of credit to, or capital contribution in any other Person (including the purchase of property from another Person subject to an understanding or agreement, contingent or otherwise, to resell such property to such Person), but excluding any such advance, loan or extension of credit having a term not exceeding ninety (90) days arising in connection with the sale of inventory or supplies by such Person in the Ordinary Course; or (c) the entering into of any Guarantee of, or other contingent obligation with respect to, Indebtedness or other liability of any other Person and (without duplication) any amount committed to be advanced, lent or extended to such Person. The amount of an Investment shall be the amount actually invested (which, in the case of any Investment constituting the contribution of an asset or property, shall be based on such Person's good faith estimate of the fair market value of such asset or property at the time such Investment is made), less the amount of cash received or returned for such Investment, without adjustment for subsequent increases or decreases in the value of such Investment or write-ups, write-downs or write-offs with respect thereto; provided that in no event shall such amount be less than zero or increase any basket or amount pursuant to **Section 9.05** above the fixed amount set forth therein.

"***IRS***" means the U.S. Internal Revenue Service or any successor agency, and to the extent relevant, the U.S. Department of the Treasury.

"***Italian Banking Law***" means Legislative Decree 1 September 1993, No. 385 ("*Testo unico delle leggi in materia bancaria e creditizia*") and the relevant implementing regulations, each as amended, integrated and supplemented from time to time.

"***Italian Civil Code***" means the Italian *codice civile*, enacted by royal decree no. 262 of 16 March 1942, as subsequently amended and supplemented from time to time.

"***Joint Product Development Agreement***" means that certain Joint Product Development Agreement, dated as of January 10, 2013, by and between Dr. Federico Mayo and Establishment Labs S.A., as amended by that certain Addendum One to Joint Product Development Agreement, dated as of August 16, 2017.

"***Joint Venture***" means a joint venture, partnership or other similar arrangement, in corporate, partnership or similar legal form with a Person other than the Borrower or its Subsidiaries.

"***Landlord Consent***" means, with respect to locations in the United States, a Landlord Consent substantially in the form of **Exhibit F** (or such other form as is acceptable to the Administrative Agent), or with respect to locations in and outside of the United States, a landlord consent or similar document in form and substance reasonably satisfactory to the Administrative Agent.

"***Law***" means, collectively, all U.S. and non-U.S. federal, state, provincial, territorial, municipal or local statutes, treaties, rules, regulations, ordinances, codes or administrative or judicial precedents or authorities, including any interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority.

"***Legal Reservations***" means (a) the principle that equitable remedies may be granted or refused at the discretion of a court and the limitation of enforcement by Laws relating to insolvency, reorganization and other laws generally affecting the right of creditors; (b) similar principles, rights and defenses under the laws of any relevant jurisdiction of organization of any Obligor; and (c) the fact that the courts of Brazil would solely recognize as valid, and enforceable against a Brazilian entity, without reconsideration of the merits thereof, any final and conclusive civil judgment rendered by a competent foreign court, if such judgment is previously confirmed by the Superior Court of Justice (*Superior Tribunal de Justiça*) of Brazil, such confirmation only occurring if such judgment: (1) complies with all formalities required for the enforcement thereof under the Laws of the jurisdiction wherein it was issued; (2) is issued by a competent court in such jurisdiction after valid service of process upon the parties to the action (such service to have been made under the authority of a court or the clerk of a court), or after sufficient evidence of the relevant defendant's absence (*revelia*) has been given in accordance with the applicable Laws of such jurisdiction; (3) is final and not subject to appeal in the jurisdiction in which was issued; (4) is rendered for the payment of a sum that is certain; (5) is duly authenticated by the competent consular official of Brazil in the jurisdiction wherein it was issued or is duly apostilled in accordance with the Convention Abolishing the Requirement of Legalisation for Foreign Public Documents dated as of October 5, 1961, pursuant to Decree No. 8,660 dated as of January 29, 2016, and is accompanied by a translation thereof into the Portuguese language prepared by a sworn translator, except if such procedure has been exempted by an international treaty entered into by Brazil; (6) is not against public policy (*ordem pública*), national sovereignty (*soberania nacional*) or good morals (*bons costumes*) of Brazil, pursuant to Article 17 of Decree-Law No. 4,657, as of September 4, 1942 (Law of Introduction to Brazilian Law); (7) does not violate a final and unappealable decision "res judicata" issued by a Brazilian court; and (8) does not violate the jurisdiction of the Brazilian judiciary authority.

"***Lenders***" has the meaning set forth in the preamble hereto.

"***Lien***" means (a) any mortgage, lien, license, pledge, hypothecation, charge, security interest, fiduciary assignment (*cessão fiduciária*) or other encumbrance of any kind or character whatsoever, whether or not filed, recorded or otherwise perfected under applicable Law, or any lease, title retention agreement, mortgage, restriction, easement, right-of-way, option or adverse claim (of ownership or possession) (including any conditional sale or other title retention agreement, any lease in the nature thereof, and any other encumbrance on title to real property,

any option or other agreement to sell, or give a security interest in, such asset and any filing of or agreement to give any financing statement under the Uniform Commercial Code (or equivalent statutes of any jurisdiction)) or any preferential arrangement that has the practical effect of creating a security interest and (b) in the case of Equity Interests, any purchase option, call or similar right of a third party with respect to such Equity Interests.

"***Loan***" means each loan advanced by a Lender pursuant to **Section 2.01**.

"***Loan Documents***" means, collectively, this Agreement, the Notes, the Costa Rican Notes, the Security Documents, the Fee Letter, any Guarantee Assumption Agreement, the Intercompany Subordination Agreement and any subordination agreement, intercreditor agreement or other present or future document, instrument, agreement or certificate delivered to the Administrative Agent (for itself or for the benefit of any other Secured Party) in connection with this Agreement or any of the other Loan Documents, in each case, as amended or otherwise modified.

"***Loans Schedule***" means **Schedule 1** attached hereto.

"***Loss***" means judgments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel on a full indemnity basis, and all costs incurred in investigating or pursuing any Claim or any proceeding relating to any Claim.

"***Majority Lenders***" means, at any time, Lenders having at such time in excess of fifty percent (50%) of the aggregate (x) unused Commitments then in effect and (y) outstanding principal amount of the Loans at such time; provided that "Majority Lenders" shall include Oaktree Capital Management, L.P. so long as Oaktree Capital Management, L.P. together with its Affiliates' managed funds or accounts hold in the aggregate at least twenty percent (20%) of the aggregate (x) unused Commitments then in effect and (y) outstanding principal amount of the Loans at such time. The Commitments of any Defaulting Lender shall be disregarded in determining Majority Lenders at any time.

"***Mandatory Prepayment***" has the meaning set forth in **Section 3.03(b)(i)**.

"***Margin Stock***" means "margin stock" within the meaning of Regulations U and X.

"***Material Adverse Change***" and "***Material Adverse Effect***" mean a material adverse change in or effect on (a) the business, financial performance, operations, financial condition, assets or liabilities of the Borrower and its Subsidiaries taken as a whole, (b) the ability of the Obligors, taken as a whole, to perform their payment obligations under the Loan Documents, as and when due, (c) the legality, validity, binding effect or enforceability of any Loan Document or (d) the rights, remedies and benefits available to, or conferred upon, the Administrative Agent or the Secured Parties under any Loan Document.

"***Material Agreement***" means any Contract (i) to the extent that the absence or termination of such Contract would reasonably be expected to result in a Material Adverse Effect or (ii) that constitutes or generates more than ten percent (10%) of the Borrower's and its Subsidiaries'

consolidated total revenue in the immediately preceding fiscal year. Without limiting the foregoing, Material Agreements includes the Joint Product Development Agreement.

"***Material Environmental Liability***" means any Environmental Liability that has had or could reasonably be expected to have a Material Adverse Effect.

"***Material Indebtedness***" means, at any time, any Indebtedness of any Obligor or Subsidiary thereof, the outstanding principal amount of which, individually or in the aggregate, exceeds $5,000,000 (or the Equivalent Amount in other currencies).

"***Material Intellectual Property***" means all Intellectual Property, whether currently owned by (or purported to be owned by), or subject to a license, covenant not to sue or similar right or immunity to (or purported to be subject to a license, covenant not to sue or similar right or immunity to) the Borrower or any of its Subsidiaries, or acquired, developed, obtained by, or otherwise subject to a license, covenant not to sue or similar right or immunity to the Borrower or any of its Subsidiaries after the date hereof that is, in each case, material to the current business of the Borrower or any of its Subsidiaries or that the loss of which could reasonably be expected to result in (i) a Material Adverse Effect or (ii) a material adverse effect on any Product Commercialization and Development Activities. For the avoidance of doubt, Material Intellectual Property includes all Intellectual Property in and to the Motiva Implants and/or the Products (including Product Commercialization and Development Activities).

"***Material Product Authorizations***" means any and all Product Authorizations, in each case, necessary to be held or maintained by, or for the benefit of, any Obligor or any of its Subsidiaries for any Product Commercialization and Development Activities, the failure of which to hold or maintain could reasonably be expect to have a Material Adverse Effect.

"***Material Real Property***" shall mean any real property owned in fee by the Borrower or any other Obligor (or owned by any person required to become an Obligor hereunder) (x) listed on **Schedule 5** hereto or (y) (a) with a fair market value in excess of $5,000,000 and (b) not located in an area determined by the U.S. Federal Emergency Management Agency (or any successor agency) to be located in a special flood hazard area.

"***Material Software***" has the meaning set forth in **Section 7.05(b)(ii)(G)**.

"***Material Subsidiary***" means any Subsidiary of the Borrower that is not an Immaterial Subsidiary.

"***Maturity Date***" means April 26, 2027; provided that if any such date is not a Business Day, then the Maturity Date shall be on the immediately preceding Business Day.

"***Maximum Rate***" has the meaning set forth in **Section 14.17**.

"***Medicaid***" means that government-sponsored entitlement program under Title XIX, P.L. 89-97 of the Social Security Act, which provides federal grants to states for medical assistance based on specific eligibility criteria, as set forth on Section 1396, et seq. of Title 42 of the United States Code.

"***Medicare***" means that government-sponsored insurance program under Title XVIII, P.L. 89-97, of the Social Security Act, which provides for a health insurance system for eligible elderly and disabled individuals, as set forth at Section 1395, et seq. of Title 42 of the United States Code.

"***Minimum Gross Sales Covenant***" has the meaning set forth in **Section 10.02**.

"***Minimum Gross Sales Covenant Termination Date***" means the date (which date shall be the last day of a calendar month) on which the Gross Sales of the Borrower and its Subsidiaries for the twelve (12) consecutive month period ending on such date are no less than $200,000,000.

"***Minimum Gross Sales Cure Right***" has the meaning set forth in **Section 11.04(a)**.

"***Minimum Liquidity Amount***" means (a) from the Closing Date until the Applicable Funding Date of the Tranche B Term Loans, $20,000,000 and (b) from the Applicable Funding Date of the Tranche B Term Loans, $25,000,000.

"***Mortgage***" means each mortgage, deed of trust and similar agreement or instrument creating a Lien on Material Real Property made by any Obligor in favor of, or for the benefit of, the Administrative Agent for the benefit of the Secured Parties, in form and substance reasonably satisfactory to the Administrative Agent and the Borrower and containing such provisions as shall be advisable under the law of the jurisdiction in which such mortgage or deed of trust is to be recorded, as the same may be amended, amended and restated, supplemented or otherwise modified from time to time.

"***Motiva Implants***" means the silicone gel-filled breast implants branded as Motiva Implants and produced by the Borrower and its Subsidiaries.

"***Multiemployer Plan***" means any multiemployer plan, as defined in Section 400l(a)(3) of ERISA, to which any ERISA Affiliate has any obligation or liability, contingent or otherwise.

"***NDA***" means a new drug application submitted to the FDA pursuant to 21 U.S.C. § 355(b) for authorization to market a drug in the United States, and all supplements or amendments thereto.

"***Net Cash Proceeds***" means, (a) with respect to any Casualty Event experienced or suffered by any Obligor or any of its Subsidiaries, the amount of cash proceeds (other than the cash proceeds of any business interruption insurance) received from time to time by or on behalf of such Person in respect thereof after deducting therefrom only (w) reasonable costs and expenses related thereto incurred by such Obligor or such Subsidiary in connection therewith, (x) Taxes (including transfer Taxes or net income Taxes) paid or payable in connection therewith, (y) reasonable reserves established for liabilities estimated to be payable in respect of such Casualty Event and deposited into escrow with a third party escrow agent on terms reasonably acceptable to the Administrative Agent or set aside in a separate deposit account that is subject to a control agreement in favor of the Administrative Agent and (z) any amounts required to be used to prepay Permitted Indebtedness pursuant to **Sections 9.01(b), 9.01(i), 9.01(k), and 9.01(l)** secured by the assets subject to such Casualty Event (other than (A) Indebtedness owing to the Administrative Agent or any Lender under this Agreement or the other Loan Documents and (B) Indebtedness assumed by the purchaser of such asset); and (b) with respect to any Asset Sale by any Obligor or any of its Subsidiaries, the amount of cash proceeds received from time to time by or on behalf of

such Person in respect thereof after deducting therefrom only (w) reasonable costs and expenses related thereto incurred by such Obligor or such Subsidiary in connection therewith, (x) Taxes (including transfer Taxes or net income Taxes) paid or payable in connection therewith, (y) reasonable reserves established for liabilities estimated to be payable in respect of such Asset Sale and deposited into escrow with a third party escrow agent on terms reasonably acceptable to the Administrative Agent or set aside in a separate deposit account that is subject to a control agreement in favor of the Administrative Agent and (z) any amounts required to be used to prepay Permitted Indebtedness pursuant to **Sections 9.01(b), 9.01(i), 9.01(k) and 9.01(l)** secured by the assets subject to such Asset Sale (other than (A) Indebtedness owing to the Administrative Agent or any Lender under this Agreement or the other Loan Documents and (B) Indebtedness assumed by the purchaser of such asset); provided that, in each case of **clauses (i)** and **(ii)**, costs and expenses shall only be deducted to the extent, that the amounts so deducted are (x) actually paid or payable to a Person that is not an Affiliate of any Obligor or any of its Subsidiaries and (y) properly attributable to such Casualty Event or Asset Sale, as the case may be; it being understood that "Net Cash Proceeds" shall include, without limitation, any cash received upon the sale or other disposition and any non-cash consideration received by any Obligor in any Casualty Event or Asset Sale.

"***Non-Cooperative Jurisdiction***" means a non-cooperative state or territory (*État ou territoire non coopératif*) as set out in the lists referred to in Article 238-0 A of the French Tax Code, as such lists may be amended from time to time.

"***Note***" means a promissory note, in substantially the form of **Exhibit G** hereto, executed and delivered by the Borrower to any Lender in accordance with **Section 2.04**.

"***Notice of Intent to Cure Gross Sales Covenant***" has the meaning set forth in **Section 11.04(b)**.

"***NY UCC***" means the UCC as in effect from time to time in the State of New York.

"***Obligations***" means, with respect to any Obligor, all amounts, obligations and liabilities of every type and description owing by such Obligor to any Secured Party (including all Guaranteed Obligations) or any other indemnitee hereunder or any participant, arising out of, under, or in connection with, any Loan Document, whether direct or indirect (regardless of whether acquired by assignment), absolute or contingent, due or to become due, whether liquidated or not, now existing or hereafter arising and however acquired, and whether or not evidenced by any instrument or for the payment of money, including, without duplication, (a) if such Obligor is the Borrower, all Loans, (b) all interest, whether or not accruing after the filing of any petition in bankruptcy or after the commencement of any insolvency, reorganization or similar proceeding, and whether or not a claim for post-filing or post-petition interest is allowed in any such proceeding, and (c) all other fees, expenses (including fees, charges and disbursement of counsel), Yield Protection Premium, Exit Fee, commissions, charges, costs, disbursements, indemnities and reimbursement of amounts paid and other sums chargeable to such Obligor under any Loan Document.

"***Obligors***" means, collectively, the Borrower and the Subsidiary Guarantors and their respective successors and permitted assigns.

"***OFAC***" has the meaning assigned to such term in the definition of "Anti-Terrorism Laws".

"***Ordinary Course***" means ordinary course of business or ordinary trade activities that are customary for similar businesses in the normal course of their ordinary operations and not while in financial distress.

"***Organic Document***" means, for any Person, such Person's formation documents, including, as applicable, its certificate of incorporation, by-laws, certificate of partnership, partnership agreement, certificate of formation, constitution, memorandum and articles of association, limited liability agreement, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to such Person's Equity Interests, in relation to a German Guarantor, its articles of association (*Satzung*) or partnership agreement (as applicable), or any equivalent document of any of the foregoing.

"***Other Connection Taxes***" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

"***Other Taxes***" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment (other than an assignment made pursuant to **Section 5.04**).

"***Participant***" has the meaning set forth in **Section 14.05(e)**.

"***Participant Register***" has the meaning set forth in **Section 14.05(e)**.

"***Patents***" means all patents and patent applications, including the Inventions and improvements described and claimed therein, the reissues, divisionals, continuations, renewals, extensions, and continuations in part thereof, and all rights whatsoever accruing thereunder or pertaining to the foregoing throughout the world.

"***Patriot Act***" has the meaning set forth in **Section 14.19**.

"***Payment Date***" means (a) the last Business Day of each March, June, September and December of each year, commencing on the first such date to occur after the Closing Date and (b) the Maturity Date.

"***Payment Recipient***" has the meaning assigned to it in **Section 12.14(a)**.

"***PBGC***" means the United States Pension Benefit Guaranty Corporation referred to and defined in ERISA and any successor entity performing similar functions.

"***Perfection Certificate***" means the Collateral, Perfection and Information Certificate, delivered pursuant to **Section 6.01(d)** to the Administrative Agent, as amended, restated, supplemented or otherwise modified from time to time.

"***Permitted Acquisition***" means any Acquisition by the Borrower or any of its Subsidiaries, whether by purchase, merger or otherwise; provided that:

(a) immediately prior to, and immediately after giving effect thereto, no Default or Event of Default shall have occurred and be continuing or could reasonably be expected to result therefrom;

(b) such Acquisition shall comply in all material respects with all applicable Laws and all applicable Governmental Approvals;

(c) in the case of any Acquisition of Equity Interests of another Person, after giving effect to such Acquisition, all Equity Interests of such other Person acquired (other than any Equity Interests in the nature of directors' qualifying shares required pursuant to applicable Law) shall be owned, directly or indirectly, beneficially and of record, by the Borrower or any of its Subsidiaries, and, the Borrower shall cause such acquired Person to satisfy each of the actions set forth in **Section 8.11** if and when required by such Section;

(d) on a Pro Forma Basis after giving effect to such Acquisition, the Borrower and its Subsidiaries shall be in compliance with the financial covenants set forth in **Section 10**;

(e) to the extent that all or any portion of the purchase price (including reasonable estimates of any Deferred Acquisition Consideration) for any such Acquisition is paid in cash on hand, the amount thereof shall not exceed $30,000,000 (or the Equivalent Amount in other currencies) (excluding (i) any proceeds of the issuance of new Qualified Equity Interests by Borrower and (ii) any proceeds of Indebtedness permitted to be incurred for such Acquisition pursuant to **Section 9.01**), in the aggregate with any other such Acquisitions in any fiscal year (or such greater amount as the Administrative Agent may agree in writing in its sole discretion);

(f) to the extent that all or any portion of the purchase price for any such Acquisition is paid in Equity Interests, all such Equity Interests shall be Qualified Equity Interests;

(g) in the case of any such Acquisition that has a purchase price (including reasonable estimates of any Deferred Acquisition Consideration) in excess of $15,000,000, (A) the Borrower shall provide to the Administrative Agent (i) at least ten (10) Business Days' (or such shorter period as agreed to by the Administrative Agent in its sole discretion) prior written notice of any such Acquisition, together with summaries, prepared in reasonable detail, of all due diligence conducted by or on behalf of the Borrower or the applicable Subsidiary, as applicable, prior to such Acquisition, in each case subject to customary confidentiality restrictions, (ii) subject to customary confidentiality restrictions, a copy of the draft purchase agreement related to the proposed Acquisition (and any related documents reasonably requested by the Administrative Agent), (iii) pro forma financial

statements of the Borrower and its Subsidiaries (as of the last day of the most recently ended fiscal quarter prior to the date of consummation of such Acquisition for which financial statements are required to be delivered pursuant to **8.01(a)** or **(b)**) after giving effect to such Acquisition and (iv) subject to customary confidentiality restrictions, any other information reasonably requested (to the extent available), by the Administrative Agent and available to the Obligors and (B) to the extent the cash purchase price exceeds $30,000,000 (excluding (i) any proceeds of the issuance of new Qualified Equity Interests by Borrower and (ii) any proceeds of Indebtedness permitted to be incurred for such Acquisition pursuant to **Section 9.01**) (including reasonable estimates of any Deferred Acquisition Consideration), the Administrative Agent shall have consented in writing to such Acquisition in its sole discretion (such consent not to be unreasonably withheld or delayed); and

(h) no Obligor or any of its Subsidiaries (including any acquired Person) shall, in connection with any such Acquisition, assume or remain liable with respect to (x) any Indebtedness of the related seller or the business, Person or assets acquired, except to the extent permitted pursuant to **Section 9.01(i)** or **Section 9.01(k)**, (y) any Lien on any business, Person or assets acquired, except to the extent permitted pursuant to **Section 9.02**, (z) any other liabilities that are not Indebtedness (including Tax, ERISA and environmental liabilities) and that are not otherwise prohibited under this Agreement, except to the extent the assumption of such liabilities could not reasonably be expected to result in a Material Adverse Effect, provided that if such assumed liabilities exceed $20,000,000 in the aggregate, the Administrative Agent shall have consented in writing to such Acquisition in its sole discretion (such consent not to be unreasonably withheld or delayed). Any other such Indebtedness, liabilities or Liens not permitted to be assumed, continued or otherwise supported by any Obligor or Subsidiary thereof hereunder shall be paid in full or released within sixty (60) days of the acquisition date (or such longer period of time as agreed by the Administrative Agent in its sole discretion) as to the business, Persons or properties being so acquired on or before the consummation of such Acquisition.

"***Permitted Cash Equivalent Investments***" means (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any member states of the European Union or any agency or any state thereof having maturities of not more than two (2) years from the date of acquisition, (b) commercial paper maturing no more than three-hundred sixty-five (365) days after the date of acquisition thereof and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue that are issued by any bank organized under the Laws of the United States, or any state thereof, or the District of Columbia, or any U.S. branch of a foreign bank having, at the date of acquisition thereof, combined capital and surplus of not less than $500,000,000, (d) any money market or similar funds that exclusively hold any of the foregoing, and (e) any other short term liquid investments approved in writing by the Administrative Agent in its sole discretion.

"***Permitted Hedging Agreement***" means a Hedging Agreement entered into by any Obligor in such Obligor's Ordinary Course for the purpose of hedging currency risks or interest rate risks (and not for speculative purposes) and (x) with respect to hedging currency risks, in an aggregate notional amount for all such Hedging Agreements not in excess of $20,000,000 (or the Equivalent

Amount in other currencies) and (y) with respect to hedging interest rate risks, in an aggregate notional amount for all such Hedging Agreements in excess of 50%, but not more than 100%, of the aggregate principal amount of Loans outstanding at such time.

"***Permitted Indebtedness***" means any Indebtedness permitted under **Section 9.01**.

"***Permitted Licenses***" means: (a) licenses of off-the-shelf software that is commercially available to the public; (b) non-exclusive intercompany licenses or grants of rights for development, manufacture, production, commercialization (including commercial sales to end users), marketing, promotion, co-promotion, sales or distribution among the Obligors; (c) any outbound non-exclusive license for the use of (or covenant not to sue with respect to) Intellectual Property of any Obligor for development, manufacture, production, commercialization (including commercial sales to end users), marketing, promotion, co-promotion, sales or distribution of any Product, in each case, entered into in the Ordinary Course; provided, that, with respect to each such license or grant described in **clause (c)** above, (A) no Event of Default has occurred or is continuing at the time of such license, and (B) such license or grant constitutes an Arm's Length Transaction, the terms of which do not provide for a sale or assignment of Intellectual Property; provided that such licenses may be exclusive as to territory only as to the People's Republic of China, (d) other licenses to which the Administrative Agent shall have consented to in writing and (e) any non-exclusive or exclusive license for the use of (or covenant not to sue with respect to) Intellectual Property of any Obligor for development, manufacture, production, commercialization (including commercial sales to end users), marketing, promotion, co-promotion, sales or distribution existing on the Closing Date, in each case, to the extent set forth on **Schedule 3**.

"***Permitted Liens***" means any Liens permitted under **Section 9.02**.

"***Permitted Refinancing***" means, with respect to any Indebtedness permitted to be refinanced, extended, renewed or replaced hereunder, any refinancings, extensions, renewals and replacements of such Indebtedness; provided that such refinancing, extension, renewal or replacement shall not (i) increase the outstanding principal amount of the Indebtedness being refinanced, extended, renewed or replaced, except by an amount equal to accrued interest and a reasonable and customary exit premium (or similar concept) on the debt being refinanced or other reasonable and customary fees, original issue discount, and expenses reasonably incurred in connection therewith, (ii) contain terms relating to outstanding principal amount, amortization, maturity, collateral security (if any) or subordination (if any), or other material terms that, taken as a whole, are less favorable in any material respect to the Obligors and their respective Subsidiaries or the Secured Parties than the terms of any agreement or instrument governing such existing Indebtedness, (iii) have an applicable interest rate which does not exceed the greater of (A) the rate of interest of the Indebtedness being replaced and (B) the then applicable market interest rate plus three percent (3%), (iv) contain any new requirement to grant any Lien or to give any Guarantee that was not an existing requirement of such Indebtedness, and (v) after giving effect to such refinancing, extension, renewal or replacement, no Default or Event of Default shall have occurred or could reasonably be expected to occur as a result thereof.

"***Person***" means any individual, corporation, company, voluntary association, partnership, limited liability company, joint venture, trust, unincorporated organization or Governmental Authority or other entity of whatever nature.

"***PMA Clearance***" means the authority to sell a medical device in the United States granted by the FDA pursuant to 21 Code of Federal Regulations Section 814.20, as amended.

"***Prepayment Price***" has the meaning set forth in **Section 3.03(a)(i)**.

"***Pro Forma Basis***" shall mean, with respect to the calculation of any financial ratio or financial covenant, as of any date, that *pro forma* effect will be given to the Transactions, any Acquisition, any issuance, incurrence, assumption or permanent repayment of Indebtedness (including Indebtedness issued, incurred or assumed as a result of, or to finance, any relevant transaction and for which any such financial ratio is being calculated), all sales, transfers and other dispositions or discontinuance of any Subsidiary, line of business or division, or any conversion of a Subsidiary Guarantor to Subsidiary or of a Subsidiary to a Subsidiary Guarantor, in each case that have occurred during the four consecutive fiscal quarter period of the Borrower being used to calculate such financial ratio (the "***Reference Period***"), or subsequent to the end of the Reference Period but prior to such date or prior to or simultaneously with the event for which a determination under this definition is made (including any such event occurring at an entity that became a Restricted Subsidiary after the commencement of the Reference Period), as if each such event occurred on the first day of the Reference Period.

"***Process Agent***" has the meaning set forth in **Section 14.10(b)**.

"***Product***" means (a) those products set forth (and described in reasonable detail) on **Schedule 4** attached hereto, and (b) any material current or future product developed, distributed, dispensed, imported, exported, labeled, promoted, manufactured, licensed, marketed, sold or otherwise commercialized by any Obligor or any of its Subsidiaries that constitutes or generates more than ten percent (10%) of the Borrower's consolidated total revenue in the immediately preceding fiscal year, including any such product in development or which may be developed.

"***Product Authorizations***" means any and all Governmental Approvals, whether U.S. or non-U.S. (including all applicable PMA Clearances, 510(k) Clearances, NDAs, INDs, supplements, amendments, variations governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), of any Regulatory Authority, in each case, necessary to be held or maintained by, or for the benefit of, any Obligor or any of its Subsidiaries for the ownership, use or commercialization of any Product or for any Product Commercialization and Development Activities with respect thereto in any country or jurisdiction.

"***Product Commercialization and Development Activities***" means, with respect to any Product, any combination of research, development, testing, manufacture, formulation, import, use, sale, licensing, importation, exportation, shipping, storage, handling, design, labeling, marketing, promotion, supply, distribution, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing (including, without limitation, in respect of licensing, royalty or similar payments), or any similar or other activities the purpose of which is to commercially exploit such Product, except for any of the foregoing activities or payments that would not reasonably be expected to be material to the Borrower and its Subsidiaries, taken as a whole.

"***Product Related Information***" means, with respect to any Product, all books, records, lists, ledgers, files, manuals, correspondence, reports, plans, drawings, data and other information of every kind (in any form or medium), and all techniques and other know-how, owned or possessed by the Obligors or any of their respective Subsidiaries that are necessary or useful for any Product Commercialization and Development Activities relating to such Product, including (i) brand materials and packaging, customer targeting and other marketing, promotion and sales materials and information, referral, customer, supplier and other contact lists and information, product, business, marketing and sales plans, research, studies and reports, sales, maintenance and production records, training materials and other marketing, sales and promotional information and (ii) clinical data, information included or supporting any Product Authorization, any regulatory filings, updates, notices and correspondence (including adverse event and other pharmacovigilance and other post-marketing reports and information, etc.), technical information, product development and operational data and records, and all other documents, records, files, data and other information, used in connection with the Product Commercialization Development Activities for such Product.

"***Prohibited Payment***" means any bribe, rebate, payoff, influence payment, kickback or other payment or gift of money or anything of value (including meals or entertainment) to any officer, employee or ceremonial office holder of any government or instrumentality thereof, political party or supra-national organization (such as the United Nations), any political candidate, any royal family member or any other person who is connected or associated personally with any of the foregoing that is prohibited under any Law for the purpose of influencing any act or decision of such payee in his official capacity, inducing such payee to do or omit to do any act in violation of his lawful duty, securing any improper advantage or inducing such payee to use his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality.

"***Proportionate Share***" means, with respect to any Lender, the percentage obtained by dividing (a) the sum of the Commitment (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of such Lender then in effect by (b) the sum of the Commitments (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of all Lenders then in effect.

"***Qatari Business Day***" has the meaning set forth in **Section 14.02(b)**.

"***QIA Lender***" means any Lender that is an Affiliate of Qatar Investment Authority.

"***QIA Lender Notice***" has the meaning set forth in **Section 14.02(b)**.

"***Qualified Equity Interest***" means, with respect to any Person, any Equity Interest of such Person that is not a Disqualified Equity Interest.

"***Qualified Plan***" means an employee pension benefit plan (as defined in Section 3(2) of ERISA) other than a Multiemployer Plan (a) that is maintained or sponsored by any Obligor or any ERISA Affiliate thereof and (b) that is intended to be tax qualified under Section 401(a) of the Code.

"***Real Property Security Documents***" means any Mortgages, Landlord Consents or Bailee Letters.

"***Recipient***" means any Lender or any other recipient of any payment to be made by or on account of any Obligation.

"***Referral Source***" has the meaning set forth in **Section 7.07(c)(i)**.

"***Register***" has the meaning set forth in **Section 14.05(d)**.

"***Regulation T***" means Regulation T of the Board of Governors of the Federal Reserve System, as amended.

"***Regulation U***" means Regulation U of the Board of Governors of the Federal Reserve System, as amended.

"***Regulation X***" means Regulation X of the Board of Governors of the Federal Reserve System, as amended.

"***Regulatory Authority***" means any Governmental Authority, whether U.S. or non-U.S., that has regulatory or supervisory oversight with respect to any Product or any Product Commercialization and Development Activities relating to any Product, including the FDA and all equivalent Governmental Authorities, whether U.S. or non-U.S.

"***Reinvestment***" has the meaning set forth in **Section 3.03(b)(i)**.

"***Reinvestment Period***" has the meaning set forth in **Section 3.03(b)(i)**.

"***Related Parties***" has the meaning set forth in **Section 14.16(a)**.

"***Resignation Effective Date***" has the meaning set forth in **Section 12.09(a)**.

"***Resolution Authority***" means an EEA Resolution Authority or, with respect to any U.K. Financial Institution, a U.K. Resolution Authority.

"***Responsible Officer***" of (a) the Borrower, means a director or any officer who is entered in the Borrower's register of officers and has been expressly authorized by the directors of the Borrower to take the action in question on behalf of the Borrower and (b) any other Person, means each of the president, chief executive officer, chief financial officer, and other similar officers of such Person (including, in relation to any German Guarantor, its managing director(s) (*Geschäftsführer*~~)~~.) authorized to represent such German Guarantor).

"***Restricted Payment***" means any dividend or other distribution (whether in cash, Equity Interests or other property) with respect to any Equity Interests of any Obligor or any of its Subsidiaries, or any payment (whether in cash, Equity Interests or other property), including any sinking fund or similar deposit, on account of the purchase, redemption, retirement, acquisition, cancellation or termination of any such Equity Interests of any Obligor or any of its Subsidiaries, or on account of any return of capital to any Obligor or any of its Subsidiary's stockholders,

partners or members (or the equivalent of any thereof), any payment of interest, principal or fees in respect of any Indebtedness owed by any Obligor or any of its Subsidiaries to (x) any director, officer, or employee of any Obligor or any of their Subsidiaries, or (y) any holder of more than 1% of the Equity Interests of any Obligor or any of its Subsidiaries, or any option, warrant or other right to acquire any such Equity Interests of any Obligor or any of its Subsidiaries.

"***Restrictive Agreement***" means any Contract or other arrangement that prohibits, restricts or imposes any condition upon (a) the ability of any Obligor or any of its Subsidiaries to create, incur or permit to exist any Lien upon any of its properties or assets (other than (w) the Loan Documents, (x) customary provisions in Contracts restricting the assignment thereof (including, without limitation, any leases and in-bound licenses of Intellectual Property), and (y) restrictions or conditions imposed by any Contract governing secured Permitted Indebtedness permitted under **Section 9.01(i)**, to the extent that such restrictions or conditions apply only to the property or assets securing such Indebtedness), or (b) the ability of any Obligor or any of its Subsidiaries to make Restricted Payments with respect to any of their respective Equity Interests or to make or repay loans or advances to any other Obligor or any of its Subsidiaries or such other Obligor or to Guarantee Indebtedness of any other Obligor or any of its Subsidiaries thereof or such other Obligor.

"***Sanction***" means any international economic or financial sanction or trade embargo imposed, administered or enforced from time to time by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, Her Majesty's Treasury or other relevant sanctions authority where the Borrower or any of its Subsidiaries is located or conducts business.

"***Sanctioned Person***" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, Her Majesty's Treasury or other relevant sanctions authority, (b) any Person organized or resident in a Designated Jurisdiction or (c) any Person fifty percent (50%) or more owned or is controlled by any such Person or Persons described in the foregoing **clauses (a)** or **(b)**.

"***Secured Parties***" means the Lenders, the Administrative Agent and any of their respective permitted transferees or assigns.

"***Securities Act***" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"***Security Agreement***" means the Security Agreement, delivered pursuant to **Section 6.01(i)**, among the Obligors and the Administrative Agent, granting a security interest in the Obligors' Collateral in favor of the Administrative Agent, for the benefit of the Secured Parties.

"***Security Documents***" means, collectively, the Security Agreement, the Brazilian Security Agreements, each Short-Form IP Security Agreement, the Perfection Certificate, each Real Property Security Document, each Belgian Security Document, each Costa Rican Security Document, each French Security Document and each other security document, control agreement

or financing statement required to perfect Liens in favor of the Secured Parties for purposes of securing the Obligations.

"***Short-Form IP Security Agreements***" means short-form Copyright, Patent or Trademark (as the case may be) security agreements, substantially in the form of Exhibit C, D and E to the Security Agreement, entered into by one or more Obligors in favor of the Secured Parties (and as amended, modified or replaced from time to time).

"***Solvent***" means, (i) as to any Person as of any date of determination, that on such date (a) the fair value of the property of such Person is greater than the total amount of liabilities, including contingent liabilities, of such Person, (b) the present fair saleable value of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured in the Ordinary Course, (c) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay such debts and liabilities as they mature in the Ordinary Course and (d) such Person is not engaged in a business or transaction, and is not about to engage in a business or transaction, for which such Person's property would constitute an unreasonably small capital after giving due consideration to the prevailing practice in the industry in which such Person is engaged or is to engage, and (ii) in respect of the Borrower, as of any date of determination, that on such date (a) it is able to pay its debts as they fall due; (b) the value of its assets exceeds the value of its liabilities (including its contingent and prospective liabilities); (c) it has not failed to comply with the requirements of a statutory demand that has not been set aside under Section 157 of the Insolvency Act of the BVI; (d) execution or other process issued on a judgment, decree or order of a court in favour of a creditor of it has not been returned wholly or partly unsatisfied; (e) it has not taken any action or steps have been taken nor have legal proceedings been started or threatened against it for (A) its winding up, liquidation, administration, dissolution, amalgamation, reconstruction, reorganisation, arrangement, adjustment, consolidation or protection or relief of creditors (whether by way of voluntary arrangement, scheme of arrangement or otherwise), (B) the enforcement of any security interest over any or all of its assets; or (C) the appointment of a liquidator, receiver, controller, inspector, manager, supervisor, administrative receiver, administrator, trustee or similar officer or official of it or of any or all of its assets; (f) action has not and is not being taken by the Registrar of Corporate Affairs pursuant to Section 213 of the BVI BCA to dissolve or strike it off the BVI register of companies; (g) it is not, in any jurisdiction, subject to or threatened by any actions, steps, procedures or other proceedings under any applicable bankruptcy, insolvency, rehabilitation or other re-organisation laws; and (h) no actions, steps, procedures or other proceedings equivalent or analogous to any of those set out in any of clauses (ii)(a) – (g) above (inclusive) of this definition have been taken, started or threatened against it in any jurisdiction, including the seeking by it (or any other person in relation to it) of winding up, liquidation, administration, dissolution, amalgamation, reconstruction, reorganisation, arrangement, adjustment, consolidation or protection or relief of creditors. The amount of any contingent liability at any time shall be computed as the amount that, in light of all of the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability and means at any time with respect to any German Guarantor, that it is neither unable to pay its debts as they fall due (*Zahlungsunfähigkeit*), nor is over indebted (*Überschuldung*), nor is threatened with insolvency (*drohende Zahlungsunfähigkeit*), nor has commenced negotiations with any one or more of its creditors with a view to the general readjustment or rescheduling of its

indebtedness or, for any of the reasons set out in Sections 17 to 19 (inclusive) of the German Insolvency Code (*Insolvenzordnung*).

"***Subsidiary***" means, with respect to any Person (the "***parent***") at any date, any corporation, limited liability company, partnership, association or other entity the accounts of which would be consolidated with those of the parent in the parent's consolidated financial statements if such financial statements were prepared in accordance with GAAP as of such date, as well as any other corporation, limited liability company, partnership, association or other entity (i) of which securities or other ownership interests representing more than fifty percent (50%) of the equity or more than fifty percent (50%) of the ordinary voting power or, in the case of a partnership, more than fifty percent (50%) of the general partnership interests are, as of such date, owned, controlled or held, directly or indirectly, or (ii) that is, as of such date, otherwise Controlled, by the parent or one or more direct or indirect subsidiaries of the parent or by the parent and one or more direct or indirect subsidiaries of the parent. Unless otherwise specified, all references herein to a "Subsidiary" or to "Subsidiaries" shall refer to a Subsidiary or Subsidiaries of the Borrower.

"***Subsidiary Guarantors***" means each Subsidiary of the Borrower identified under the caption "SUBSIDIARY GUARANTORS" on the signature pages hereto and each Subsidiary of the Borrower that becomes, or is required to become, a "Subsidiary Guarantor" after the date hereof pursuant to **Section 8.11**. For the avoidance of doubt, no Immaterial Subsidiary shall be required to be a Subsidiary Guarantor.

"***Target Gross Sales***" means, with respect to each fiscal quarter end where the covenant in **Section 10.02** is tested, the amount set forth opposite such date on **Schedule 2** under the caption "Target Gross Sales".

"***Taxes***" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other similar charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"***Technical Information***" means all (a) Product Related Information and (b) all other know-how, trade secrets, proprietary or confidential information, information of a scientific, technical, or business nature in any form or medium, Invention disclosures, documented research, developmental, demonstration or engineering work, and all other technical data and information.

"***Termination Conditions***" has the meaning set forth in **Section 13.03**.

"***Title IV Plan***" means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time within the preceding five years maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has within the preceding five years ever made, or was within the preceding five years obligated to make, contributions, and (ii) that is or was subject to Section 412 of the Code, Section 302 of ERISA or Title IV of ERISA.

"***Trademarks***" means all trade names, trademarks and service marks, corporate names, logos, Internet domain names and other indicia of origin, in each case, whether or not registered, trademark and service mark registrations, and applications for trademark and service mark registrations, including (i) all renewals of trademark and service mark registrations and (ii) all

rights whatsoever accruing thereunder or pertaining thereto throughout the world (including common law rights), together, in each case, with the goodwill associated therewith or symbolized thereby.

"***Tranche A Commitment***" means, with respect to each Lender, the obligation of such Lender to make Tranche A Term Loans to the Borrower on the Closing Date in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Applicable Commitment" for Tranche A Term Loans, as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise. The aggregate amount of Tranche A Commitments on the date of this Agreement equals $150,000,000.

"***Tranche A Funding Condition***" has the meaning set forth in the Loans Schedule.

"***Tranche A Term Loans***" has the meaning assigned to such term in **Section 2.01(a)(i)**.

"***Tranche B Availability Period***" has the meaning set forth in the Loans Schedule.

"***Tranche B Commitment***" means, with respect to each Lender, the obligation of such Lender to make Tranche B Term Loans to the Borrower on the Applicable Funding Date in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Applicable Commitment" for Tranche B Term Loans, as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise. The aggregate amount of Tranche B Commitments on the date of this Agreement equals $25,000,000.

"***Tranche B Funding Condition***" has the meaning set forth in the Loans Schedule.

"***Tranche B Term Loans***" has the meaning assigned to such term in **Section 2.01(a)(ii)**.

"***Tranche C Availability Period***" has the meaning set forth in the Loans Schedule.

"***Tranche C Commitment***" means, with respect to each Lender, the obligation of such Lender to make Tranche C Term Loans to the Borrower on the Applicable Funding Date in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Applicable Commitment" for Tranche C Term Loans, as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise. The aggregate amount of Tranche C Commitments on the date of this Agreement equals $25,000,000.

"***Tranche C Funding Condition***" has the meaning set forth in the Loans Schedule.

"***Tranche C Funding Milestone***" has the meaning set forth in the Loans Schedule.

"***Tranche C Term Loans***" has the meaning assigned to such term in **Section 2.01(a)(iii)**.

"***Tranche D Availability Period***" has the meaning set forth in the Loans Schedule.

"***Tranche D Commitment***" means, with respect to each Lender, the obligation of such Lender to make Tranche D Term Loans to the Borrower on the Applicable Funding Date in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Applicable Commitment" for Tranche D Term Loans, as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise. The aggregate amount of Tranche D Commitments on the date of this Agreement equals $25,000,000.

"***Tranche D Funding Condition***" has the meaning set forth in the Loans Schedule.

"***Tranche D Funding Milestone***" has the meaning set forth in the Loans Schedule.

"***Tranche D Term Loans***" has the meaning assigned to such term in **Section 2.01(a)(iv)**.

"***Transactions***" means (a) the negotiation, preparation, execution, delivery and performance by each Obligor of this Agreement and the other Loan Documents to which such Obligor is (or is intended to be) a party, the making of the Loans hereunder, and all other transactions contemplated pursuant to this Agreement and the other Loan Documents, including the creation of the Liens pursuant to the Security Documents and (b) the payment of all fees and expenses incurred or paid by the Obligors in connection with the foregoing.

"***UCC***" means, with respect to any applicable jurisdictions, the Uniform Commercial Code as in effect in such jurisdiction, as may be modified from time to time.

"***U.K. Financial Institution***" means any BRRD Undertaking (as such term is defined under the PRA Rulebook (as amended form time to time) promulgated by the United Kingdom Prudential Regulation Authority) or any person falling within IFPRU 11.6 of the FCA Handbook (as amended from time to time) promulgated by the United Kingdom Financial Conduct Authority, which includes certain credit institutions and investment firms, and certain affiliates of such credit institutions or investment firms.

"***U.K. Resolution Authority***" means the Bank of England or any other public administrative authority having responsibility for the resolution of any U.K. Financial Institution.

"***United States***" or "***U.S.***" means the United States of America, its fifty states and the District of Columbia.

"***U.S. Person***" means a "United States Person" within the meaning of Section 7701(a)(30) of the Code.

"***U.S. Tax Compliance Certificate***" has the meaning set forth in **Section 5.03(f)(ii)(B)(3)**.

"***Withholding Agent***" means the Borrower and the Administrative Agent.

"***Write-Down and Conversion Powers***" means, (a) with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule, and (b) with respect

to the United Kingdom, any powers of the applicable Resolution Authority under the Bail-In Legislation to cancel, reduce, modify or change the form of a liability of any U.K. Financial Institution or any contract or instrument under which that liability arises, to convert all or part of that liability into shares, securities or obligations of that person or any other person, to provide that any such contract or instrument is to have effect as if a right had been exercised under it or to suspend any obligation in respect of that liability or any of the powers under that Bail-In Legislation that are related to or ancillary to any of those powers.

"***Yield Protection Premium***" means with respect to any prepayment of all or any portion of the Loans, whether by optional or mandatory prepayment, acceleration or otherwise occurring (a) on or prior to April 26, 2024, an amount equal to the amount of interest that would have been paid on the principal amount of the Loans being so repaid or prepaid for the period from and including the date of such repayment or prepayment (excluding, for the avoidance of doubt, any interest on the Loans paid prior to such date) to but excluding April 26, 2024, *plus* four percent (4%) of the principal amount of the Loans being so repaid or prepaid, (b) at any time after April 26, 2024 but on or prior to April 26, 2025, an amount equal to four percent (4%) of the aggregate outstanding principal amount of the Loans being so repaid or prepaid, (c) at any time after April 26, 2025 but on or prior to April 26, 2026, an amount equal to two percent (2%) of the aggregate outstanding principal amount of the Loans being so repaid or prepaid and (d) if the prepayment is made after April 26, 2026, zero percent (0%).

"***510(k) Clearance***" means the FDA's written authorization to market a medical device pursuant to a premarket notification submitted under section 510 of the Federal Food, Drug, and Cosmetic Act.

1.02 Accounting Terms and Principles. Unless otherwise specified, all accounting terms used in each Loan Document shall be interpreted, and all accounting determinations and computations thereunder (including under **Section 10** and any definitions used in such calculations) shall be made, in accordance with GAAP or IFRS, as applicable. Unless otherwise expressly provided, all financial covenants and defined financial terms shall be computed on a consolidated basis for the Borrower and its Subsidiaries, in each case without duplication. If the Borrower requests an amendment to any provision hereof to eliminate the effect of (a) any change in GAAP or IFRS or the application thereof or (b) the issuance of any new accounting rule or guidance or in the application thereof, in each case, occurring after the date of this Agreement, then the Lenders and Borrower agree that they will negotiate in good faith amendments to the provisions of this Agreement that are directly affected by such change or issuance with the intent of having the respective positions of the Lenders and Borrower after such change or issuance conform as nearly as possible to their respective positions as of the date of this Agreement and, until any such amendments have been agreed upon, (i) the provisions in this Agreement shall be calculated as if no such change or issuance has occurred and (ii) the Borrower shall provide to the Lenders a written reconciliation in form and detail reasonably satisfactory to the Lenders, between calculations of any baskets and other requirements hereunder before and after giving effect to such change or issuance.

1.03 Interpretation. For all purposes of this Agreement, except as otherwise expressly provided herein or unless the context otherwise requires,

(a) the terms defined in this Agreement include the plural as well as the singular and vice versa;

(b) words importing gender include all genders;

(c) any reference to a Section, Annex, Schedule or Exhibit refers to a Section of, or Annex, Schedule or Exhibit to, this Agreement;

(d) any reference to "this Agreement" refers to this Agreement, including all Annexes, Schedules and Exhibits hereto, and the words herein, hereof, hereto and hereunder and words of similar import refer to this Agreement and its Annexes, Schedules and Exhibits as a whole and not to any particular Section, Annex, Schedule, Exhibit or any other subdivision;

(e) references to days, months and years refer to calendar days, months and years, respectively;

(f) all references herein to "include" or "including" shall be deemed to be followed by the words "without limitation";

(g) the word "from" when used in connection with a period of time means "from and including" and the word "until" means "to but not including";

(h) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer broadly to any and all assets and properties, whether tangible or intangible, real or personal, including cash, securities, rights under contractual obligations and permits and any right or interest in any such assets or property;

(i) accounting terms not specifically defined herein (other than "property" and "asset") shall be construed in accordance with GAAP or IFRS, as applicable, subject to **Section 1.02**;

(j) the word "will" shall have the same meaning as the word "shall";

(k) where any provision in this Agreement or any other Loan Document refers to an action to be taken by any Person, or an action which such Person is prohibited from taking, such provision shall be applicable whether such action is taken directly or, to the knowledge of such Person, indirectly; and

(l) references to any Lien granted or created hereunder or pursuant to any other Loan Document securing any Obligations shall deemed to be a Lien for the benefit of the Secured Parties.

Unless otherwise expressly provided herein, references to organizational documents, agreements (including the Loan Documents) and other contractual instruments shall be deemed to include all subsequent amendments, restatements, extensions, supplements and other modifications thereto permitted by the Loan Documents. Any definition or reference to any Law shall include all statutory and regulatory provisions consolidating, amending, replacing, supplementing or interpreting such Law.

If any payment required to be made pursuant to the terms and conditions of any Loan Document falls due on a day which is not a Business Day, then such required payment date shall be extended to the immediately following Business Day. For purposes of determining compliance with any covenant (including the computation of any financial covenant) contained herein, Indebtedness of the Obligors and their Subsidiaries will be deemed to be equal to 100% of the outstanding principal amount thereof or payment obligations with respect thereto at the time of determination thereof, or with respect to any Hedging Agreements, the amount that would be payable if the agreement governing such Hedging Agreements were terminated on the date of termination.

1.04 Division. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws) (a "**Division**"), if (a) any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (b) any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.05 Currency Generally. For purposes of determining compliance with **Section 9** with respect to the amount of any Indebtedness or Investment in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred solely as a result of changes in rates of currency exchange occurring after the time such Indebtedness or Investment is incurred, made or acquired (so long as such Indebtedness or Investment, at the time incurred, made or acquired, was permitted hereunder).

1.06 Belgian Terms. In this Agreement, where it relates to Belgian Law or a Belgian Obligor, a reference to:

(a) a liquidator, receiver, trustee, custodian, conservator, liquidator, rehabilitator, administrator or similar officer includes any *insolventiefunctionaris/praticien de l'insolvabilité, curator/curateur*, *vereffenaar/liquidateur*, *gedelegeerd rechter/juge délégué, gerechtsmandataris/mandataire de justice, voorlopig bewindvoerder/administrateur judiciaire*, *ondernemingsbemiddelaar/médiateur d'entreprise*, *gerechtelijk bewindvoerder/administrateur judiciaire*, *mandataris ad hoc/mandataire ad hoc* and any *sekwester/sequester*, as applicable;

(b) a security interest includes any mortgage (*hypotheek/hypothèque*), mortgage mandate (*hypothecair mandaat/mandat hypothécair*), pledge (*pand/nantissement*), privilege (*voorrecht/privilège*), retention right (*eigendomsvoorbehoud/droit de retention*), any real surety (*zakelijke zekerheid/sûreté réelle*) and any transfer by way of security (*overdracht ten titel van zekerheid/transfert à titre de garantie*);

(c) a suspension of payments, moratorium of any indebtedness, or reorganisation includes any *gerechtelijke reorganisatie/réorganisation judiciaire*;

(d) a person being unable to pay its debts is that person being in a state of cessation of payments (*staking van betaling/cessation de paiements*);

(e) commences negotiations with one or more of its creditors with a view to rescheduling any of its indebtedness includes any negotiations conducted with a view to reaching

a settlement agreement (*minnelijk akkoord/accord amiable*) with two or more of its creditors pursuant to Book XX of the Belgian Code of Economic Law;

(f) a composition includes any *minnelijk akkoord met schuldeisers/accord amiable avec des créanciers* or any *gerechtelijke reorganisatie/réorganisation judiciaire*;

(g) a receivership, winding-up, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition, dissolution or other judicial proceeding includes any *gerechtelijke reorganisatie/réorganisation judiciaire*, *vereffening/liquidation*, *ontbinding/dissolution*, *faillissement/faillite*, *sluiting van een onderneming/fermeture d'enterprise* and any other concurrence between creditors (*samenloop van schuldeisers/concours des créanciers*);

(h) a writ or warrant of attachment, sequestration, distress or execution or similar process includes any *uitvoerend beslag/saisie exécutoire* and *bewarend beslag/saisie conservatoire*;

(i) an amalgamation, demerger, merger or corporate reconstruction includes an *overdracht van algemeenheid/transfert d'universalité*, an *overdracht van bedrijfstak/transfert de branche d'activité*, a *splitsing/scission* and a *fusie/fusion* as well as assimilated transactions (*gelijkgestelde verrichtingen/operations assimilées*) in accordance with articles 12:7 and 12:8 of the Belgian Code of Companies and Associations;

(j) a guaranty refers, only for the purpose of the Guaranty granted pursuant to this Agreement, to the Belgian legal concept of a guarantee (*garantie/vrijwaring*) and not a surety (*borg/cautionnement*);

(k) an Obligor being incorporated in Belgium or of which its jurisdiction of incorporation is Belgium, means that that Obligor has its registered office (*zetel/siège*) in Belgium; and

(l) Organic Documents means the *oprichtingsakte/acte constitutif*, *statuten/statuts*, *uittreksel van de Kruispuntbank voor Ondernemingen/extrait de la Banque-Carrefour des Entreprises* and the results of a search in the Belgian Central Solvency Register (RegSol) with respect to bankruptcy and judicial reorganization proceedings.

1.07 German Terms. In this Agreement, where it relates to a Person incorporated in the Federal Republic of Germany, a reference to:

(a) a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, voluntary administrator, receiver and manager or other similar official includes any:

(i) insolvency administrator (*Insolvenzverwalter*) or preliminary insolvency administrator (*vorläufiger Insolvenzverwalter*) appointed under the German Insolvency Code (*Insolvenzordnung*);

(ii) court supervisor (*Sachwalter*) or preliminary court supervisor (*vorläufiger Sachwalter*) appointed under the German Insolvency Code;

(iii) liquidator (*Liquidatoren*) appointed under the German Commercial Code (*Handelsgesetzbuch*) or under the German Act on Limited Liability Companies (*Gesetz betreffen die Gesellschaften mit beschränkter Haftung*); and

(b) a bankruptcy, reorganization, liquidation, receivership, insolvency, winding-up, administration, dissolution, compromise, arrangement, plans of arrangement or relief or protection of debtors, includes, without limitation, insolvency (*Insolvenz*), insolvency proceedings (*Insolvenzverfahren*), preliminary insolvency proceedings (*vorläufiges Insolvenzverfahren*), debtor-in-possession proceedings (*Eigenverwaltung*), including any protective shield procedure (*Schutzschirmverfahren*), any insolvency plan (*Insolvenzplan*), any proceedings pursuant to the enactment of the directive (EU) 2019/1023 and a combination of any of the foregoing and a liquidation (Liquidation) or dissolution (*Auflösung*).

1.08 French Terms. Insofar as it applies to a Person incorporated in France or an asset located in France, a reference in this Agreement to:

(i) a **winding-up, insolvency, liquidation, administration** or **dissolution** includes, without limitation, a *redressement judiciaire*, a *cession totale ou partielle de l'entreprise*, a *liquidation judiciaire*, a *sauvegarde* or a *sauvegarde accélérée* under Book VI (*Livre Sixième*) of the French Commercial Code (*Code de commerce*);

(ii) a **composition** or **assignment** includes a *conciliation* or a *mandat ad hoc* under Articles L. 611-3 to L. 611-16 of the French Commercial Code (*Code de commerce*);

(iii) a **moratorium** includes (without limitation) a moratorium under a *conciliation* procedure in accordance with Articles L. 611-4 to L. 611-16 of the French Commercial Code (*Code de commerce*);

(iv) an **Insolvency Proceeding** or **any equivalent or analogous procedure or step** includes, without limitation: (i) proceedings for the appointment of a *mandataire ad hoc* or for the opening of a procedure of *conciliation* in accordance with Articles L. 611-3 to L. 611-16 of the French Commercial Code (*Code de commerce*), and (ii) the entry of a judgment for *sauvegarde* (including the *sauvegarde accélérée*), *redressement judiciaire*, *cession totale ou partielle de l'entreprise* or *liquidation judiciaire* under Book VI (*Livre Sixième*) of the French Commercial Code (*Code de commerce*).

(v) a **receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, examiner, trustee, liquidator, voluntary administrator, receiver and manager** or **similar official** includes an *administrateur judiciaire*, a *mandataire ad hoc*, a *conciliateur*, a *mandataire liquidateur* or any other person appointed as a result of any proceedings described in paragraphs (i) to (iv) above;

(vi) a **guarantee** includes any type of *sûreté personnelle* as defined in Article 2287-1 of the French Civil Code (*Code civil*);

(vii) a **gross negligence** means *faute lourde*;

(viii) a **lease** includes an *opération de crédit-bail*;

(ix) a **merger** includes any fusion implemented in accordance with Articles L. 236-1 to L. 236-24 of the French Commercial Code (*Code de commerce*);

(x) a **reconstruction**, **demerger**, **consolidation** or **amalgamation** includes in relation to any company any contribution of part of its business in consideration of shares (*apport partiel d'actifs*) and any demerger (*scission*) implemented in accordance with Articles L. 236-1 to L. 236-24 of the French Commercial Code (*Code de commerce*);

(xi) a **security** or **security interest** includes any type of security (*sûreté réelle*) and transfer by way of security;

(xii) an **attachment** includes a *saisie*;

(xiii) a person being **unable to pay its debts** includes that person being in a state of *cessation des paiements* as defined in Article L. 631-1 of the French Commercial Code (*Code de commerce*);

(xiv) a **willful misconduct** means *dol*; and

(xv) **control** has the meaning given in Article L. 233-3 I and II of the French Commercial Code (*Code de commerce*).

SECTION 2.
THE COMMITMENT AND THE LOANS

2.01 Loans.

(a) On the terms and subject to the conditions of this Agreement, each Lender agrees:

(i) to make Loans to the Borrower in a principal amount equal to the amount of such Lender's Tranche A Commitment on the Closing Date ("***Tranche A Term Loans***");

(ii) to make Loans to the Borrower in a principal amount equal to the amount of such Lender's Tranche B Commitment ("***Tranche B Term Loans***"), on a date specified by the Borrower in accordance with **Section 2.02** during the Applicable Availability Period for the Tranche B Term Loans;

(iii) to make Loans to the Borrower in a principal amount equal to the amount of such Lender's Tranche C Commitment ("***Tranche C Term Loans***"), on a date specified by the Borrower in accordance with **Section 2.02** during the Applicable Availability Period for the Tranche C Term Loans; and

(iv) to make Loans to the Borrower in a principal amount equal to the amount of such Lender's Tranche D Commitment ("***Tranche D Term Loans***"), on a date specified by the Borrower in accordance with **Section 2.02** during the Applicable Availability Period for the Tranche D Term Loans.

(b) No amounts paid or prepaid with respect to any Loan may be reborrowed.

(c) Any term or provision hereof (or of any other Loan Document) to the contrary notwithstanding, Loans made to the Borrower will be denominated solely in Dollars and will be repayable solely in Dollars and no other currency.

2.02 Borrowing Procedures. Prior to 11:00 a.m. Eastern Time at least five (5) Business Days prior to any Applicable Funding Date (or such shorter period agreed by the Lenders), the Borrower shall deliver to the Administrative Agent an irrevocable written Borrowing Notice in the form of **Exhibit B** or such other form approved by the Administrative Agent signed by a duly authorized representative of the Borrower (which notice, if received by the Administrative Agent on a day that is not a Business Day or after 11:00 a.m. (Eastern time) on a Business Day, may be deemed to have been delivered on the next Business Day). Each Borrowing Notice shall be for the full amount of each of the Applicable Commitments and no Borrowing Notice for less than such full amount shall be permitted.

2.03 Funding of Borrowings. Promptly following receipt of any written Borrowing Notice the Administrative Agent shall advise each Lender of the details thereof and of the amount of such Lender's Loan to be made as part of the requested Borrowing. Each Lender shall make each Loan to be made by it hereunder on the proposed date thereof solely by wire transfer of immediately available funds, by 2:00 p.m. New York City time, to the account of the Administrative Agent most recently designated by it for such purpose by notice to the Lenders. Upon receipt of all funds the Administrative Agent will make such Loans available to the Borrower promptly by wire transfer of the amounts so received, in like funds, to an account designated by the Borrower in the applicable Borrowing Notice.

2.04 Notes.

(a) If requested by any Lender, the Loan of such Lender shall be evidenced by one or more Notes. The Borrower shall prepare, execute and deliver to the Lender such promissory note(s) substantially in the form attached hereto as **Exhibit G.**

(b) To further evidence its obligation to repay the Loans, and to pay accrued interest, the Costa Rican Guarantor shall issue and deliver to each Lender, as the case may be, on each disbursement date, a promissory note for such disbursement of each Loan, each in the amount of the relevant disbursement and substantially in the form of **Exhibit H** (collectively, the "**Costa Rican Notes**"). At any Lender's request, the Costa Rican Guarantor shall promptly execute and deliver one or more new Costa Rican Notes satisfactory to such Lender to substitute for one or more Costa Rican Notes previously delivered hereunder. The issuance, execution and delivery of any Costa Rican Notes pursuant to this Agreement shall not be construed as a novation hereunder or under any other agreement between any Lender and such Costa Rican Guarantor and shall not affect the obligations or rights of such Costa Rican Guarantor hereunder, and the rights and claims

of any Lender under any Costa Rican Note shall not replace or supersede its rights and claims hereunder.

2.05 Use of Proceeds. The Borrower shall use the proceeds of the Loans for (a) the refinancing of the Existing Indebtedness, (b) funding the ongoing commercialization of other product offerings outside the United States, (c) construction of the Borrower's third manufacturing facility in Costa Rica, (d) ongoing United States regulatory filings related to the Motiva Implants and (e) other working capital and general corporate purposes, including the payment of fees and expenses associated with this Agreement.

2.06 [Reserved].

2.07 Defaulting Lenders.

(a) **Adjustments**. Notwithstanding anything to the contrary contained in this Agreement, if any Lender becomes a Defaulting Lender, then, until such time as that Lender is no longer a Defaulting Lender, to the extent permitted by applicable Law:

(i) **Waivers and Amendment**. The Defaulting Lender's right to approve or disapprove any amendment, waiver or consent with respect to this Agreement shall be restricted as set forth in **Section 14.04**.

(ii) **Reallocation of Payments**. Any payment of principal, interest, fees or other amounts received by the Administrative Agent for the account of that Defaulting Lender (whether voluntary or mandatory, at maturity, pursuant to **Section 11** or otherwise, and including any amounts made available to the Administrative Agent by that Defaulting Lender pursuant to **Section 4.03**), shall be applied at such time or times as may be determined by the Administrative Agent as follows: first, to the payment of any amounts owing by that Defaulting Lender to the Administrative Agent hereunder; second, as the Borrower may request (so long as no Default or Event of Default exists), to the funding of any Loan in respect of which that Defaulting Lender has failed to fund its portion thereof as required by this Agreement, as determined by the Administrative Agent; third, if so determined by the Administrative Agent and the Borrower, to be held in a non-interest bearing deposit account and released in order to satisfy obligations of that Defaulting Lender to fund Loans under this Agreement; fourth, to the payment of any amounts owing to the Lenders as a result of any judgment of a court of competent jurisdiction obtained by any Lender against that Defaulting Lender as a result of that Defaulting Lender's breach of its obligations under this Agreement; fifth, so long as no Default or Event of Default exists, to the payment of any amounts owing to the Borrower as a result of any judgment of a court of competent jurisdiction obtained by the Borrower against that Defaulting Lender as a result of that Defaulting Lender's breach of its obligations under this Agreement; and sixth, to that Defaulting Lender or as otherwise directed by a court of competent jurisdiction; provided, that, if (x) such payment is a payment of the principal amount of any Loans in respect of which that Defaulting Lender has not fully funded its appropriate share and (y) such Loans were made at a time when the conditions set forth in **Section 6.02** were satisfied or waived, such payment shall be applied solely to pay the Loans of all non-Defaulting Lenders on a *pro rata* basis prior to being applied to the payment of any Loans of that Defaulting Lender. Any payments, prepayments, repayments or other amounts paid or payable to a Defaulting Lender that are applied (or held) to pay amounts owed by a

Defaulting Lender pursuant to this **Section 2.07(a)(ii)** shall be deemed paid to and redirected by that Defaulting Lender, and each Lender irrevocably consents hereto.

(b) **Defaulting Lender Cure**. If the Borrower and the Administrative Agent agree in writing in their sole discretion that a Defaulting Lender should no longer be deemed to be a Defaulting Lender, the Administrative Agent will so notify the parties hereto, whereupon as of the effective date specified in such notice and subject to any conditions set forth therein, that Lender will cease to be a Defaulting Lender; provided, that, no adjustments will be made retroactively with respect to fees accrued or payments made by or on behalf of the Borrower while that Lender was a Defaulting Lender; provided, further, that, except to the extent otherwise expressly agreed by the affected parties, no change hereunder from Defaulting Lender to Lender will constitute a waiver or release of any claim of any party hereunder arising from that Lender having been a Defaulting Lender.

(c) **Certain Fees**. No Defaulting Lender shall be entitled to receive any upfront fee set forth in the Fee Letter for any period during which that Lender is a Defaulting Lender (and the Borrower shall not be required to pay any such upfront fee that otherwise would have been required to have been paid to that Defaulting Lender).

SECTION 3.
PAYMENTS OF PRINCIPAL AND INTEREST, ETC.

3.01 Scheduled Repayments and Prepayments Generally; Application. The Borrower hereby promises to pay to the Administrative Agent for the account of each Lender (as such amounts may in each case be reduced from time to time in accordance with **Section 3.03**), on the Maturity Date, all outstanding Obligations (including the Exit Fee, accrued and unpaid interest and any other accrued and unpaid charges thereon and all other obligations due and payable by the Borrower under this Agreement but excluding any inchoate indemnification and expense reimbursement obligations for which no claim has been made) in full. Except as otherwise provided in this Agreement, each payment (including each repayment and prepayment) by the Borrower (other than fees payable pursuant to the Fee Letter) will be deemed to be made ratably in accordance with the Lenders' Proportionate Shares and applied ratably among each tranche of the Loans. On any date occurring prior to the Maturity Date that payment or prepayment in full of the Loans hereunder occurs, the Borrower shall pay in full all outstanding Obligations (other than any inchoate indemnification and expense reimbursement obligations for which no claim has been made), which shall include the Yield Protection Premium, if applicable and the Exit Fee.

3.02 Interest.

(a) **Interest Generally**. The outstanding principal amount of the Loans shall accrue interest from the date made to (but excluding) the date of repayment (whether by acceleration or otherwise and whether voluntary or mandatory) at the Interest Rate.

(b) **Default Interest**. Notwithstanding the foregoing, upon the occurrence and during the continuance of any Event of Default, the Interest Rate shall increase (i) automatically, in the case of any Event of Default under **Section 11.01(a)**, **11.01(b)** or **11.01(h)** and (ii) upon the request

of the Majority Lenders, in the case of any other Event of Default, by two percent (2.0%) *per annum* (the Interest Rate, as increased pursuant to this **Section 3.02(b)**, being the "***Default Rate***"); provided that, with respect to the preceding clause (ii), the Majority Lenders may impose the Default Rate retroactively to the occurrence of such Event of Default. If any Obligation (including, without limitation, fees, costs and expenses payable hereunder) is not paid when due (giving effect to any applicable grace period) under any applicable Loan Document, the amount thereof shall accrue interest at the Default Rate. Any interest due by any French Guarantor and unpaid under the Loan Documents (including any default interest accrued) shall be compounded on an annual basis in accordance with the provisions of article 1343-2 of the French Civil Code (*Code civil*).

(c) **Interest Payment Dates**. Accrued interest on the Loans shall be payable in arrears on each Payment Date in cash, and upon the payment or prepayment of the Loans (on the principal amount being so paid or prepaid); provided that interest payable at the Default Rate shall also be payable in cash from time to time on demand by the Administrative Agent.

(d) **PIK Interest**. Notwithstanding **Section 3.02(c)**, prior to April 26, 2024, the Borrower may pay an amount of interest on the outstanding principal amount of Loans corresponding to 600 basis points of the Interest Rate then applicable pursuant to **Section 3.02(a)** in kind (in lieu of payment in cash for such portion, with the remainder to be paid in cash) on each applicable Payment Date, by irrevocable written election of the Borrower to the Administrative Agent, to be delivered either (i) prior to 3:00 p.m. (Eastern time) at least six (6) Business Days (or such shorter period as the Administrative Agent may agree) prior to such Payment Date or (ii) if the Borrower wishes to elect payment in kind on an annual basis, notification of such annual election prior to 3:00 p.m. (Eastern time) at least six (6) Business Days (or such shorter period as the Administrative Agent may agree) prior to the first Payment Date in the relevant calendar year; provided that, upon such written election by Borrower, Borrower shall be deemed to have continued to make the same election on each subsequent Payment Date until Borrower delivers a written notice to Administrative Agent changing such election. The aggregate outstanding principal amount of the Loan shall be automatically increased without the need for any action by any Person and capitalized on such Payment Date by the amount of such interest paid in kind in accordance with this **Section 3.02(d)**. For the avoidance of doubt, the portion of the interest payable pursuant to **Section 3.02(a)** not paid in kind shall be paid in cash.

3.03 Prepayments.

(a) **Optional Prepayments**.

(i) Subject to prior written notice pursuant to **clause (ii)** below, the Borrower shall have the right to optionally prepay in whole or in part the outstanding principal amount of the Loans and/or any tranche thereof (i.e., any of the Tranche A Term Loans, the Tranche B Term Loans, the Tranche C Term Loans and the Tranche D Term Loans) on any Business Day for an amount equal to the sum of (A) the aggregate principal amount of the Loans being prepaid, (B) any accrued but unpaid interest on the principal amount of the Loans being prepaid, (C) any applicable Yield Protection Premium and (D) the Exit Fee and any other unpaid amounts then due and owing pursuant to this Agreement and the other Loan Documents (such aggregate amount, the "***Prepayment Price***"); provided that each partial prepayment of principal of Loans shall be in an

aggregate amount at least equal to $5,000,000 and integral multiples of $1,000,000 in excess thereof (or any remaining outstanding principal amount of the Loans and/or any tranche thereof).

(ii) A notice of optional prepayment shall be effective only if received by the Administrative Agent not later than 2:00 p.m. (Eastern time) on a date not less than three (3) (nor more than seven (7)) Business Days prior to the proposed prepayment date; provided that a notice of optional prepayment may state that such notice is conditional upon the effectiveness of other credit facilities or the receipt of the proceeds from the issuance of other Indebtedness or the occurrence of some other identifiable event or condition, in which case such notice of prepayment may be revoked by the Borrower (by notice to the Administrative Agent on or prior to the specified date of prepayment) if such condition is not satisfied. Each notice of optional prepayment shall specify the proposed prepayment date, the Prepayment Price, the principal amount to be prepaid, the applicable tranche or tranches to be prepaid (if a partial prepayment) and any conditions to prepayment (if applicable).

(b) **Mandatory Prepayments**.

(i) **Mandatory Prepayments for Casualty Events or Asset Sales**. Within three (3) Business Days following the receipt of Net Cash Proceeds from the occurrence of any Casualty Event or within three (3) Business Days from the occurrence of any Asset Sale (other than pursuant to **Section 9.09 (a), (b), (c), (d), (e), (f), (h), (m), (n), (o),** or **(p)**) for which the Net Cash Proceeds from such individual Casualty Event or Asset Sale exceeds $2,500,000, or which causes the aggregate total of Net Cash Proceeds from all such Casualty Events or Asset Sales to exceed $5,000,000, the Borrower shall make a mandatory prepayment of the Loans, together with any accrued but unpaid interest on any principal amount of the Loans being prepaid and any applicable Yield Protection Premium and Exit Fee (collectively, the "***Mandatory Prepayment***"), which Mandatory Prepayment (which, for avoidance of doubt, shall include any accrued but unpaid interest on any principal amount of the Loans being prepaid and any applicable Yield Protection Premium and Exit Fee) shall be in an amount equal to one hundred percent (100%) of the Net Cash Proceeds received by the Borrower or any of its Subsidiaries with respect to such Asset Sale or insurance proceeds or condemnation awards in respect of such Casualty Event (above the foregoing thresholds), as the case may be; provided that, so long as no Default has occurred and is continuing or shall result therefrom, if, within three (3) Business Days following the receipt of such Net Cash Proceeds, a Responsible Officer of the Borrower delivers to the Administrative Agent a written notice to the effect that the Borrower or the applicable Subsidiary intends to apply the Net Cash Proceeds from such Asset Sale (which Net Cash Proceeds, in the case of an Asset Sale, shall be in an aggregate amount of less than $2,500,000) or insurance proceeds or condemnation awards in respect of such Casualty Event, to reinvest in the business of the Borrower or any of its Subsidiaries (a "***Reinvestment***"), then such Net Cash Proceeds of such Asset Sale or insurance proceeds or condemnation awards in respect of such Casualty Event may be applied for such purpose in lieu of such mandatory prepayment to the extent such Net Cash Proceeds of such Asset Sale or insurance proceeds or condemnation awards in respect of such Casualty Event are actually applied for such purpose; provided, further, that, if such Casualty Event or Asset Sale occurs with respect to any Obligor, such Reinvestment shall be made in the business of an Obligor; provided, further, that, in the event that Net Cash Proceeds have not been so applied within two hundred seventy (270) days following the receipt of such Net Cash Proceeds with respect to an Asset Sale or within three hundred sixty-five (365) days following the receipt of such Net Cash

Proceeds with respect to a Casualty Event (such applicable period, the "***Reinvestment Period***") (or, if the Borrower or any of its Subsidiaries has entered into a binding commitment prior to the last day of such Reinvestment Period to reinvest such proceeds no later than ninety-five (95) days following the last day of the Reinvestment Period, ninety-five (95) days after the expiry of the Reinvestment Period (or such longer period as the Administrative Agent may agree), the Borrower shall no later than the end of such period make a Mandatory Prepayment (which, for avoidance of doubt, shall include any accrued but unpaid interest on any principal amount of the Loans being prepaid and any applicable Yield Protection Premium and Exit Fee) in an aggregate amount equal to one hundred percent (100%) of the unused balance of such Net Cash Proceeds received by any Obligor or any of its Subsidiaries with respect to such Asset Sale or insurance proceeds or condemnation awards in respect of such Casualty Event.

(ii) **Mandatory Prepayments for Debt Issuances**. Immediately upon receipt by any Obligor or any of its Subsidiaries of proceeds from any issuance, incurrence or assumption of Indebtedness other than Indebtedness permitted by **Section 9.01**, the Borrower shall prepay the Loans and other Obligations in an amount equal to 100% of the cash proceeds received, *plus* the Yield Protection Premium, if applicable and the Exit Fee.

(iii) **Notice**. A notice of mandatory prepayment shall be effective only if received by the Administrative Agent not later than 2:00 p.m. (New York City time) on a date not less than one (1) Business Day (or such shorter period agreed by the Administrative Agent) prior to the proposed prepayment date. Each notice of mandatory prepayment shall specify the proposed prepayment date, the amount of the Mandatory Prepayment, the principal amount to be prepaid and the subsection under which the prepayment is required.

(c) **Application**. All optional prepayments of the Loans shall be applied in the manner specified by the Borrower at the time of such prepayment, including to any principal installments on the Loans; provided that if not specified by the Borrower, optional prepayments of the Loans shall be applied to principal installments of the Loans in the direct order of maturity. All mandatory prepayments of the Loans shall be applied first to the next two (2) scheduled principal installments on the Loans in direct order of maturity and second to principal installments on the Loans ratably among such remaining installments by maturity.

(d) **Yield Protection Premium**. Without limiting the foregoing, whenever the Yield Protection Premium is in effect and payable pursuant to the terms hereof, such Yield Protection Premium shall be payable on each prepayment of all or any portion of the Loans, whether by optional or mandatory prepayment, acceleration or otherwise (other than any scheduled amortization payment).

(e) **Partial Prepayments**. Prepayments shall be accompanied by accrued interest to the extent required by **Section 3.02** and the applicable Exit Fee.

3.04 Commitment Termination. Each Applicable Commitment shall terminate automatically without further action upon the earlier of (a) the making by the Lenders of the Loans to which such Applicable Commitment relates on the Applicable Funding Date and (b) the last day of the Applicable Availability Period. The Borrower shall have the right at any time or from time to time to terminate in full (but not in part) all of the then outstanding Applicable Commitments with

respect to the Tranche B Term Loans, the Tranche C Term Loans and the Tranche D Term Loans; provided that the Borrower shall give the Lender and the Administrative Agent at least three (3) Business Days' written notice of each such termination. Any notice of termination delivered pursuant to this **Section 3.04** may state that such notice is conditional upon the effectiveness of other credit facilities or the receipt of the proceeds from the issuance of other Indebtedness or the occurrence of some other identifiable event or condition, in which case such notice of termination may be revoked by the Borrower (by written notice to the Administrative Agent on or prior to the specified date of termination) if such condition is not satisfied. The termination of any Applicable Commitment shall be permanent.

3.05 Exit Fee. Upon any payment or prepayment in full or in part of the Loans hereunder, whether voluntary or involuntary, prior to, on or after the Maturity Date or following the acceleration of the Obligations hereunder, including as a result of the commencement of any Insolvency Proceeding, the Borrower shall pay to each of the Lenders for its own account a fee equal to 3.0% of the aggregate principal amount of such Loans to be paid or prepaid (the "***Exit Fee***"). The Exit Fee shall be earned, due and payable immediately upon any such payment or prepayment, and shall be in addition to any accrued and unpaid interest, reimbursement obligations, Yield Protection Premium or other amounts payable in connection therewith.

3.06 Original Issue Discount. The Borrower and the Lenders acknowledge that the Loans will be treated as issued with original issue discount for U.S. federal tax purposes, within the meaning of section 1273 of the Code. The issue price, amount of original issue discount, issue date and yield to maturity for the Loans may be obtained by submitting a written request for such information to the Borrower care of the Chief Financial Officer at Establishment Labs Holdings Inc., Building B15 and 25, Coyol Free Zone, Alajuela, Costa Rica (which request shall also be sent via email to rdenhoy@establishmentlabs.com).

SECTION 4.
PAYMENTS, ETC.

4.01 Payments.

(a) **Payments Generally**. Subject to **Section 3.02(d)**, each payment of principal, interest and other amounts to be made by the Obligors under this Agreement or any other Loan Document shall be made (i) in Dollars, in immediately available funds, without deduction, set off or counterclaim, to the Administrative Agent, for the account of the respective Lenders to which such payment is owed, to the deposit account of the Administrative Agent designated by the Administrative Agent by notice to the Borrower, and (ii) not later than 2:00 p.m. (Eastern time) on the date on which such payment is due (each such payment made after such time on such due date may, in the Administrative Agent's discretion, be deemed to have been made on the next succeeding Business Day).

(b) **Application of Payments**. Notwithstanding anything herein to the contrary, following the occurrence and continuance of an Event of Default, all payments shall be applied as follows:

(i) first, to the payment of that portion of the Obligations constituting unpaid fees, indemnities, expenses or other amounts (including fees and disbursements and other charges of counsel payable under **Section 14.03**) payable to the Administrative Agent in its capacity as such;

(ii) second, to the payment of that portion of the Obligations constituting unpaid fees, indemnities, costs, expenses and other amounts (other than principal and interest, but including fees and disbursements and other charges of counsel payable under **Section 14.03**, any Yield Protection Premium and any Exit Fees) payable to the Lenders arising under the Loan Documents, ratably among them in proportion to the respective amounts described in this **clause (B)** payable to them;

(iii) third, to the payment of that portion of the Obligations constituting accrued and unpaid interest on the Loans, ratably among the Lenders in proportion to the respective amounts described in this **clause (C)** payable to them;

(iv) fourth, to the payment of that portion of the Obligations constituting unpaid principal of the Loans, ratably among the Lenders in proportion to the respective amounts described in this **clause (D)** payable to them;

(v) fifth, in reduction of any other Obligation then due and owing, ratably among the Administrative Agent and the Lenders based upon the respective aggregate amount of all such Obligations owing to them in accordance with the respective amounts thereof then due and payable; and

(vi) sixth, the balance, if any, after all Obligations (other than inchoate obligations for indemnification and reimbursement for which no claim has been made) have been paid in full, to the Borrower or such other Person as may be lawfully entitled to or directed by the Borrower to receive the remainder.

(c) **Non-Business Days**. If the due date of any payment under this Agreement (whether in respect of principal, interest, fees, costs or otherwise) would otherwise fall on a day that is not a Business Day, such date shall be extended to the next succeeding Business Day, and, in the case of any payment accruing interest, interest thereon shall continue to accrue and be payable for the period of such extension; provided that if such next succeeding Business Day would fall after the Maturity Date, payment shall be made on the immediately preceding Business Day.

4.02 Computations. All computations of interest and fees hereunder shall be computed on the basis of a year of three hundred and sixty (360) days and actual days elapsed during the period for which payable. For the avoidance of doubt, no date of payment shall be included in any computation.

4.03 Set-Off.

(a) **Set-Off Generally**. Upon the occurrence and during the continuance of any Event of Default, the Administrative Agent, each of the Lenders and each of their Affiliates is hereby authorized at any time and from time to time, to the fullest extent permitted by Law, to set off and apply, in accordance with the applicable Laws, any and all deposits (general or special, time or

demand, provisional or final) at any time held and other indebtedness at any time owing by the Administrative Agent, any Lender and any of their Affiliates to or for the credit or the account of any Obligor against any and all of the Obligations, whether or not such Person shall have made any demand and although such obligations may be unmatured; provided, that, in the event that any Defaulting Lender shall exercise any such right of setoff, (x) all amounts so set off shall be paid over immediately to the Administrative Agent for further application in accordance with the provisions of **Section 2.07** and, pending such payment, shall be segregated by such Defaulting Lender from its other funds and deemed held in trust for the benefit of the Administrative Agent and the Lenders and (y) the Defaulting Lender shall provide promptly to the Administrative Agent a statement describing in reasonable detail the Obligations owing to such Defaulting Lender as to which it exercised such right of setoff. Any Person exercising rights of set off hereunder agrees promptly to notify the Borrower after any such set-off and application; provided that the failure to give such notice shall not affect the validity of such set-off and application. The rights of the Administrative Agent, the Lenders and each of their Affiliates under this **Section 4.03** are in addition to other rights and remedies (including other rights of set-off) that such Persons may have.

(b) **Exercise of Rights Not Required**. Nothing contained in **Section 4.03(a)** shall require the Administrative Agent, any Lender or any of their Affiliates to exercise any such right or shall affect the right of such Persons to exercise, and retain the benefits of exercising, any such right with respect to any other indebtedness or obligation of any Obligor.

(c) **Payments Set Aside.** To the extent that any payment by or on behalf of any Obligor is made to the Administrative Agent or any Lender, or the Administrative Agent, any Lender or any Affiliate of the foregoing exercises its right of setoff pursuant to this **Section 4.03**, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by the Administrative Agent, such Lender or such Affiliate in its discretion) to be repaid to a trustee, receiver or any other party, in connection with any Insolvency Proceeding or otherwise, then (i) to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred, and (ii) each Lender severally agrees to pay to the Administrative Agent upon demand its applicable share (without duplication) of any amount so recovered from or repaid by the Administrative Agent, plus interest thereon from the date of such demand to the date such payment is made at a rate per annum equal to the Federal Funds Effective Rate from time to time in effect.

SECTION 5.
YIELD PROTECTION, TAXES, ETC.

5.01 Additional Costs.

(a) **Change in Law Generally**. If, on or after the date hereof (or, with respect to any Lender, such later date on which such Lender becomes a party to this Agreement), the adoption of any Law, or any change in any Law, or any change in the interpretation or administration thereof by any court or other Governmental Authority charged with the interpretation or administration thereof, or compliance by the Administrative Agent or any of the Lenders (or its lending office) with any request or directive (whether or not having the force of law) of any such Governmental

Authority, shall impose, modify or deem applicable any reserve (including any such requirement imposed by the Board of Governors of the Federal Reserve System), special deposit, contribution, insurance assessment or similar requirement, in each case that becomes effective after the date hereof (or, with respect to any Lender, such later date on which such Lender becomes a party to this Agreement), against assets of, deposits with or for the account of, or credit extended by, a Lender (or its lending office) or shall impose on a Lender (or its lending office) any other condition affecting the Loans or the Commitment, and the result of any of the foregoing is to increase the cost to such Lender of making or maintaining the Loans, or to reduce the amount of any sum received or receivable by such Lender under this Agreement or any other Loan Document, or subject any Lender to any Taxes on its Loan, Commitment or other obligations, or its deposits, reserves, other liabilities or capital (if any) attributable thereto by an amount reasonably deemed by such Lender in good faith to be material (other than (i) Indemnified Taxes and (ii) Excluded Taxes), then the Borrower shall pay to such Lender, within three (3) Business Days of receipt of the certificate contemplated by **Section 5.01(c)**, such additional amount or amounts as will compensate such Lender for such increased cost or reduction.

(b) **Change in Capital Requirements**. If a Lender shall have determined that, on or after the date hereof (or, with respect to any Lender, such later date on which such Lender becomes a party to this Agreement), the adoption of any Law regarding capital adequacy, or any change therein, or any change in the interpretation or administration thereof by any Governmental Authority charged with the interpretation or administration thereof, or any request or directive regarding capital adequacy (whether or not having the force of law) of any such Governmental Authority, in each case that becomes effective after the date hereof (or, with respect to any Lender, such later date on which such Lender becomes a party to this Agreement), has or would have the effect of reducing the rate of return on capital of a Lender (or its parent) as a consequence of a Lender's obligations hereunder or the Loans to a level below that which a Lender (or its parent) could have achieved but for such adoption, change, request or directive by an amount reasonably deemed by it to be material, then the Borrower shall pay to such Lender, within three (3) Business Days of receipt of the certificate contemplated by **Section 5.01(c)**, such additional amount or amounts as will compensate such Lender (or its parent) for such reduction.

(c) **Notification by Lender**. Each Lender promptly will notify the Borrower of any event of which it has knowledge, occurring after the date hereof (or, with respect to any Lender, such later date on which such Lender becomes a party to this Agreement), which will entitle such Lender to compensation pursuant to this **Section 5.01**. Before giving any such notice pursuant to this **Section 5.01(c)** such Lender shall designate a different lending office if such designation (x) will, in the reasonable judgment of such Lender, avoid the need for, or reduce the amount of, such compensation and (y) will not, in the reasonable judgment of such Lender, be materially disadvantageous to such Lender. A certificate of such Lender claiming compensation under this **Section 5.01**, setting forth the additional amount or amounts to be paid to it hereunder, shall be conclusive and binding on the Borrower in the absence of manifest error. The Borrower shall not be required to compensate a Lender pursuant to the foregoing provisions of this **Section 5.01** for any increased costs incurred or reductions suffered more than six (6) months prior to the date that such Lender notifies the Borrower of the change in law giving rise to such increased costs or reductions and of such Lender's intention to claim compensation therefor (except that, if the change in law giving rise to such increased costs or reductions is retroactive, then the six-month period referred to above shall be extended to include the period of retroactive effect thereof).

(d) Notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to constitute a change in Law for all purposes of this **Section 5.01**, regardless of the date enacted, adopted or issued.

5.02 [Reserved].

5.03 Taxes.

(a) **Payments Free of Taxes**. Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by any Law. If any Law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Laws and, if such Tax is an Indemnified Tax, then the sum payable by such Obligor shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this **Section 5.03**) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) **Payment of Other Taxes by the Obligors**. The Obligors shall timely pay to the relevant Governmental Authority in accordance with applicable Laws, or at the option of the Administrative Agent or each Lender, timely reimburse it for the payment of any Other Taxes.

(c) **Evidence of Payments**. As soon as practicable after any payment of Taxes by an Obligor to a Governmental Authority pursuant to this **Section 5.03**, such Obligor shall deliver to the Administrative Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Administrative Agent.

(d) **Indemnification by the Obligors**. The Obligors shall reimburse and indemnify each Recipient, within ten (10) days after written demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this **Section 5.03**) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to the Obligors by a Lender (with a copy to the Administrative Agent), or by the Administrative Agent on its own behalf or on behalf of a Lender shall be conclusive absent manifest error.

(e) **Indemnification by the Lender**. Each Lender shall severally indemnify the Administrative Agent, within ten (10) days after demand therefor, for (i) any Indemnified Taxes

attributable to such Lender (but only to the extent that the Obligors have not already indemnified the Administrative Agent for such Indemnified Taxes and without limiting the obligation of the Obligors to do so), and (ii) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by the Administrative Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by the Administrative Agent shall be conclusive absent manifest error. Each Lender hereby authorizes the Administrative Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by the Administrative Agent to the Lender from any other source against any amount due to the Administrative Agent under this **Section 5.03(e)**.

(f) **Status of Lenders**.

(i) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Administrative Agent, at the time or times reasonably requested by the Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Administrative Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by the Borrower or the Administrative Agent, shall deliver such other documentation prescribed by Law as reasonably requested by the Borrower or the Administrative Agent as will enable the Borrower or the Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two (2) sentences, the completion, execution and submission of such documentation (other than such documentation set forth in **Section 5.03(f)(ii)(A), (v)(B),** and **(v)(D)**) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

(ii) Without limiting the generality of the foregoing, in the event that the Borrower is a U.S. Person:

(A) any Lender that is a U.S. Person shall deliver to the Borrower and the Administrative Agent on or prior to the date on which such Lender becomes a Lender under or party to this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), executed copies of IRS Form W-9 (or successor form) certifying that such Lender is exempt from U.S. federal backup withholding tax;

(B) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Administrative Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under or party to this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), whichever of the following is applicable:

(1) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest

under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E as applicable (or successor forms) establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E as applicable (or successor forms) establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) executed copies of IRS Form W-8ECI (or successor form);

(3) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of **Exhibit I-1** to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3)(A) of the Code, a "10-percent shareholder" of the Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to the Borrower as described in Section 881(c)(3)(C) of the Code (a "***U.S. Tax Compliance Certificate***") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E as applicable (or successor forms); or

(4) to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY (or successor form), accompanied by IRS Form W-8ECI (or successor form), IRS Form W-8BEN or IRS Form W-8BEN-E (or successor form), a U.S. Tax Compliance Certificate, substantially in the form of **Exhibit I-2** or **I-3**, IRS Form W-9 (or successor form), and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of **Exhibit I-4** on behalf of each such direct and indirect partner.

(C) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Administrative Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under or party to this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), executed copies of any other form prescribed by applicable Laws as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable Laws to permit the Borrower or the Administrative Agent to determine the withholding or deduction required to be made; and

(D) if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to the Borrower and the Administrative Agent at the time or times prescribed by law and at such time or times reasonably requested by the Borrower or the Administrative Agent such documentation prescribed by applicable Law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by the Borrower or the Administrative Agent as may be necessary for the Borrower and the Administrative Agent to comply with their obligations

under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this **clause (D)**, "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Administrative Agent in writing of its legal inability to do so.

(g) **Treatment of Certain Tax Benefits**. If any party to this Agreement determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this **Section 5** (including by the payment of additional amounts pursuant to this **Section 5**), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this **Section 5** with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party incurred in connection with such refund and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this **Section 5.03(g)** (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this **Section 5.03(g)**, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this **Section 5.03(g)** the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This **Section 5.03(g)** shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

5.04 Mitigation Obligations; Replacement of Lenders.

(a) If ~~the Borrower~~any Obligor is required to pay any Indemnified Taxes or additional amounts to any Lender or to any Governmental Authority for the account of any Lender pursuant to **Section 5.01** or **Section 5.03**, or if any amount payable under an Obligation by an Obligor becomes not deductible from that Obligor's taxable income for French tax purposes by reason of that amount being (i) paid or accrued to a Recipient incorporated, domiciled, established or acting through a lending office situated in a Non-Cooperative Jurisdiction or (ii) paid to an account opened in the name of or for the benefit of that Recipient in a financial institution situated in a Non-Cooperative Jurisdiction, then such Lender shall (at the request of the Borrower) use commercially reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign and delegate its rights and obligations hereunder to another of its offices, branches or Affiliates if, in the sole reasonable judgment of such Lender, such designation or assignment and delegation would (i) eliminate or reduce amounts payable pursuant to **Section 5.01** or **Section~~-~~ 5.03**, as the case may be, in the future, (ii) not subject such Lender to any unreimbursed cost or expense and (iii) not otherwise be disadvantageous to such Lender. The

Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment and delegation.

(b) If any Lender requests compensation pursuant to **Section 5.01**, or if the Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or to any Governmental Authority for the account of any Lender pursuant to **Section 5.01** or **Section 5.03**, or if any amount payable under an Obligation by an Obligor becomes not deductible for French tax purposes as described in **Section 5.04(a)** above, and such Lender has declined or is unable to designate a different lending office in accordance with **Section 5.04(a)**, or if any Lender is a Defaulting Lender, then the Borrower may, at such Lender's sole expense and effort, upon notice to such Lender and the Administrative Agent, require such Lender to assign and delegate, without recourse (in accordance with and subject to the restrictions contained in, and consents required by, **Section 14.05(b)** (other than such Lender's consent)), all of its interests, rights (other than its existing rights to payments pursuant to **Section 5.01** or **Section 5.03**) and obligations under this Agreement and the related Loan Documents to any assignee permitted under **Section 14.05(b)** that shall assume such obligations (which assignee may be another Lender, if a Lender accepts such assignment); provided that: (i) the Borrower shall have paid to the Administrative Agent the assignment fee (if any) specified in **Section 14.05(b)**; (ii) such Lender shall have received payment of an amount equal to (A) the outstanding principal of its Loans, (B) accrued interest thereon, (C) accrued fees and (D) all other amounts payable to it hereunder and under the other Loan Documents from the assignee (to the extent of such outstanding principal and accrued interest and fees) or the Borrower (in the case of all other amounts); (iii) in the case of any such assignment resulting from a claim for compensation under **Section 5.01** or payments required to be made pursuant to **Section 5.03**, such assignment will result in a reduction in such compensation or payments thereafter; and (iv) such assignment does not conflict with applicable Law. A Lender shall not be required to make any such assignment or delegation if, prior thereto, as a result of a waiver by such Lender or otherwise, the circumstances entitling the Borrower to require such assignment and delegation cease to apply.

5.05 Survival. Each party's obligations under this **Section 5** shall survive the resignation or replacement of the Administrative Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all Obligations under any Loan Document.

SECTION 6.
CONDITIONS

6.01 Conditions to the Closing Date. The obligation of each Lender to make the Tranche A Terms Loans shall be subject to the delivery of a Borrowing Notice as required pursuant to **Section 2.02** and the prior or concurrent satisfaction or waiver of each of the conditions precedent set forth below in this **Section 6.01**.

(a) **Loan Documents**. The Administrative Agent shall have received each Loan Document required to be executed by the appropriate Obligor on the Closing Date and delivered by each applicable Obligor in such number as reasonably requested by the Administrative Agent (which may be delivered by electronic means for the purposes of satisfying this clause (a) on the

Closing Date) and such Loan Documents shall be in form and substance satisfactory to the Administrative Agent and the Lenders and their respective counsels.

(b) **Brazil**. The Administrative Agent shall have received evidence satisfactory to it that arrangements have been made with respect to all registrations, notices or actions required under this Agreement to be effected, including the sworn translation, notarization, consularization or apostillation, as applicable, to register, file and record this Agreement in the competent registry of deeds and documents in Brazil.

(c) **Secretary's Certificate, Etc.** The Administrative Agent shall have received from each Obligor (x) a copy of a good standing certificate or equivalent, to the extent such exists in the relevant jurisdiction of organization or incorporation of such Obligor, dated a date reasonably close to the Closing Date, for each such Person and (y) a certificate, dated as of the Closing Date, duly executed and delivered by such Person's Responsible Officer, as to:

(i) resolutions of each such Person's Board then in full force and effect~~,~~ (or, in the case of a German Guarantor, a resolution of such German Guarantor's shareholder(s)), authorizing the execution, delivery and performance of each Loan Document to be executed by such Person and the Transactions (and, with respect to (A) the Belgian Obligors, the reasons it is considered that the entry into this Agreement and the assumption of the Guaranty in particular is of benefit to such Belgian Obligor and (B) the Costa Rican Guarantor, the relevant resolution pursuant to Article 32Ter of the Costa Rican Commercial Code);

(ii) the incumbency (as applicable) and signatures of Responsible Officers authorized to execute and deliver each Loan Document to be executed by such Person;

(iii) the full force and validity of each Organic Document of such Person and copies thereof; and

(iv) in respect of the Borrower, a registered agent's certificate issued by the Borrower's BVI registered agent dated no more than one (1) month prior to the date of this Agreement with certified copies of the Borrower's register of members, register of directors and register of charges (if any);

which certificates shall be in form and substance reasonably satisfactory to the Administrative Agent and upon which the Administrative Agent and the Lenders may conclusively rely until they shall have received a further certificate of the Responsible Officer of any such Person updating the prior certificate of such Person.

(d) **Perfection Certificate**. The Administrative Agent shall have received a fully completed Perfection Certificate in form and substance reasonably satisfactory to the Administrative Agent, dated as of the Closing Date, duly executed and delivered by a Responsible Officer of the Borrower. All documents and agreements required to be appended to the Perfection Certificate, shall be in form and substance reasonably satisfactory to the Administrative Agent, shall have been executed and delivered by the requisite parties and shall be in full force and effect.

(e) **Funding Date Certificate**. The Administrative Agent shall have received a Funding Date Certificate, dated as of the Closing Date and substantially in the form of **Exhibit C**, duly executed and delivered by a Responsible Officer of the Borrower.

(f) **Delivery of Notes**.

(i) Each Lender shall have received a Note for the Tranche A Term Loans to the extent requested by such Lender at least one (1) Business Day prior to the Closing Date and pursuant to **Section 2.04**, duly executed and delivered by a Responsible Officer of the Borrower.

(ii) Each Lender shall have received a Costa Rican Note for the Tranche A Term Loans at least one (1) Business Day prior to the Closing Date and pursuant to **Section 2.04(b)**, duly executed and delivered by a Responsible Officer of the Costa Rican Guarantor.

(g) **Financial Information, Etc.** The Administrative Agent shall have received, or such information shall be publicly available on "EDGAR," (i) audited consolidated financial statements of the Borrower and its Subsidiaries for the fiscal year ended December 31, 2021 and (ii) the unaudited consolidated balance sheet of the Borrower and its Subsidiaries for the first fiscal quarter ended after December 31, 2021 together with the related consolidated statement of operations and cash flows for such fiscal quarter.

(h) **Solvency**. The Administrative Agent shall have received a solvency certificate, in the form of **Exhibit J** duly executed and delivered by a director of the Borrower, dated as of the Closing Date.

(i) **Security Documents**. The Administrative Agent shall have received an executed counterpart of the Security Agreement, in form and substance reasonably acceptable to the Administrative Agent, dated as of the Closing Date, duly executed and delivered by each Obligor, together with all documents required to be delivered or filed under the Security Documents (other than those to be delivered following the Closing Date pursuant to **Section 8.17**) and evidence satisfactory to it that arrangements have been made with respect to all registrations, notices or actions required under the Security Documents to be effected, given or made in order to establish a valid and perfected first priority security interest in the Collateral in accordance with the terms of the Security Documents, including:

(i) in the case of Equity Interests that are uncertificated securities (as defined in the UCC), confirmation and evidence reasonably satisfactory to the Administrative Agent and the Lenders that the security interest required to be pledged therein under the Security Agreement has been transferred to and perfected by the Administrative Agent and the Lenders in accordance with Articles 8 and 9 of the NY UCC and all laws otherwise applicable to the perfection of the pledge of such Equity Interests;

(ii) financing statements naming each Obligor as a debtor and the Administrative Agent as the secured party, or other similar instruments or documents, in each case suitable for filing, filed under the UCC (or equivalent law) of all jurisdictions as may be necessary or, in the opinion of the Administrative Agent, desirable to perfect the Liens of the Secured Parties pursuant to the Security Agreement;

(iii) UCC-3 termination statements and/or any equivalent termination statements or satisfaction statements required to be delivered to any other registries, if any, necessary to release all Liens and other rights of any Person in any collateral described in the Security Agreement previously granted by any Person (other than with respect to Permitted Liens);

(iv) all applicable Short-Form IP Security Agreements required to be provided under the Security Agreement, each dated as of the Closing Date, duly executed and delivered by each applicable Obligor; and

(v) the Intercompany Subordination Agreement or such other subordination agreement in form and substance reasonably satisfactory to the Administrative Agent.

(j) **Lien Searches**. The Administrative Agent shall be satisfied with Lien searches regarding the Borrower and the Subsidiary Guarantors made as of a date reasonably close to the Closing Date.

(k) **Opinions of Counsel**. The Administrative Agent shall have received a duly executed legal opinion of (i) New York counsel to the Obligors, (ii) Costa Rican counsel to the Administrative Agent, (iii) BVI counsel to the Administrative Agent, (iv) Belgian counsel to the Administrative Agent and (v) Brazilian counsel to the Administrative Agent, in each case dated as of the Closing Date, in form and substance reasonably acceptable to the Administrative Agent.

(l) **Fee Letter**. The Administrative Agent shall have received an executed counterpart of the Fee Letter, duly executed and delivered by the Borrower.

(m) **Closing Fees, Expenses, Etc**. Each of the Administrative Agent and each Lender shall have received for its own account, (i) the upfront fee as set forth in the Fee Letter, which shall be paid by way of the Administrative Agent retaining such amount from the proceeds of the Loan and (ii) all fees, costs and expenses due and payable to it pursuant to the Fee Letter and **Section 14.03**, including all reasonable and documented closing costs and fees and all unpaid reasonable and documented expenses of the Administrative Agent and the Lenders incurred in connection with the Transactions (including the Administrative Agent's and the Lenders' reasonable and documented legal fees and expenses), plus fees and expenses of any local counsel, plus all collateral filing fees and security fees, in each case, (A) to the extent invoiced (or as to which a good faith estimate has been provided to the Borrower) at least two (2) Business Days prior to the Closing Date and (B) in the case of the fees, costs and expenses pursuant to clause (ii), net of any amounts previously paid by the Borrower to the Administrative Agent or any Lender as a deposit against such fees, costs and expenses.

(n) **Material Adverse Change**. Since December 31, 2021, no event, circumstance or change shall have occurred that has caused or could reasonably be expected to cause, either individually or in the aggregate, a Material Adverse Change, both before and after giving effect to the Loans to be made on the Closing Date.

(o) **Know Your Customer**. (i) The Administrative Agent shall have received, as applicable, all documentation and other information required by bank regulatory authorities under applicable "know your customer" and Anti-Terrorism Laws, and a duly executed IRS Form W-9 or applicable IRS Form W-8 (or other applicable tax form) of the Borrower and (ii) the

Administrative Agent and/or the Lenders, as applicable, shall have received all other "know your customer" documentation and other information requested from the Borrower prior to the Closing Date.

(p) **No Default**. No event shall have occurred or be continuing that would constitute a Default or Event of Default.

(q) **Representations and Warranties**. The representations and warranties contained in this Agreement and in the other Loan Documents delivered pursuant to **Section 6.01(a)** shall be true and correct in all material respects (unless such representations are already qualified by reference to materiality, Material Adverse Effect or similar language, in which case such representations and warranties shall be true and correct in all respects) on and as of the Closing Date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects on and as of such earlier date.

(r) **Minimum Liquidity**. The Administrative Agent shall have received written evidence reasonably satisfactory to it that, as of the Closing Date, the Borrower is in compliance with **Section 10.01**.

(s) **Beneficial Ownership Certificate**. To the extent requested by any Lender or the Administrative Agent at least three (3) Business Days prior to the Closing Date, the Borrower shall have provided to such Lender and the Administrative Agent all documentation and other information so requested, including a duly executed IRS Form W-9 or applicable IRS Form W-8 of the Borrower (or such other applicable tax form), in connection with applicable "know your customer" and anti-money laundering rules and regulations, including the Patriot Act, and if the Borrower qualifies as a "legal entity customer" under the Beneficial Ownership Regulation, a Beneficial Ownership Certification, in each case prior to the Closing Date.

(t) **Tranche A Funding Condition**. The Tranche A Funding Condition shall have been satisfied as set forth on the Loans Schedule.

(u) **Repayment of Existing Indebtedness**. The Administrative Agent shall have received evidence of the repayment in full and termination of the Existing Indebtedness and the release of all security interests granted in connection therewith, in form and substance satisfactory to the Administrative Agent.

(v) **Payoff Letter**. The Administrative Agent shall have received evidence of the executed payoff letter, in form and substance satisfactory to the Administrative Agent, from Madryn Health Partners, LP and Intermanagement Costa Rica, Ltda (as security agent) in respect of the repayment of the Existing Indebtedness and release of the existing Liens in Costa Rica, in respect of such Existing Indebtedness, specifying that, if such Existing Indebtedness is paid to such existing lenders satisfaction, then such existing lenders and security agent will automatically release any and all Liens securing Existing Indebtedness in Costa Rica, and will take all actions necessary to effect such release, including executing and delivering all reasonably necessary documentation and forms suitable for filing with all appropriate authorities.

6.02 Conditions to the Borrowing of All Loans. The obligation of each Lender to make all Loans (other than the Tranche A Term Loans) shall be subject to the delivery of a Borrowing Notice as required pursuant to **Section 2.02**, and the prior or concurrent satisfaction or waiver of each of the conditions precedent set forth below in this **Section 6.02**:

(a) **Applicable Funding Date Certificate**. The Administrative Agent shall have received a Funding Date Certificate substantially in the form of **Exhibit C** dated as of the Applicable Funding Date, duly executed and delivered by a Responsible Officer of the Borrower.

(b) **Delivery of Notes**.

(i) The Administrative Agent shall have received a Note to the extent requested by any Lender at least one (1) Business Day prior to the Applicable Funding Date and pursuant to **Section 2.04(a)** for the Loans made on such Applicable Funding Date duly executed and delivered by a Responsible Officer of the Borrower.

(ii) The Administrative Agent shall have received a Costa Rican Note for the benefit of each Lender at least one (1) Business Day prior to the Applicable Funding Date and pursuant to **Section 2.04(b)** for the Loans made on such Applicable Funding Date duly executed and delivered by a Responsible Officer of the Costa Rican Guarantor.

(c) **Solvency**. The Administrative Agent shall have received a solvency certificate, in the form of **Exhibit J**, duly executed and delivered by a director of the Borrower, dated as of the Applicable Funding Date.

(d) **Fees, Expenses, Etc.** Each of the Administrative Agent and each Lender shall have received for its own account all fees, costs and expenses due and payable to it on or prior to the Applicable Funding Date pursuant to the Fee Letter and **Section 14.03**, including all reasonable and documented closing costs and fees and all unpaid reasonable and documented expenses of the Administrative Agent and the Lenders incurred in connection with the Transactions (including the Administrative Agent's and the Lenders' reasonable and documented legal fees and expenses) in each case, to the extent invoiced (or as to which a good faith estimate has been provided to the Borrower) at least two (2) Business Days prior to the Applicable Funding Date.

(e) **Material Adverse Change**. Since December 31, 2021, no event, circumstance or change shall have occurred that has caused or could reasonably be expected to cause, either individually or in the aggregate, a Material Adverse Change, both before and after giving effect to the Loans to be made on the Applicable Funding Date.

(f) **No Default**. No event shall have occurred or be continuing or would result from the making of the Loans on the Applicable Funding Date that would constitute a Default or Event of Default.

(g) **Representations and Warranties; Updated Schedules**. The representations and warranties contained in this Agreement and in the other Loan Documents delivered pursuant to **Section 6.01(a)** shall be true and correct in all material respects (unless such representations are already qualified by reference to materiality, Material Adverse Effect or similar language, in which case such representations and warranties shall be true and correct in all respects) on and as of the

Applicable Funding Date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects on and as of such earlier date. The Borrower shall have delivered to the Administrative Agent updated copies of **Schedules 7.06(c)**, **7.12**, **7.16**, **7.17** and **7.23**, to the extent required to satisfy the foregoing requirements set forth in this **Section 6.02(g)**.

(h) **Applicable Funding Condition**. The Applicable Funding Condition shall have been satisfied as set forth on the Loans Schedule.

(i) **Applicable Availability Period**. The Loans shall be borrowed on or prior to the last day of the Applicable Availability Period.

SECTION 7.
REPRESENTATIONS AND WARRANTIES

The Borrower and each other Obligor hereby jointly and severally represents and warrants to the Administrative Agent and each Lender on the Closing Date and each Bringdown Date, as set forth below:

7.01 Power and Authority. Each Obligor and each of its Subsidiaries (i) is duly incorporated or organized, validly existing and, where applicable, in good standing under the Laws of its jurisdiction of incorporation or organization, (ii) has all requisite corporate or other power, and has all Governmental Approvals necessary to own its assets and carry on its business as now being or as proposed to be conducted, except to the extent that failure to have the same could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (iii) is qualified to do business and is in good standing in all jurisdictions in which the nature of the business conducted by it makes such qualification necessary except where failure so to qualify could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and (iv) has full power, authority and legal right to enter into and perform its obligations under each of the Loan Documents to which it is a party and, in the case of the Borrower, to borrow the Loans hereunder.

7.02 Authorization; Enforceability. Each Transaction to which an Obligor is a party (or to which it or any of its assets or properties is subject) are within such Obligor's corporate or other organizational powers and have been duly authorized by all necessary corporate or other organizational action including, if required, approval by all necessary holders of its Equity Interests. This Agreement has been duly executed and delivered by each Obligor and constitutes, and each of the other Loan Documents to which it is a party when executed and delivered by such Obligor will constitute, a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, subject to the Legal Reservations and except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

7.03 Governmental and Other Approvals; No Conflicts. None of the execution, delivery and performance by each Obligor of the Loan Documents to which it is a party or the consummation

by each Obligor of the Transactions (i) requires any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any other Person, except for (w) such as have been obtained or made and are in full force and effect, (x) filings and recordings in respect of perfecting or recording the Liens created pursuant to the Security Documents, (y) any registrations or filings made on or prior to the Closing Date or in the Ordinary Course in connection with the performance under the Loan Documents, and (z) registrations or filings required under applicable securities Laws, (ii) will violate (1) any Law, (2) any Organic Document of any Obligor or any of its Subsidiaries or (3) any order of any Governmental Authority, that in the case of **clause (ii)(1)** or **clause (ii)(3)**, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect, (iii) will violate or result in a default under any Material Agreement binding upon any Obligor or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect or (iv) will result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of any Obligor or any of its Subsidiaries.

7.04 Financial Statements; Material Adverse Change.

(a) **Financial Statements**. The Borrower has heretofore furnished to the Administrative Agent (who shall forward to the Lenders) consolidated financial statements required to be delivered pursuant to this Agreement. Such financial statements present fairly, in all material respects, the consolidated financial position and results of operations and cash flows of the Borrower and its Subsidiaries as of such dates and for such periods in accordance with GAAP, subject to year-end audit adjustments and the absence of footnotes in the case of the statements of the type described in **Section 8.01(a)**.

(b) **No Material Adverse Change**. Since December 31, 2021, no event, circumstance or change has occurred that has caused or could reasonably be expected to cause, individually or in the aggregate, a Material Adverse Change.

7.05 Properties.

(a) **Property Generally**. Each Obligor and each of its Subsidiaries has good and marketable fee simple title to, or valid leasehold interests in, or license to, all its real and personal property material to its business, including (i) all properties and assets, whether tangible or intangible, relating to its Products as of the Closing Date or Product Commercialization and Development Activities with respect to the Products as of the Closing Date, except for minor defects in title that (A) do not materially interfere with its ability to conduct its business as currently conducted or to utilize such properties for their intended purposes and (B) could not reasonably be expected to prevent or materially interfere with the ability of any Obligor or any of its Subsidiaries to conduct any Product Commercialization and Development Activities with respect to the Products as of the Closing Date and (ii) all Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date, subject only to Permitted Liens.

(b) **Intellectual Property**.

(i) Except as set forth in **Schedule 7.05(b)(i)**,

(A) the Obligors are the sole and exclusive legal and beneficial (and to the extent applicable, record) owners of all right, title and interest in and to all Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date and all other Intellectual Property that is, in each case, owned or purported to be owned by the Obligors, free and clear of any Liens or Claims other than Permitted Liens; and

(B) the Obligors own or have sufficient and valid, written rights to use all Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date.

(ii) Without limiting **Section 7.05(b)(i)**, and except as set forth in **Schedule 7.05(b)(ii)**:

(A) other than (1) customary restrictions in in-bound licenses of Intellectual Property and non-disclosure Contracts, or (2) as would have been or is permitted by **Section 9.09**, there are no judgments, licenses, covenants not to sue, grants, Liens (other than Permitted Liens), or other Claims, Contracts or arrangements relating to any Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date, which materially restrict any Obligor or any of its Subsidiaries with respect to its use, enforcement, or other exploitation of any Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date or in connection with any Obligor's Product Commercialization and Development Activities with respect to the Products as of the Closing Date;

(B) the operation and conduct of the business of the Borrower or any of its Subsidiaries, including their use of their respective Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date, does not violate, infringe or constitute a misappropriation of Intellectual Property rights of any other Person (1) as of the Closing Date, in any material respect and (2) as of any Bringdown Date, that could reasonably be expected to result in a Material Adverse Effect or a material adverse effect on any Product Commercialization and Development Activities with respect to Products as of the Closing Date;

(C) (1) there are no pending Claims, or Claims threatened in writing, against any Obligor or any of its Subsidiaries asserted by any other Person relating to Intellectual Property, including any material Claims alleging ownership, invalidity or unenforceability of any Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date, or infringement, misappropriation, or violation of such Person's Intellectual Property in any material respect; and (2) neither any Obligor nor any of its Subsidiaries has received any notice from, or Claim by, any Person that the operation and conduct of the business of the Borrower or any of its Subsidiaries (including their use of Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date), or any Product Commercialization and Development Activities with respect to Products as of the Closing Date, infringes upon, violates or constitutes a misappropriation of, any Intellectual Property of any other Person in each case of **clause (1)** and **(2)**, that would reasonably be expected to result in material liability to any Obligor or any of their Subsidiaries;

(D) to the knowledge of the Obligors, no Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date is being

infringed, violated, or misappropriated by any other Person in any material respect; and neither such Obligor nor any of its Subsidiaries has put any other Person on notice of such actual or potential infringement, violation or misappropriation of any such Material Intellectual Property, and neither any Obligor nor any of their Subsidiaries has initiated any Claim with respect to any such Material Intellectual Property;

(E) all current and former employees and contractors that have developed Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date for or on behalf of any Obligor or any of its Subsidiaries have executed written confidentiality and invention assignment Contracts with such Obligor or such Subsidiary, as applicable, that irrevocably and presently assign to such Obligor or such Subsidiary, as applicable, all rights of such employees and contractors in or to any such Material Intellectual Property;

(F) each Obligor and its Subsidiaries has taken reasonable precautions to protect the secrecy, confidentiality and value of its Material Intellectual Property that constitutes Material Intellectual Property as of the Closing Date consisting of trade secrets and confidential information, and no such trade secrets or confidential information constituting Material Intellectual Property has been used or discovered by, or disclosed to, any Person except pursuant to written, valid and enforceable non-disclosure agreements protecting the confidentiality thereof, which agreements, to the knowledge of each Obligor and its Subsidiaries, have not been breached in any material respect; and

(G) except as would not, individually or in the aggregate, be reasonably expected to be material to any Obligor or any of its Subsidiaries or to the value of any material proprietary software owned or purported to be owned by any Obligor or any of its Subsidiaries that constitute Collateral ("***Material Software***"), no Obligor or any of its Subsidiaries has embedded, used, linked to, distributed or made available any software that is licensed pursuant to any "open source," "copyleft" or similar license in conjunction with any Material Software in a manner that requires (i) any such Material Software to be disclosed, licensed or distributed in source code form or be licensed for the purpose of making derivative works or other modifications; (ii) any restriction on the consideration to be charged for the licensing or distribution of such Material Software; or (iii) the grant to any third party of any rights or immunities under such Material Software.

(iii) With respect to Material Intellectual Property consisting of Patents as of the Closing Date, except as set forth in **Schedule 7.05(b)(iii)**, and without limiting the representations and warranties in **Section 7.05(b)(i)** and **Section 7.05(b)(ii)**:

(A) each of the issued claims in such Patents is valid and enforceable;

(B) subsequent to the issuance of such Patents, no Obligor nor any of its Subsidiaries or predecessors-in-interest, has filed any disclaimer or made or permitted any other voluntary reduction in the scope of the Inventions claimed in such Patents;

(C) to the knowledge of any Obligor, (1) no allowable or allowed subject matter of such Patents is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject

of any interference, and are not and have not been the subject of any re-examination, opposition, or any other post-grant proceedings, nor is any Obligor or its Subsidiaries aware of any basis for any such interference, re-examination, opposition, *inter partes* review, post grant review, or any other post-grant proceedings;

(D) no such Patents have ever been finally adjudicated to be invalid, unpatentable or unenforceable for any reason in any administrative, arbitration, judicial or other proceeding, and, with the exception of publicly available documents with respect to any such Material Intellectual Property, no Obligor nor any of its Subsidiaries has received any written notice asserting that such Patents are invalid, unpatentable or unenforceable; and

(E) all maintenance fees, registration fees, renewal fees, annuities, and the like due or payable on or with respect to any Material Intellectual Property consisting of Patents or Trademarks have been timely paid (1) as of the Closing Date and (2) as of any Bringdown Date, except where failure to so pay would not reasonably be expected to result in a Material Adverse Change.

7.06 No Actions or Proceedings.

(a) **Litigation**. Except as set forth in **Schedule 7.06(a)**, there is no litigation, investigation or proceeding pending or, to the knowledge of any Obligor threatened in writing, with respect to such Obligor or any such Subsidiaries by or before any Governmental Authority or arbitrator that, (i) individually or in the aggregate, could reasonably be expected to have a Material Adverse Effect or (ii) involves this Agreement or any other Loan Document.

(b) **Environmental Matters**. Except with respect to any matters that (either individually or in the aggregate) could not reasonably be expected to result in a Material Adverse Effect, no Obligor nor any of its Subsidiaries (i) has failed to comply with any Environmental Law in all material respects or to obtain, maintain or comply with any material permit, license or other approval required under any Environmental Law, (ii) has become subject to any Material Environmental Liability, (iii) has received any material Environmental Claim, or has knowledge that any is threatened in writing, (iv) has entered into any agreement in which such Obligor or any Subsidiary has assumed or undertaken material responsibility or obligations of any other person with respect to any Material Environmental Liability or (v) has knowledge of any basis for any other Material Environmental Liability.

(c) **Labor Matters**. No Obligor or any of its Subsidiaries has engaged in unfair labor practices as defined in 29 U.S.C. § §152(8) and 158 of the National Labor Relations Act (or similar practices under any equivalent laws or regulations applicable to them in any non-United States jurisdiction) and there are no pending or, to the knowledge of any Obligor, threatened in writing labor actions, disputes, grievances, arbitration proceedings, or similar Claims or actions involving the employees of any Obligor or any of its Subsidiaries, in each case, that could reasonably be expected to have a Material Adverse Effect. There are no strike or work stoppages in existence or, to the knowledge of any Obligor, threatened in writing against such Obligor and to the knowledge of such Obligor, no union organizing activity is taking place, in each case, that could reasonably be expected to have a Material Adverse Effect. Except as set forth on **Schedule 7.06(c)** (as such

schedule may be updated on any Bringdown Date), there are no collective bargaining agreements covering employees of any Obligor or any of its Subsidiaries.

7.07 Compliance with Laws and Agreements.

(a) Each Obligor is in compliance in all material respects with all applicable Laws and all material Contracts binding upon it or its property. No Default has occurred and is continuing. The Obligors and their Subsidiaries are, and all Product Commercialization and Development Activities of such Persons with respect to Products as of the Closing Date are being conducted in compliance with all applicable Healthcare Laws in all material respects.

(b) [Reserved].

(c) Without limiting the generality of the foregoing:

(i) Except where the failure to do so could not reasonably be expected to have any Material Adverse Effect or material adverse effect on any Product Commercialization and Development Activities with respect to Products as of the Closing Date, to the knowledge of the Obligors, any direct ownership, investment or financial interest in the Borrower, any other Obligor or any such Subsidiary by a physician, other licensed healthcare professional, or any other Person who is in a position to refer patients or other business to the Borrower, any other Obligor or any Subsidiaries (collectively, a "**Referral Source**") complies with the Federal Anti-Kickback Statute and all other applicable anti-kickback Laws, whether U.S. or non-U.S.; and

(ii) each Obligor and each of its Subsidiaries has implemented policies and procedures to monitor, collect, and report any payments or transfers of value to certain healthcare providers and teaching hospitals, in accordance, in all material respects, with industry standards and the Affordable Care Act of 2010 and the Physician Payments Sunshine Act and their implementing regulations and state disclosure and transparency laws.

7.08 Taxes. Except as set forth on **Schedule 7.08**, each Obligor and its Subsidiaries has timely filed or caused to be filed all tax returns and reports required to have been filed and has paid or caused to be paid all material taxes required to have been paid by it, except (a) taxes that are being contested in good faith by appropriate proceedings and for which such Obligor or such Subsidiary, as applicable, has set aside on its books adequate reserves with respect thereto in accordance with GAAP or IFRS, as applicable, and (b) to the extent that the failure to do so would not reasonably be expected to have an Material Adverse Effect.

7.09 Full Disclosure. None of the written reports, financial statements, certificates or other written information (other than projections, forward-looking information, budgets, estimates and information of a general economic or industry specific nature) furnished by or on behalf of the Obligors to the Administrative Agent (on behalf of itself and the Lenders) in connection with the negotiation of this Agreement and the other Loan Documents or delivered hereunder or thereunder (as modified or supplemented by other information so furnished) contains when furnished any material misstatement of material fact or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not materially misleading; provided that, with respect to projected financial information, the Borrower represents only that such information was prepared in good faith based upon assumptions believed to be

reasonable at the time delivered, and it being understood that such projected financial information and all other forward looking information are not to be viewed as facts and are subject to uncertainties and contingencies, many of which are beyond the control of the Borrower or any of its Subsidiaries, and that actual results during the period or periods covered thereby may differ from such projected results and that the differences may be material.

7.10 Investment Company Act and Margin Stock Regulation.

(a) **Investment Company Act**. No Obligor is an "investment company" as defined in, or subject to regulation under, the Investment Company Act of 1940, as amended.

(b) **Margin Stock**. No Obligor is engaged principally, or as one of its important activities, in the business of extending credit for the purpose, whether immediate, incidental or ultimate, of buying or carrying Margin Stock, and no part of the proceeds of the Loans will be used, whether immediately, incidentally or ultimately, to buy or carry any Margin Stock, to extend credit to others for the purpose of buying or carrying any Margin Stock, or in any way that is in violation of Regulation T, U or X.

7.11 Solvency. The Obligors, on a consolidated basis, are and, immediately after giving effect to the making of the Loans, the use of proceeds thereof, and the consummation of the Transactions, will be, Solvent.

7.12 Subsidiaries. Set forth on **Schedule 7.12** is a complete and correct list of all direct and indirect Subsidiaries of the Borrower (as such schedule may be updated on any Bringdown Date). Each such Subsidiary is duly organized and validly existing under the jurisdiction of its organization shown in said **Schedule 7.12** (as such schedule may be updated on any Bringdown Date), and the percentage ownership by each Obligor of each such Subsidiary thereof is as shown in said **Schedule 7.12** (as such schedule may be updated on any Bringdown Date).

7.13 [Reserved].

7.14 Material Agreements. Except as set forth on **Schedule 7.14**, no Obligor nor any of its Subsidiaries is in default under any Material Agreement (x) as of the Closing Date, in any material respect and (y) as of any Bringdown Date, that could reasonably be expected to result in a Material Adverse Effect or a material adverse effect on any Product Commercialization and Development Activities with respect to Products as of the Closing Date, nor does any Obligor have knowledge of any written Claim against it or any of its Subsidiaries for any breach of any such Material Agreement in any material respect.

7.15 Restrictive Agreements. Except as set forth in **Schedule 7.15**, as of the Closing Date, no Obligor or any of its Subsidiaries is subject to any Restrictive Agreement, except (i) those permitted under **Section 9.11**, (ii) restrictions and conditions imposed by Law or by the Loan Documents, (iii) any stockholder agreement, charter, by-laws, or other organizational documents of an Obligor or any of its Subsidiaries as in effect on the date hereof and (iv) limitations associated with Permitted Liens.

7.16 Real Property. **Schedule 7.16** correctly sets forth all real property that is owned or leased by the Obligors (as such schedule may be updated on any Bringdown Date), indicating in each

case whether the respective property is owned or leased, the identity of the owner and lessee (if applicable) and the location of the respective property. Except as set forth in **Schedule 7.16** (as such schedule may be updated on any Bringdown Date), no Obligor owns or leases (as tenant thereof) any real property as of the Closing Date.

7.17 Pension Matters. Except as could not reasonably be expected to result in a Material Adverse Effect, each Qualified Plan has received a favorable determination or may rely upon an opinion letter for a prototype plan letter from the IRS or an application for such a letter is currently being processed by the IRS with respect thereto and, as of the date of this Agreement, to the knowledge of the Obligors, nothing has occurred that would reasonably be expected to prevent, or cause the loss of, such qualification. Except as could not, in the aggregate, reasonably be expected to result in a Material Adverse Effect, (x) each Benefit Plan is in compliance with applicable provisions of ERISA, the Code and other applicable Laws, and (y) no ERISA Event has occurred or is reasonably expected to occur. Except as could not reasonably be expected to result in a Material Adverse Effect, each Obligor and each of its ERISA Affiliates has met all applicable requirements under the ERISA Funding Rules with respect to each Title IV Plan. Except as could not reasonably be expected to result in a Material Adverse Effect, as of the most recent valuation date for any Title IV Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Code) is at least sixty percent (60%), and neither any Obligor nor any of its ERISA Affiliates knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage to fall below sixty percent (60%) as of the most recent valuation date. Except as could not reasonably be expected to result in a Material Adverse Effect, as of the Closing Date, no ERISA Event has occurred in connection with which obligations and liabilities (contingent or otherwise) of any Obligor or its Subsidiaries remain outstanding. To the extent applicable, each Foreign Plan has been maintained in compliance with its terms and with the requirements of any and all applicable requirements of law and has been maintained, where required, in good standing with applicable regulatory authorities, except to the extent that the failure so to comply could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect. Except as could not reasonably be expected to result in a Material Adverse Effect, no Obligor, nor any ERISA Affiliate or Subsidiary thereof, has incurred any obligation in connection with the termination of or withdrawal from any Foreign Plan. Except as could not reasonably be expected to result in a Material Adverse Effect, the present value of the accrued benefit liabilities (whether or not vested) under each Foreign Plan that is funded, determined as of the end of the most recently ended fiscal year of the Obligor or ERISA Affiliate or Subsidiary, as applicable, on the basis of actuarial assumptions, each of which is reasonable, did not exceed the current value of the property of such Foreign Plan, and for each Foreign Plan that is not funded, the obligations of such Foreign Plan are properly accrued.

7.18 Regulatory Approvals.

(a) Each Obligor and each of its Subsidiaries holds, either directly or through licensees and agents, all Product Authorizations necessary or required for the Borrower and each of its Subsidiaries to conduct, their respective operations and businesses, including its Product Commercialization and Development Activities with respect to Products as of the Closing Date, in the manner currently conducted (x) as of the Closing Date, in all material respects and (y) as of any Bringdown Date, except in each case, where the failure to hold any such Product Authorizations could not reasonably be expected to result in a Material Adverse Effect or a

material adverse effect on any Product Commercialization and Development Activities with respect to Products as of the Closing Date.

(b) No Obligor nor its Subsidiaries has received any written notice from the FDA or any Regulatory Authority that: (i) the FDA or such Regulatory Authority is considering suspending, revoking or materially limiting any Product Authorization (x) as of the Closing Date or (y) as of any Bringdown Date, where such suspension, revocation or limitation could reasonably be expected to result in a Material Adverse Effect or a material adverse effect on any Product Commercialization and Development Activities with respect to Products as of the Closing Date, or (ii) as of the Closing Date, the FDA or such Regulatory Authority will not likely approve any PMA Clearances or comparable applications submitted to the FDA or such Regulatory Authority with respect to any of the Products or any Material Agreement. To the knowledge of the Obligors, the Obligors and their Subsidiaries have made all required notices, registrations and reports (including field alerts or other reports of adverse drug experiences) and other filings with respect to the Products, and their Product Commercialization and Development Activities, in each case, (x) as of the Closing Date, which are material and (y) as of any Bringdown Date, except where the failure to do so could not reasonably be expected to have a Material Adverse Effect on its Product Commercialization and Development Activities with respect to the Products as of the Closing Date.

(c) Except as set forth on **Schedule 7.18(c)**, and without limiting the generality of any other representation or warranty made by any Obligor hereunder or under any other Loan Document (x) as of the Closing Date and (y) as of any Bringdown Date, except as could not reasonably be expected to have a Material Adverse Effect or a material adverse effect on its Product Commercialization and Development Activities with respect to the Products as of the Closing Date: (i) no Obligor, nor any of its Subsidiaries nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensors or licensees have received any inspection reports, warning letters or similar written notices with respect to Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date, from any Regulatory Authority within the last two (2) years that asserts material lack of compliance with any applicable Healthcare Laws or Product Authorizations; (ii) no Obligor, nor any of its Subsidiaries nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensors or licensees have received any material written notification from any Regulatory Authority within the last two (2) years, asserting that the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date, lacks a Material Product Authorization; (iii) there is no pending regulatory action, investigation (other than non-material routine or periodic inspections or reviews) against any Obligor, any of its Subsidiaries or, to the knowledge of any Obligor, any of their respective suppliers, licensors or licensees with respect to the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date, and, to the knowledge of any Obligor, there is no basis in fact for any material adverse regulatory action against such Obligor or any of its Subsidiaries or, to the knowledge of any Obligor, any of their respective suppliers agents, licensors or licensees with respect to the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date; and (iv) without limiting the foregoing, (A) there have been no material product recalls, safety alerts, corrections,

withdrawals, marketing suspensions, product removals or comparable post-market actions conducted, undertaken or issued by any Obligor or any of its Subsidiaries, whether voluntary, at the request, demand or order of any Regulatory Authority or otherwise, relating to an alleged lack of safety or regulatory compliance with respect to the Products that constitute Products as of the Closing Date, any Product Commercialization and Development Activities with respect to the Products as of the Closing Date or any Material Product Authorization within the last two (2) years, (2) no such product recall, safety alert, correction, withdrawal, marketing suspension, removal or comparable post-market action has been requested, demanded or ordered by any Regulatory Authority within the last two (2) years, and, (3) to the knowledge of any Obligor, there is no basis in fact for the issuance of any such product recall, safety alert, correction, withdrawal, marketing suspension, removal or comparable post-market action relating to an alleged lack of safety or regulatory compliance with respect to the Products that constitute Products as of the Closing Date, any Product Commercialization and Development Activities with respect to the Products as of the Closing Date or any Material Product Authorization; and (B) no criminal, injunctive, seizure, detention or civil penalty action has been commenced or threatened in writing by any Regulatory Authority within the last two (2) years with respect to or in connection with the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date, and there are no consent decrees (including plea agreements) that relate to the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date, and, to the knowledge of each Obligor, there is no basis in fact for the commencement of any criminal injunctive, seizure, detention or civil penalty action by any Regulatory Authority relating to the Products that constitute Products as of the Closing Date, or any Product Commercialization and Development Activities with respect to the Products as of the Closing Date or for the issuance of any consent decree. No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensees or licensors has been debarred within the last two (2) years from any federal healthcare program, where such debarment would reasonably be expect to have a Material Adverse Effect or a material adverse effect on the Product Commercialization and Development Activities with respect to Products as of the Closing Date.

7.19 Mortgages. Subject to **Section 8.17**, each of the Mortgages will be effective, upon delivery of the same to the Administrative Agent in accordance with the terms of this Agreement, to create in favor of the Administrative Agent, for the benefit of the Secured Parties, a legal, valid and enforceable Lien on the Material Real Properties described therein and proceeds thereof, and when the Mortgages are validly filed in the applicable recorder's offices and all relevant mortgage Taxes and recording and registration charges are duly paid, each such Mortgage shall constitute a fully perfected Lien on, and security interest in, all right, title and interest of the Obligors in such Material Real Property and the proceeds thereof, as security for the Obligations, subject only to Permitted Liens.

7.20 OFAC; Anti-Terrorism Laws.

(a) No Obligor nor any of its Subsidiaries is in violation of any Anti-Terrorism Law or engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any applicable Anti-Terrorism Laws.

(b) No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective directors, officers, or employees (i) is currently the target of any Sanctions, (ii) is located, organized or residing in any Designated Jurisdiction in violation of Sanctions, or (iii) is or has been (within the previous five (5) years) engaged in any transaction with, or for the benefit of, any Person who is now or was then the target of Sanctions or who is located, organized or residing in any Designated Jurisdiction, in violation of Sanctions. No Loan, nor the proceeds from any Loan, has been or will be used, directly or, to the knowledge of any Obligor, indirectly, to lend, contribute or provide to, or has been or will be otherwise made available for the purpose of funding, any activity or business in any Designated Jurisdiction in violation of Sanctions or for the purpose of funding any activity or business of any Person located, organized or residing in any Designated Jurisdiction or who is the subject of any Sanctions, in violation of Sanctions, or in any other manner that will result in any violation by any party to this Agreement of Sanctions.

(c) This **Section 7.20** shall only apply to a party hereto, to the extent that it would not result in any violation of, conflict with or liability under (i) EU Regulation (EC) 2271/96, as last amended by EU Regulation (EC) No 1100/2018, (ii) section 7 of the German Foreign Trade Regulation (*Außenwirtschaftsverordnung, AWV*) (in connection with section 4 of the German Foreign Trade Act (*Außenwirtschaftsgesetz, AWG*)) and/or (iii) any other similar antiboycott law or regulation, by such party.

7.21 Anti-Corruption. No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective directors, officers or employees, directly or, to the knowledge of any Obligor, indirectly, has (i) materially violated or is in material violation of any applicable anti-corruption Law, or (ii) made, offered to make, promised to make or authorized the payment or giving of, directly or, to the knowledge of any Obligor, indirectly, any Prohibited Payment.

7.22 Priority of Obligations. Unless otherwise permitted under the terms of the Loan Documents, the Obligations constitute unsubordinated obligations of the Obligors, and except for any obligations which have priority under applicable Law, rank at least pari passu in right of payment with all other unsubordinated Indebtedness of the Obligors.

7.23 Royalty and Other Payments. Unless otherwise permitted under the terms of the Loan Documents and except as set forth on **Schedule 7.23** (as such schedule may be updated on any Bringdown Date), no Obligor, nor any of its Subsidiaries, is obligated to pay any royalty, milestone payment or any other contingent payment in respect of the Products that constitute Products as of the Closing Date.

7.24 Non-Competes. Neither the Borrower, any other Obligor, nor any of their respective Subsidiaries, nor any of their respective directors, officers or employees, is subject to a non-compete agreement that prohibits or will interfere in any material respect with any of the Product Commercialization and Development Activities, including the development, commercialization or marketing of the Products that constitute Products as of the Closing Date.

7.25 Centre of main interest and establishments. For the purposes of the EU Insolvency Regulation, the centre of main interest (as that term is used in Article 3(1) of the EU Insolvency Regulation) of each Obligor which is organized under the laws of a member state of the European

Union is situated in its jurisdiction of incorporation and it has no "establishment" (as that term is used in Article 2(10) of the EU Insolvency Regulation) in any other jurisdiction.

7.26 Data Privacy. Neither any Obligor nor any of their Subsidiaries has experienced any breach of security or unauthorized access by third parties of any personally identifiable information from any individuals, including, without limitation, any customers, prospective customers, employees or other third parties that is in its possession, custody, or control, in each case, except as would not reasonably be expected to have a Material Adverse Effect.

7.27 SEC Documents. The reports, schedules, forms, statements and other documents filed or furnished by the Borrower with the U.S. Securities and Exchange Commission pursuant to the Securities Act or the Exchange Act complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as the case may be, applicable to such documents, and the information contained in such documents is and was true and correct in all material respects and none of such documents contained any untrue statement of a material fact or omitted to state a material fact (including as such documents relate to the real and personal property and the Intellectual Property of the Borrower) necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

7.28 Registration of Borrower. The Borrower shall not take or permit any action that will result in it ceasing to be registered under the BVI BCA.

7.29 No Interest in BVI Land. Neither the Borrower, nor any of its Subsidiaries has an interest in any:

(a) land located in the BVI; or

(b) shares, debt obligations or securities of any body corporate which has an interest in any land located in the BVI.

7.30 Mergers. The Borrower shall not (without the prior written consent of the Majority Lenders in each such case):

(a) merge or consolidate with any person whether pursuant to any of Sections 170 to 174 (inclusive) of the BVI BCA or otherwise;

(b) enter into any amalgamation, demerger, merger, consolidation, arrangement (including, without limitation, a separation of two or more businesses carried on by it), compromise, scheme of arrangement or corporate reorganisation or reconstruction whether pursuant to any of Sections 170 to 174 (inclusive), 177 and 179A of the BVI BCA or otherwise; or

(c) continue as a company incorporated under the laws of a jurisdiction outside the BVI whether pursuant to Section 184 of the BVI BCA or otherwise.

SECTION 8.
AFFIRMATIVE COVENANTS

Each Obligor covenants and agrees with the Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than any inchoate indemnification and expense reimbursement obligations for which no claim has been made) have been paid in full in cash:

8.01 Financial Statements and Other Information. The Borrower will furnish to the Administrative Agent:

(a) as soon as available and in any event within forty-five (45) days after the end of each fiscal quarter of each fiscal year (including the last fiscal quarter of each fiscal year) (i) the consolidated balance sheets of the Borrower and its Subsidiaries as of the end of such fiscal quarter and (ii) the related consolidated statements of income, shareholders' equity and cash flows of the Borrower and its Subsidiaries for such quarter and the portion of the fiscal year through the end of such fiscal quarter, in each case prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with (iii) a certificate of a Responsible Officer of the Borrower stating that (x) such financial statements fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as at such date and (y) the results of operations of the Borrower and its Subsidiaries for the period ended on such date have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes; provided that documents required to be furnished pursuant to this **Section 8.01(a)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or the Borrower's website (without the need to separately deliver the related certificate referred to in (iii) above);

(b) as soon as available and in any event within ninety (90) days after the end of each fiscal year (i) the consolidated balance sheets of the Borrower and its Subsidiaries as of the end of such fiscal year and (ii) the related consolidated statements of income, shareholders' equity and cash flows of the Borrower and its Subsidiaries for such fiscal year, in each case prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of Marcum LLP or another firm of independent certified public accountants of recognized national standing reasonably acceptable to the Administrative Agent, which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to any "going concern" or like qualification or exception or emphasis of matter of going concern footnote or any qualification or exception as to the scope of such audit; provided that documents required to be furnished pursuant to this **Section 8.01(b)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or the Borrower's website;

(c) together with the financial statements required pursuant to **Sections 8.01(a)** and **(b)**, a compliance certificate signed by a Responsible Officer of the Borrower as of the end of the applicable accounting period (which delivery may be by electronic communication including fax or email and shall be deemed to be an original, authentic counterpart thereof for all purposes) substantially in the form of **Exhibit K** (a "***Compliance Certificate***") including (i) details of any

issues that are material that are raised by auditors and any occurrence or existence of any event, circumstance, act or omission that would cause any representation or warranty contained in **Section 7.07**, **Section 7.18** or **Section 7.22** to be incorrect in any material respect (or in any respect if such representation or warranty is qualified by materiality or by reference to Material Adverse Effect or Material Adverse Change) if such representation or warranty were to be made at the time of delivery of a Compliance Certificate, (ii) starting with the Compliance Certificate delivered with respect to the fiscal quarter ending on September 30, 2022, a certificate as to whether or not the Borrower is in compliance with **Section 10.02** and (iii) a list of any Claims made during the applicable fiscal quarter related to any Product or inventory involving more than $2,000,000 (or the Equivalent Amount in other currencies), which list shall include a statement setting forth details of such Claim. For the avoidance of doubt, no representation or warranty contained in **Section 7.07**, **Section 7.18** or **Section 7.22** is required to be, shall be or shall be deemed to be made in connection with a delivery of any Compliance Certificate;

(d) after being prepared by the Borrower and approved by its Board, and promptly following the Administrative Agent's request therefor, a consolidated budget for the Borrower and its Subsidiaries for the fiscal year to which such budget relates; provided that, for each fiscal year, the Borrower shall prepare, and its Board shall approve such consolidated budgets for such fiscal year as required by the Board;

(e) promptly after the same are released, copies of all press releases (other than any press release that is immaterial, routine or administrative in nature); provided that documents required to be furnished pursuant to this **Section 8.01(e)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or the Borrower's website;

(f) promptly, and in any event within five (5) Business Days after receipt thereof by an Obligor thereof, copies of each notice or other correspondence received from any securities regulator or exchange to the authority of which any Obligor may become subject from time to time concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of such Obligor, in each case, excluding any investigation or inquiry that is immaterial, routine or administrative in nature; provided that documents required to be furnished pursuant to this **Section 8.01(f)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or the Borrower's website;

(g) promptly after the same are available, copies of each annual report, proxy or financial statement or other report or communication sent to the stockholders of each Obligor and its Subsidiaries in their capacities as such (other than any report or any communication that is immaterial, routine or administrative in nature), and copies of all annual, regular, periodic and special reports and registration statements which any Obligor or its Subsidiaries may file or be required to file with any securities regulator or exchange to the authority of which such Obligor or such Subsidiary, as applicable, may become subject from time to time; provided that documents required to be furnished pursuant to this **Section 8.01(g)** shall be deemed furnished on the date that such documents are publicly available on "EDGAR" or the Borrower's website;

(h) the information regarding insurance maintained by the Borrower and its Subsidiaries as and when required under **Section 8.05**;

(i) (i) concurrently with the delivery of the Compliance Certificate pursuant to Section 8.01(c), written notice of any Claim related to any Product or inventory involving more than $2,000,000 (or the Equivalent Amount in other currencies), including a statement setting forth details of such Claim and (ii) promptly, and in any event within five (5) Business Days after the Borrower obtains knowledge of any Claim related to any Product or inventory involving more than $5,000,000 (or the Equivalent Amount in other currencies), written notice thereof from a Responsible Officer of the Borrower which notice shall include a statement setting forth details of such Claim;

(j) as soon as possible and in any event within five (5) Business Days after the end of each calendar month, a certificate signed by a Responsible Officer of the Borrower certifying that as of the last day of such calendar month, the Borrower is in compliance with the Minimum Liquidity Amount requirement set forth in **Section 10.01** and upon reasonable request of Administrative Agent, attaching evidence reasonably satisfactory to the Administrative Agent, based upon the Borrower's bank account statements, that the Borrower has met the Minimum Liquidity Amount requirement set out in **Section 10.01**; and

(k) such other information respecting the businesses, financial performance, operations condition of the assets or liabilities of the Obligors (including with respect to the Collateral), taken as a whole, as the Administrative Agent may from time to time reasonably request.

8.02 Notices of Material Events. The Borrower will furnish to the Administrative Agent written notice of the following (w) with respect to **clauses (h)**, **(g)(iii)**, **(g)(v)** and **(n)** below, concurrently with the delivery of the Compliance Certificate pursuant to **Section 8.01(c)** above, (x) with respect to **clause (a)** below, within three (3) Business Days, (y) with respect to **clauses (b), (f),** and **(j)** below, involving an amount exceeding $2,000,000, concurrently with the delivery of the Compliance Certificate pursuant to **Section 8.01(c)** above (with respect to such fiscal quarter) and involving an amount exceeding $10,000,000, within five (5) Business Days of such event, and (z) with respect to **clauses (c), (d), (e), (g)(i), (g)(ii), (g)(iv), (i), (k)**, **(l)** and **(m)** below, within five (5) Business Days, in each case, after a Responsible Officer of the Borrower first learns of or acquires knowledge with respect to:

(a) the occurrence of any Default or Event of Default;

(b) the occurrence of any event with respect to the property or assets of the Borrower or any of its Subsidiaries resulting in a Loss;

(c) (i) any proposed acquisition of stock, assets or property by the Borrower or any of its Subsidiaries that could reasonably be expected to result in Material Environmental Liability, and (ii) any spillage, leakage, discharge, disposal, leaching, migration or release of any Hazardous Material by the Borrower or any of its Subsidiaries required to be reported to any Governmental Authority and that would reasonably be expected to result in Material Environmental Liability;

(d) the assertion of any Claim under any Environmental Law by any Person against, or with respect to the activities of, the Borrower or any of its Subsidiaries and any alleged liability or non-compliance with any Environmental Laws or any permits, licenses or authorizations issued

pursuant to Environmental Laws, in each case, which could reasonably be expected to result in a Material Environmental Liability;

(e) the filing or commencement of any action, suit or proceeding by or before any arbitrator or Governmental Authority against or affecting the Borrower or any of its Affiliates that would reasonably be expected to result in a Material Adverse Effect;

(f) (i) the intention of any ERISA Affiliate to file any notice of intent to terminate any Title IV Plan, together with a copy of such notice and (ii) the filing by any ERISA Affiliate of a request for a minimum funding waiver under Section 412 of the Code with respect to any Title IV Plan, in each case in writing and in reasonable detail (including a description of any action that any ERISA Affiliate proposes to take with respect thereto, together with a copy of any notice filed with the PBGC or the IRS pertaining thereto);

(g) (i) the termination of any Material Agreement other than in accordance with its terms and not as a result of a breach or default, (ii) the receipt by the Borrower or any of its Subsidiaries of any notice of a material breach or default under any Material Agreement (and a copy thereof) asserting a default by such Obligor or any of its Subsidiaries where such alleged default would permit such counterparty to terminate such Material Agreement, (iii) the entering into of any new Material Agreement by any Obligor (and a copy thereof), (iv) any material amendment to a Material Agreement that would be adverse in any material respect to the Lenders (and a copy thereof) (provided that it is agreed that amendments that would not reasonably be expected to result in a reduction of consolidated total revenue of Borrower and its Subsidiaries by more than five percent (5%) of the consolidated total revenue of Borrower and its Subsidiaries for the immediately preceding fiscal year shall not be considered adverse in a material respect to the Lenders solely as a result of a reduction of consolidated total revenue) or (v) any other material amendment to a Material Agreement (and a copy thereof); provided, that the Borrower shall not be required to provide such notice if such documents become publicly available on "EDGAR" or the Borrower's website within the time period notice would otherwise be required pursuant to this **Section 8.02**;

(h) any material change in accounting policies or financial reporting practices by the Borrower or any of its Subsidiaries (other than as required under GAAP or IFRS);

(i) any labor controversy resulting in or threatening to result in any strike, work stoppage, boycott, shutdown or other material labor disruption against or involving an Obligor that could reasonably be expected to result in a Material Adverse Effect;

(j) any Contract entered into by the Borrower or any of its Subsidiaries in connection with any material Claim of actual alleged violation, infringement or misappropriation of any Intellectual Property by or against the Borrower or any of its Subsidiaries;

(k) the creation, development or other acquisition (including any in-bound exclusive licenses) of any Material Intellectual Property by the Borrower or any Subsidiary after the Closing Date that is registered or becomes registered or the subject of an application for registration with any Governmental Authority; provided that, notice pursuant to this **Section 8.02(k)** shall be made

in accordance with the timing of the financial statements for such fiscal year required pursuant to **Section 8.01(b)**;

(l) any change to any Obligor's ownership of any Controlled Account, by delivering the Administrative Agent a notice setting forth a complete and correct list of all such accounts as of the date of such change;

(m) any other development that results in, or could reasonably be expected to result in, a Material Adverse Effect; and

(n) any current or future product of any Obligor satisfying the criteria set forth in **clause (b)** of the definition of "Product".

Each notice delivered under this **Section 8.02** shall be accompanied by a statement of a Responsible Officer of the Borrower setting forth the details of the event or development requiring such notice and any action taken or proposed to be taken with respect thereto. Nothing in this **Section 8.02** is intended to waive, consent to or otherwise permit any action or omission that is otherwise prohibited by this Agreement or any other Loan Document.

8.03 Existence. Such Obligor shall, and shall cause each of its Subsidiaries to, preserve, renew and maintain in full force and effect its legal existence; provided that the foregoing shall not prohibit any merger, amalgamation, consolidation, liquidation or dissolution permitted under **Section 9.03** or any Asset Sale permitted under **Section 9.09**.

8.04 Payment of Obligations. Such Obligor will, and will cause each of its Subsidiaries to, pay and discharge its obligations, including (i) all material Taxes, fees, assessments and governmental charges or levies imposed upon it or upon its properties or assets prior to the date on which penalties attach thereto, and all lawful claims for labor, materials and supplies which, if unpaid, might become a Lien upon any properties or assets of such Obligor or any of its Subsidiaries not constituting a Permitted Lien, except to the extent such Taxes, fees, assessments or governmental charges or levies or such claims are being contested in good faith by appropriate proceedings and are adequately reserved against in accordance with GAAP or IFRS, as applicable, and (ii) all lawful claims which, if unpaid, would by law become a Lien upon its property not constituting a Permitted Lien.

8.05 Insurance. Such Obligor will, and will cause each of its Subsidiaries to maintain, with financially sound and reputable insurance companies, insurance in such amounts and against such risks as are customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations. Upon the request of the Administrative Agent, the Borrower shall furnish the Administrative Agent from time to time with (i) material information as to the insurance carried by it and, if so requested, copies of all such insurance policies and (ii) a certificate from the Borrower's insurance broker or other insurance specialist stating that all premiums then due on the policies relating to insurance on the Collateral have been paid and that such policies are in full force and effect. Receipt of notice of termination or cancellation of any such insurance policies or reduction of coverages or amounts thereunder to levels which do not meet the levels required pursuant to the first sentence of this **Section 8.05** shall entitle the Secured Parties to renew any such policies, cause the coverages and amounts thereof to be maintained at

levels required pursuant to the first sentence of this **Section 8.05** or otherwise to obtain similar insurance in place of such policies, and in each case, the Borrower will be responsible for the reasonable and documented cost of such insurance (to be payable promptly upon receipt by the Borrower of an invoice). The amount of any such reasonable and documented expenses shall accrue interest at the Default Rate if not paid within five (5) Business Days of Borrower's receipt of an invoice for such expenses and shall constitute "Obligations."

8.06 Books and Records; Inspection Rights. Such Obligor will, and will cause each of its Subsidiaries to, keep proper books of record and account in which full, true and correct (in all material respects) entries are made of all dealings and transactions in relation to its business and activities. Such Obligor will, and will cause each of its Subsidiaries to, permit any representatives designated by the Administrative Agent or the Lenders, upon reasonable prior notice, to visit and inspect its properties, to examine and make extracts from its books and records, and to discuss its affairs, finances and condition (financial or otherwise) with its officers and independent accountants (so long as a representative of the Borrower is provided a reasonable opportunity to participate in any such discussion), during normal business hours (but not more often than once per year in total for all such visits and inspections unless an Event of Default has occurred and is continuing) as the Administrative Agent or the Lenders may reasonably request; provided that such representative shall use its commercially reasonable efforts to minimize disruption to the business and affairs of the Borrower as a result of any such visit, inspection, examination or discussion. Notwithstanding anything to the contrary contained herein or any other provision of the Loan Documents, no Obligor nor any of its Subsidiaries will be required to disclose or permit the inspection or discussion of, any document, information or other matter (i) that constitutes trade secrets or proprietary information, (ii) in respect of which disclosure to any Lender (or their respective representatives or contractors) is prohibited by any applicable Law or any binding agreement with a third party (so long as such agreement is not entered into in contemplation of this Agreement) or (iii) that is subject to attorney-client or similar privilege, which could reasonably be expected to be lost or forfeited if disclosed to the Administrative Agent or any Lender. The Borrower shall pay all reasonable and documented costs of no more than one (1) such inspection per year unless an Event of Default has occurred and is continuing, in which case the Borrower shall pay all costs of any such inspections.

8.07 Compliance with Laws and Other Obligations. Such Obligor will, and will cause each of its Subsidiaries to, (i) comply with all Laws (including Anti-Terrorism Laws, Sanctions and Environmental Laws) applicable to it and its business activities, (ii) comply with all Healthcare Laws and Governmental Approvals (including Product Authorizations) applicable to it and its business activities and (iii) maintain in full force and effect (other than in accordance with its terms), remain in compliance with, and perform all obligations under all Material Agreements to which it is a party, except, in the case of **clauses (i)**, **(ii)** and **(iii)** above, where the failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Within 60 days after the Closing Date, each Obligor shall institute (if not already in effect) and thereafter maintain in effect and enforce policies and procedures reasonably designed to promote compliance by such Obligor, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Terrorism Laws and Sanctions. This **Section 8.07** shall only apply to a party hereto, to the extent that it would not result in any violation of, conflict with or liability under (i) EU Regulation (EC) 2271/96, as last amended by EU Regulation (EC) 1100/2018, (ii) section 7 of the German Foreign Trade Regulation (*Außenwirtschaftsverordnung, AWV*) (in

connection with section 4 of the German Foreign Trade Act (*Außenwirtschaftsgesetz, AWG*)) and/or (iii) any other similar antiboycott law or regulation, by such party.

8.08 Maintenance of Properties, Etc. Such Obligor shall, and shall cause each of its Subsidiaries to, maintain and preserve all of its assets and properties (including all assets and properties, whether tangible or intangible, relating to its Products or Product Commercialization and Development Activities) necessary or useful in the conduct of its business in good working order and condition in accordance with the general practice of other Persons of similar character and size, ordinary wear and tear and damage from casualty or condemnation excepted and except where the failure to do so, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect; provided that the foregoing shall not prohibit any merger, amalgamation, consolidation, liquidation or dissolution permitted under **Section 9.03** or any Asset Sale permitted under **Section 9.09**.

8.09 Governmental Licenses. Such Obligor shall, and shall cause each of its Subsidiaries to, obtain and maintain all Governmental Approvals necessary in connection with the execution, delivery and performance of the Loan Documents, the consummation of the Transactions or the operation and conduct of its business and ownership of its properties (including its Product Commercialization and Development Activities), except where the failure to do so could not reasonably be expected to have a Material Adverse Effect.

8.10 Use of Proceeds. The proceeds of the Loans will be used only as provided in **Section 2.05**. No part of the proceeds of the Loans will be used, whether directly or indirectly, for any purpose that entails a violation of any of the Regulations of the Board of Governors of the Federal Reserve System, including Regulations T, U and X, nor for the financing or refinancing of the acquisition of or subscription for shares in the Belgian Guarantor~~.~~ and/or in the French Guarantor.

8.11 Certain Obligations Respecting Subsidiaries; Further Assurances.

(a) **Subsidiary Guarantors, etc**. Subject, in the case of Subsidiaries in existence as of the Closing Date formed under the laws of Germany, France, Spain, Italy and the United Kingdom, to the time periods set forth in Schedule 8.17(g), in the event that the Borrower or any of its Subsidiaries shall form or acquire any Subsidiary that constitutes a Material Subsidiary or any Subsidiary ceases to be an Immaterial Subsidiary, the Borrower shall promptly (and in any event within thirty (30) calendar days of such formation, acquisition or Subsidiary ceasing to be an Immaterial Subsidiary, or such longer period as the Administrative Agent may agree to in its sole discretion):

(i) cause such Material Subsidiary to become a "Subsidiary Guarantor" hereunder pursuant to a Guarantee Assumption Agreement and a "Grantor" under the Security Agreement;

(ii) take such action or cause such Material Subsidiary to take such action (including joining the Security Agreement, preparing, executing and delivering similar security agreements under non-U.S. law and delivering shares of stock together with undated transfer powers and/or share transfer forms executed in blank, applicable control agreements and other instruments) as shall be reasonably necessary or desirable (as determined by the Administrative

Agent) in order to create and perfect, in favor of the Administrative Agent, for the benefit of the Secured Parties, valid and enforceable first priority Liens (subject only to Permitted Liens), on substantially all of the personal property of such Material Subsidiary as collateral security for the Obligations hereunder as and when required by the terms of the Security Agreement; provided that any such security interest or Lien shall be subject to the relevant requirements of the Security Documents and the Intercompany Subordination Agreement; provided, further that any Material Subsidiary formed under the Laws of Germany, France, Spain or Italy shall not be required to take actions to create such first priority Liens over its assets unless requested by the Administrative Agent, in which case such Material Subsidiary shall take all such actions to create such first priority Liens within sixty (60) days;

(iii) to the extent that the parent of such Subsidiary has not otherwise pledged or secured Equity Interests in its Subsidiaries but is required to do so in accordance with the terms of any Security Document or this Agreement, cause the parent (if possible) of such Subsidiary to prepare, execute and deliver a pledge or other security agreement in favor of the Administrative Agent, for the benefit of the Secured Parties, in respect of all outstanding issued shares of such Subsidiary;

(iv) deliver such proof of corporate action, incumbency of officers, opinions of counsel of the Borrower and its Subsidiaries and other applicable documents as is consistent with those delivered by each Obligor pursuant to **Section 6.01** or as the Administrative Agent shall reasonably request; ~~and~~it being specified that the list of documents required with respect to the French Material Subsidiary is set out in **Schedule 8.11(a)**; and

(v) cause each such Subsidiary (other than any Subsidiary that is not an Obligor) to become a party to the Intercompany Subordination Agreement.

(b) **Further Assurances.**

(i) Such Obligor will take such action from time to time as shall reasonably be requested by the Administrative Agent to effectuate the purposes and objectives of this Agreement and the Security Agreement; and

(ii) In the event that such Obligor creates, develops or otherwise acquires Intellectual Property or Real Property during the term of this Agreement, then the provisions of this Agreement and the Security Agreement shall and hereby do automatically apply thereto and any such Intellectual Property or Real Property shall automatically constitute and hereby does constitute part of the Collateral under the Security Documents (other than Excluded Assets (as defined in the Security Agreement)), without further action by any party, in each case from and after the date of such creation, development or acquisition;

(iii) Without limiting the generality of the foregoing, each Obligor will, and will cause each Person that is required to be a Guarantor to, take such action from time to time (including joining the Security Agreement and delivering shares of stock together with undated transfer powers and/or share transfer forms executed in blank, applicable control agreements and other instruments) as shall be required by the terms of the Security Documents or reasonably requested by the Administrative Agent to create, in favor of the Administrative Agent for the

benefit of the Secured Parties, perfected security interests and Liens in substantially all of the Collateral (other than Excluded Assets (as defined in the Security Agreement)) of such Obligor as collateral security for the Obligations; provided that any such security interest or Lien shall be subject to the relevant requirements of the Security Documents; provided, further that, without limiting the right of the Administrative Agent to require a Lien or security interest in any newly acquired or created Subsidiary or asset, upon the prior written request of the Borrower, the Borrower and the Administrative Agent shall consult, in good faith, as to whether the cost of obtaining a Lien or security interest thereon would be unreasonably excessive relative to the benefit thereof; and

(iv) If the Borrower or any other Obligor acquires any Material Real Property located in the United States or Costa Rica after the Closing Date (i) the Borrower shall notify the Administrative Agent thereof promptly (and in any event, within five (5) Business Days following the acquisition thereof) and (ii) within sixty (60) days of the date of such acquisition (or such longer period as may be agreed by the Administrative Agent) the Borrower shall or shall cause the applicable Obligor to satisfy the requirements in **Section 8.17(b)** with respect to such Material Real Property.

8.12 Termination of Non-Permitted Liens. In the event that any Obligor shall become aware of, or be notified by the Administrative Agent or any Lender of the existence of, any outstanding Lien against any assets or property of such Obligor or any of its Subsidiaries, which Lien is not a Permitted Lien, such Obligor shall use its commercially reasonable efforts to promptly terminate or cause the termination of such Lien.

8.13 Board Materials. The Borrower shall deliver to the Administrative Agent (for distribution to any Lenders at their request): (i) copies of any agenda and other written materials provided to the Board (or any committee thereof) of the Borrower prior to any meeting of such Board (or such committee thereof), at or promptly after the time such materials are furnished to the members of such Board (or such committee thereof) but in any event within five (5) Business Days, (ii) copies of all minutes of meetings of the Board (or any committee thereof) of the Borrower at or promptly after the time such minutes are furnished to the members of such Board (or such committee thereof) but in any event within five (5) Business Days, (iii) copies of all material written consents duly passed by the Board (or any committee thereof) of the Borrower and (iv) promptly after presentation (but in any event within five (5) Business Days) of any regular periodic materials to the Board (or any committee thereof) of the Borrower reporting on the current, past or future financial performance and business and operations of the Borrower or any of its Subsidiaries (which shall include, among other things, development updates with respect to material Products, and updates with respect to material events relating to other Material Agreements), copies of such materials; provided that any such material may be redacted by the Borrower to (A) exclude information relating to the performance of the Administrative Agent or any Lender hereunder or to the Borrower's strategy regarding the Loans (including any potential refinancing thereof), (B) preserve attorney-client privilege or (C) protect individually identifiable health information (as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) or other confidential information relating to healthcare patients; provided, further that such redactions are restricted so as to be only as extensive as is reasonably necessary in order to exclude information described in clauses (A), (B) or (C).

8.14 Maintenance of Regulatory Approvals, Contracts, Intellectual Property, Etc. Each Obligor shall, and shall cause each of its Subsidiaries (to the extent applicable) to, (i) maintain in full force and effect all Material Product Authorizations, Material Agreements and Material Intellectual Property, (ii) maintain in full force and effect, and pay all costs and expenses relating to, such Material Product Authorizations, Material Agreements and Material Intellectual Property owned, used or controlled by such Obligor or any such Subsidiary that are used in or necessary for any related Product Commercialization and Development Activities, except as would not be reasonably expected to have a Material Adverse Effect, (iii) promptly after obtaining knowledge thereof, notify the Administrative Agent of any material violation, misappropriation or other infringement by any Person of any Material Intellectual Property, and use commercially reasonable efforts to stop, curtail or abate such violation, misappropriation or infringement if determined appropriate by the Borrower in the exercise of its prudent business judgment, and (iv) except as set forth on **Schedule 7.05(b)**, promptly after obtaining knowledge thereof, notify the Administrative Agent of any Claim by any Person that the conduct of the business of any Obligor or any of its Subsidiaries, including in connection with any Product Commercialization and Development Activities, has violated, misappropriated or otherwise infringed any Intellectual Property of such Person, where such Claim could reasonably be expected to result in a Material Adverse Effect.

8.15 ERISA Compliance and Pension Plans. Such Obligor shall comply, and shall cause each of its Subsidiaries to comply, with the provisions of ERISA with respect to any Benefit Plans to which such Obligor or such Subsidiary is a party as an employer, except where the failure to do so could not reasonably be expected to have a Material Adverse Effect.

8.16 Cash Management.

(a) No later than the expiration of each of the periods set forth in **Sections 8.17(a)** and **(f)**, such Obligor shall, and shall cause each of its Subsidiaries to, maintain an aggregate amount of cash of the Borrower and its Subsidiaries equal to the Minimum Liquidity Amount in deposit accounts, disbursement accounts, investment accounts (and other similar accounts) and lockboxes either with a bank or financial institution within the U.S. which has executed and delivered to the Administrative Agent an account control agreement, in form and substance reasonably acceptable to the Administrative Agent or with any bank or financial institution outside the U.S. so long as such accounts are subject to a valid and perfected Lien in favor of the Administrative Agent, for the benefit of the Secured Parties (each such deposit account, disbursement account, investment account (or similar account) and lockbox, a "***Controlled Account***"); provided that each such Controlled Account shall be a cash collateral account, with all cash, checks and other similar items of payment in such account securing payment of the Obligations, and each Obligor shall have granted a Lien to the Administrative Agent, for the benefit of the Secured Parties, over such Controlled Accounts; provided further that following the occurrence and continuance of an Event of Default, no amounts shall be transferred from any Controlled Accounts within the U.S. to any Controlled Accounts outside the U.S.;

(b) No later than the expiration of periods set forth in **Sections 8.17(a)** (with respect to U.S. Obligors) and **(f)** (with respect to any Obligor other than Obligors organized under the laws of Brazil, France, Germany, Italy or Spain), such Obligor shall deposit promptly, and in any event no later than five (5) Business Days after the date of receipt thereof, all cash, checks, drafts

or other similar items of payment relating to or constituting payments made in respect of any and all accounts and other rights and interests into Controlled Accounts or into deposit accounts that will become Controlled Accounts pursuant to the terms of this Agreement; and

(c) Such Obligor shall, and shall cause each of its Subsidiaries to, at any time after the occurrence and during the continuance of an Event of Default, at the request of the Administrative Agent, each Obligor shall cause all payments constituting proceeds of accounts to be directed into lockbox accounts under agreements in form and substance satisfactory to the Administrative Agent.

8.17 Post-Closing Obligations.

(a) **Controlled Accounts**. Within thirty (30) days following the Closing Date (or such longer period of time as agreed by the Administrative Agent in its sole discretion), the Borrower shall deliver to the Administrative Agent evidence that (i) all deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts (other than Excluded Accounts) of each Obligor located within the U.S. are Controlled Accounts and (ii) such Controlled Accounts are subject to one or more account control agreements, in favor of, and satisfactory in form and substance to, the Administrative Agent that (A) ensures, to the extent necessary under applicable Law, the perfection of a first priority security interest in favor of the Administrative Agent on such Controlled Account, (B) provides that, upon written notice from the Administrative Agent, such bank or financial institution shall comply with instructions originated by the Administrative Agent directing disposition of the funds in such Controlled Account without further consent by the applicable Obligor, and (C) may not be terminated without prior written consent of the Administrative Agent.

(b) **Mortgages**. Within sixty (60) days following the Closing Date (or such longer period as the Administrative Agent may agree in its sole discretion), with respect to any Material Real Property owned by any Obligor located in the United States or Costa Rica, the Administrative Agent shall have received (i) counterparts of a Mortgage with respect to each such mortgaged property duly executed, notarized (to the extent required by applicable Law) and delivered by the applicable Obligor and suitable for recording or filing in all filing or recording offices that the Administrative Agent may reasonably deem necessary or desirable in order to create a valid and enforceable Lien subject to no other Liens except Permitted Liens, at the time of recordation thereof, with all filing and recording taxes and fees (including public notary fees) having been paid or otherwise provided for in a manner reasonably satisfactory to the Administrative Agent; (ii) with respect to the Mortgage encumbering such Material Real Property located in the U.S., customary opinions of local counsel in the state or jurisdiction in which such Material Real Property is located regarding the enforceability of such Mortgage, and any related fixtures and, in the state or jurisdiction where the applicable Obligor granting such Mortgage is organized, an opinion regarding due authorization, execution and delivery of such Mortgage, (iii) with respect to each such mortgaged property located in the United States, the completed "Life-of-Loan" Federal Emergency Management Agency ("***FEMA***") Standard Flood Hazard Determination with respect to each such mortgaged property subject to the applicable FEMA rules and regulations; provided that in the event that any such property is located in an area determined by FEMA to have special flood hazards, such property shall not become subject to a Mortgage.

(c) **Landlord Consents; Bailee Letters**. Within sixty (60) days following the Closing Date (or such longer period as the Administrative Agent may agree in its sole discretion), if Collateral having an aggregate fair market value in excess of $5,000,000 or any substantial portion of an Obligor's books and records or any of its material books and records, is (i) in the possession of any single bailee, warehouseman or consignee, or (ii) located at any single leased real property, such Obligor shall use commercially reasonable efforts to cause such bailee, warehouseman or consignee, or the applicable landlord, as the case may be, to sign and deliver a Landlord Consent or Bailee Letter, as applicable.

(d) **Insurance Policies**. Within thirty (30) days following the Closing Date (or such longer period of time as agreed by the Administrative Agent in its sole discretion), all such insurance policies required pursuant to each Loan Document shall name the Administrative Agent (for its benefit and the benefit of the Lenders) loss payee or additional insured, as applicable, and, to the extent the applicable insurance provider agrees after the Borrower has made commercially reasonable efforts, provide that no cancellation of the policies will be made without at least ten (10) days prior written notice to the Administrative Agent and the Administrative Agent shall have received certified copies of such insurance policies (or binders in respect thereof).

(e) **Certificates**. Within five (5) Business Days following the Closing Date (or such longer period of time as agreed by the Administrative Agent in its sole discretion), the Borrower shall deliver to the Administrative Agent all certificates (in the case of Equity Interests that are certificated securities (as defined in the UCC)) evidencing the issued and outstanding capital securities owned by each Obligor that are required to be pledged or otherwise secured and so delivered under the Security Documents, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank.

(f) **Costa Rican Security Documents**. Within five (5) Business Days following the Closing Date (or such longer period of time as agreed by the Administrative Agent in its sole discretion), the Borrower shall deliver to the Administrative Agent:

(i) copy of each executed CR Moveable Guarantee Agreement;

(ii) delivery of the applicable registrations of each CR Moveable Guarantee Agreement within the *Sistema de Garantías Mobiliarias* of the Costa Rican National Registry;

(iii) if requested by the Administrative Agent, copy of each Costa Rican Conditional Assignment Agreement with respect to any lease agreement and/or purchase agreement related to real estate assets in Costa Rica;

(iv) if requested by the Administrative Agent, all relevant notices and consents, acknowledgements and documents necessary or advisable to perfect any security interest over each Costa Rican Conditional Assignment Agreement with respect to any lease agreement and/or purchase agreement related to real estate assets in Costa Rica; and

(v) a copy of the (A) executed termination agreement with respect to the existing security trust agreement, in connection with the existing debt with Madryn Health Partners LP, which such security is registered under security number GM-6899-2017 and GM-6901-2017;

and (B) relevant notices filed with the *Sistema de Garantias Mobiliarias* of the Costa Rican National Registry to cancel all collateral securing such debt.

(g) **Other Non-U.S. Law Security Documents**. The actions set forth on **Schedule 8.17(g)** to be taken in respect of certain non-U.S. Security Documents shall be completed within the time periods set forth therein.

(h) **Dissolution of Certain U.S. Subsidiaries**. Promptly following the Closing Date, the Borrower shall wind up and dissolve any U.S. Subsidiary of the Borrower that is not an Obligor.

(i) **Intellectual Property Filings**. Within ninety (90) days following the Closing Date (or such later date as the Administrative Agent may agree in its discretion), the Borrower shall (i) make or cause to be made all filings necessary in the United States to reflect a full and accurate chain of title for all Patents that are owned or purported to be owned by the Obligors and constitute Material Intellectual Property, and (ii) provide confirmation and evidence reasonably satisfactory to the Administrative Agent that the foregoing has been completed.

(j) **Joint Product Development Agreement**. Borrower shall, and shall cause Establishment Labs S.A., to take all actions necessary to preserve the license or similar rights with respect to Material Intellectual Property granted pursuant to the Joint Product Development Agreement in full force and effect, including by entering into a written agreement to extend the term of the Joint Product Development Agreement, or by entry into another agreement containing similar rights with respect to such Material Intellectual Property, through May 1, 2027; provided that, for the avoidance of doubt, Borrower shall not be obligated to maintain such Joint Product Development Agreement or any similar rights with respect to any Intellectual Property that does not constitute Material Intellectual Property.

SECTION 9.
NEGATIVE COVENANTS

Each Obligor covenants and agrees with the Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than inchoate indemnification and expense reimbursement obligations for which no claim has been made), have been paid in full in cash:

9.01 Indebtedness. Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Indebtedness, whether directly or indirectly, except:

(a) the Obligations;

(b) Indebtedness existing on the date hereof and set forth on **Schedule 9.01(b)** and Permitted Refinancings thereof; provided that, if such Indebtedness is intercompany Indebtedness, such Indebtedness shall be subject to the Intercompany Subordination Agreement;

(c) to the extent considered Indebtedness, obligations owing under operating leases entered into in the Ordinary Course and not otherwise prohibited hereunder;

(d) Indebtedness consisting of guarantees resulting from the endorsement of negotiable instruments for collection in the Ordinary Course;

(e) Indebtedness of an Obligor owing to any other Obligor, in each case subject to the Intercompany Subordination Agreement;

(f) Indebtedness of any Subsidiary that is not an Obligor owing to any other Subsidiary that is not an Obligor;

(g) Indebtedness of (i) any Obligor owing to any Subsidiary that is not the Borrower or a Subsidiary Guarantor, in each case subject to the Intercompany Subordination Agreement and (ii) any Subsidiary that is not an Obligor owing to any Obligor, in each case subject to the Intercompany Subordination Agreement; provided any Indebtedness owing pursuant to this **clause (g)** shall not exceed $12,500,000 in the aggregate outstanding at any one time (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(h) Guarantees (i) by any Obligor of Permitted Indebtedness of another Obligor and (ii) by any Subsidiary that is not an Obligor of Permitted Indebtedness of any Obligor;

(i) Capital Lease Obligations and purchase money Indebtedness; provided that (i) if secured, the collateral therefor consists solely of the assets being financed, the products and proceeds thereof and books and records related thereto, and (ii) the aggregate outstanding principal amount of such Indebtedness does not exceed $10,000,000 (or the Equivalent Amount in other currencies) at any time (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(j) Indebtedness under Permitted Hedging Agreements;

(k) Indebtedness assumed pursuant to any Permitted Acquisition; provided that except with the prior written consent of Administrative Agent, (i) no such Indebtedness (individually) shall exceed 15% of the total purchase price paid in connection with such Permitted Acquisition, (ii) the aggregate outstanding principal amount of Indebtedness permitted pursuant to this **Section 9.01(k)** shall not exceed $5,000,000 (or the Equivalent Amount in other currencies) at any time outstanding (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion) and (iii) no such Indebtedness was created or incurred in connection with, or in contemplation of, such Permitted Acquisition;

(l) in addition to the other Permitted Indebtedness set forth in this **Section 9.01**, other Indebtedness in an aggregate outstanding principal amount not to exceed $5,000,000 (or the Equivalent Amount in other currencies) (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(m) Indebtedness in respect of letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments issued or created, or related to obligations or liabilities incurred, in the Ordinary Course, including in respect of workers compensation claims, health, disability or other employee benefits or leases, commercial contracts, Indebtedness permitted pursuant to **Section 9.01(o)**, property, casualty or liability insurance or self-insurance or other

Indebtedness with respect to reimbursement-type obligations regarding workers compensation claims;

(n) Indebtedness arising in connection with the financing of insurance premiums in the Ordinary Course;

(o) Indebtedness in respect of (i) performance bonds, bid bonds, appeal bonds, surety bonds, customs bonds, government bonds, performance and completion guarantees and similar obligations arising in the Ordinary Course and (ii) customary indemnification obligations to purchasers in connection with Asset Sales permitted by **Section 9.09**;

(p) Indebtedness in respect of netting services, overdraft protections, business credit cards, purchasing cards, payment processing, automatic clearinghouse arrangements, arrangements in respect of pooled deposit or sweep accounts, check endorsement guarantees, and otherwise in connection with deposit accounts or cash management services;

(q) purchase price adjustments, indemnity payments, incentive, non-compete, consulting or other similar arrangements, contingent obligations and other Deferred Acquisition Consideration in connection with any Permitted Acquisition, in each case that are permitted pursuant to the definition of "Permitted Acquisition"; or

(r) deferred compensation and accounts payable incurred in the Ordinary Course overdue by more than forty-five (45) days in an amount not to exceed $5,000,000 (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion).

9.02 Liens. Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Lien on any property now owned by it or such Subsidiary, except:

(a) Liens securing the Obligations;

(b) any Lien on any property or asset of such Obligor or any of its Subsidiaries existing on the date hereof and set forth on **Schedule 9.02(b)** and renewals and extensions thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien; provided that (i) no such Lien (including any renewal or extension thereof) shall extend to any other property or asset of such Obligor or any of its Subsidiaries (other than improvements and accessions to such property or asset) and (ii) any such Lien shall secure only those obligations which it secures on the date hereof and renewals, extensions and replacements thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien that do not increase the outstanding principal amount thereof (other than by an amount equal to unpaid interest and premiums thereon, including tender premium, and any customary underwriting discounts, fees, commissions and expenses associated with such extension, renewal or replacement);

(c) Liens securing Indebtedness permitted under **Section 9.01(i)**; provided that such Liens are restricted solely to the collateral described in **Section 9.01(i)**;

(d) Liens imposed by any Law and arising in the Ordinary Course, including (but not limited to) carriers', warehousemen's, landlords', and mechanics' liens, liens relating to leasehold improvements and other similar Liens arising in the Ordinary Course that (x) do not in the

aggregate materially detract from the value of the property subject thereto or materially impair the use thereof in the operations of the business of such Person or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing the forfeiture or sale of the property subject to such Liens and for which adequate reserves have been made if required in accordance with GAAP or IFRS, as applicable;

(e) pledges or deposits made in the Ordinary Course in connection with bids, contracts, leases, appeal bonds, workers' compensation, unemployment insurance or other similar social security legislation;

(f) Liens securing Taxes, assessments and other governmental charges, the payment of which is not past due or is being contested in good faith by appropriate proceedings promptly initiated and diligently conducted and for which such reserve or other appropriate provisions, if any, as shall be required by GAAP or IFRS, as applicable, shall have been made;

(g) any (i) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any Law, (ii) Liens consisting of zoning or building restrictions, (iii) easements, licenses, restrictions on the use of real property or minor imperfections in title thereto which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or materially interfere with the ordinary conduct of the business of any of the Obligors or any of their Subsidiaries;

(h) with respect to any real property, (i) such defects or encroachments as might be revealed by an up-to-date survey of such real property; (ii) the reservations, limitations, provisos and conditions expressed in the original grant, deed or patent of such property by the original owner of such real property pursuant to all applicable Laws; and (iii) rights of expropriation, access or user or any similar right conferred or reserved by or in any Law, which, in the aggregate for **clauses (i)**, **(ii)** and **(iii)**, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of the Obligors or its Subsidiaries;

(i) (i) Liens that are contractual or common law rights of set-off relating to (A) the establishment of depository relations in the Ordinary Course with banks not given in connection with the issuance of Indebtedness or (B) pooled deposit or sweep accounts of the Borrower and any Subsidiary to permit satisfaction of overdraft or similar obligations incurred in the Ordinary Course, (ii) other Liens securing cash management obligations (that do not constitute Indebtedness) in the Ordinary Course and (iii) Liens encumbering reasonable customary initial deposits and margin deposits and similar Liens attaching to commodity trading accounts or other brokerage accounts, in each case, incurred in the Ordinary Course and not for speculative purposes;

(j) Liens securing Indebtedness permitted under **Section 9.01(k)**; provided that (i) such Lien is not created in contemplation of or in connection with such Permitted Acquisition pursuant to which such Indebtedness was assumed, (ii) such Lien shall not apply to any other property or assets of the Borrower or any Subsidiary and (iii) such Lien shall secure only those obligations that it secured immediately prior to the consummation of such Permitted Acquisition and extensions, renewals and replacements thereof that do not increase the outstanding principal amount thereof;

(k) Liens securing Indebtedness permitted under **Sections 9.01(l), (m), (n), (o)** and **(p)**;

(l) any judgment Lien or Lien arising from decrees or attachments not constituting an Event of Default;

(m) Liens arising from precautionary UCC financing statement filings regarding operating leases of personal property and consignment arrangements entered into in the Ordinary Course in an Arm's Length Transaction;

(n) in addition to the other Permitted Liens set forth in this **Section 9.02**, other Liens which secure obligations in an aggregate amount not to exceed $5,000,000 (or the Equivalent Amount in other currencies) at any time outstanding (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(o) (i) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods and incurred in the Ordinary Course and (ii) Liens on specific items of inventory or other goods and proceeds thereof of any Person securing such Person's obligations in respect of bankers' acceptances or letters of credit permitted under **Section 9.01** issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods in the Ordinary Course;

(p) Permitted Licenses;

(q) Liens on cash and Permitted Cash Equivalent Investments securing obligations under Permitted Hedging Agreements;

(r) (i) Liens to secure payment of workers' compensation, employment insurance, old age pensions, social security and other like obligations incurred in the Ordinary Course (other than Liens imposed by ERISA) and (ii) deposits in respect of letters of credit, bank guarantees or similar instruments issued for the account of any Obligor or any Subsidiary in the Ordinary Course supporting obligations of the type set forth in clause (i) above and with respect to German pension scheme, Liens on amounts deposited to secure any obligations in connection with pension liabilities (*Altersteilzeitverpflichtungen*) pursuant to §8 German Partial Retirement Act (*Altersteilzeitgesetz*) or in connection with time credits (*Wertguthaben*) pursuant to § 7e German Social Code IV (*Sozialgesetzbuch IV*);

(s) to the extent constituting a Lien, customary cash escrow arrangements securing indemnification obligations or cash earnest money deposits associated with a Permitted Acquisition or any other Investment permitted under **Section 9.05** not to exceed $5,000,000 in the aggregate (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(t) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code on items in the course of collection;

(u) Liens of sellers of goods to the Borrower or any of its Subsidiaries arising under Article 2 of the Uniform Commercial Code or similar provisions of applicable law in the Ordinary

Course, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(v) Liens on Equity Interests of any Joint Venture or other Persons that are not Subsidiaries;

(w) any Lien arising under conditional sale, title retention (including extended retention of title), consignment or similar arrangements for the sale of goods in the Ordinary Course; provided that such Lien attaches only to the goods subject to such sale, title retention, consignment or similar arrangement;

(x) any Lien required to be granted under mandatory law in favor of creditors as a consequence of a merger or a conversion permitted under this Agreement due to §§22, 204 German Conversion Act (*Umwandlungsgesetz*); and

(y) Liens arising under the general terms and conditions (*Allgemeine Geschäftsbedingungen der Banken und Sparkassen*) in relation to bank accounts held in Germany;

(z) provided that no Lien otherwise permitted under any of the foregoing **clauses (c), (d), (e)**, **(g)** through **(k), (m), (n), (o)** and **(q)** through **(w)** of this **Section 9.02** shall apply to any Material Intellectual Property.

9.03 Fundamental Changes and Acquisitions. Such Obligor will not, and will not permit any of its Subsidiaries to, (i) enter into any transaction of merger, amalgamation or consolidation, (ii) liquidate, wind up or dissolve itself (or suffer any liquidation or dissolution), (iii) sell or issue any of its Disqualified Equity Interests or (iv) other than Permitted Acquisitions and any Acquisition permitted by **Section 9.05(a)** or **Section 9.05(s)**, make any Acquisition or otherwise acquire any business or substantially all the property from, or Equity Interests of, or be a party to any Acquisition of, any Person, except:

(a) the merger, amalgamation, consolidation, dissolution, winding up or liquidation of any (i) Subsidiary with or into any Obligor; provided that with respect to any such transaction involving (x) the Borrower, the Borrower must be the surviving or successor entity of such transaction or (y) any other Obligor, an Obligor must be the surviving or successor entity of such transaction or the surviving Person shall concurrently therewith become an Obligor or (ii) Subsidiary that is not a Subsidiary Guarantor with or into any other Subsidiary that is not a Subsidiary Guarantor;

(b) the sale, lease, transfer or other disposition by (i) any Obligor of any or all of its property (upon voluntary liquidation, dissolution, winding-up or otherwise) to any other Obligor or to any entity that concurrently therewith shall become an Obligor or (ii) any Subsidiary that is not an Obligor of any or all of its property (upon voluntary liquidation, dissolution, winding-up or otherwise) to Borrower or any other Subsidiary;

(c) the sale, transfer or other disposition of the Equity Interests of (i) any Subsidiary to any Obligor or (ii) any Subsidiary that is not an Obligor to any other Subsidiary that is not an Obligor;

(d) mergers, amalgamations, consolidations, dissolutions or liquidations of any Subsidiary to effectuate any Asset Sales permitted under **Section 9.09**; provided that such merger, amalgamation, consolidation, dissolution or liquidation does not include the loss of corporate identity of the Borrower;

(e) in connection with any Permitted Acquisition or other Investment permitted under **Section 9.05**, any Obligor or any of its Subsidiaries may merge into or consolidate with any other Person or permit any other Person to merge into or consolidate with it, so long as (i) the Person surviving such merger with any Subsidiary shall be a direct or indirect wholly-owned Subsidiary of the Borrower, (ii) in the case of any such merger to which the Borrower is a party, the Borrower is the surviving Person, and (iii) in the case of any such merger to which a Subsidiary Guarantor is a party, the surviving Person is such Subsidiary Guarantor or concurrently therewith becomes a Subsidiary Guarantor; and

(f) any Subsidiary of the Borrower may dissolve, liquidate or wind up its affairs at any time, provided, that, such dissolution, liquidation or winding up could not reasonably be expected to have a Material Adverse Effect and all of such Subsidiary's assets and business are transferred to an Obligor or solely in the case of a Subsidiary that is not an Obligor, another Subsidiary that is not an Obligor prior to or concurrently with such dissolution, liquidation or winding up.

9.04 Lines of Business. Such Obligor will not, and will not permit any of its Subsidiaries to, engage in any material line of business other than the business engaged in on the date hereof by such Persons or a business reasonably related, incidental or complementary thereto or reasonable expansions or extensions thereof.

9.05 Investments. Such Obligor will not, and each Obligor will not permit any of its Subsidiaries to, make, directly or indirectly, or permit to remain outstanding any Investments except:

(a) Investments (but without giving effect to the cash return provision contained in the definition thereof) outstanding on the date hereof and identified in **Schedule 9.05(a)** and any renewals, amendments and replacements thereof that do not increase the amount thereof of any such Investment, net of cash returns thereon, or require that any additional Investment be made (unless otherwise permitted hereunder);

(b) deposit accounts with banks (or similar deposit-taking institutions) and securities accounts maintained by the Obligors and their respective Subsidiaries, which in the case of the Obligors shall be Controlled Accounts (unless Excluded Accounts);

(c) extensions of credit in the nature of accounts receivable or notes receivable arising from the sales of goods or services or the grant of trade credit in the Ordinary Course in an Arm's Length Transaction;

(d) Investments in cash and Permitted Cash Equivalent Investments (including Investments in assets that were Permitted Cash Equivalent Investments when such Investment was made), which in the case of the Obligors shall be maintained in Controlled Accounts (unless maintained in Excluded Accounts);

(e) Investments by (i) an Obligor in another Obligor and (ii) a Subsidiary that is not an Obligor in any other Subsidiary that is not an Obligor;

(f) (i) Investments by a Subsidiary that is not an Obligor in an Obligor; provided that any Investment made by any Subsidiary that is not an Obligor pursuant to this **clause (f)(i)** shall be subordinated in right of payment to the Obligations pursuant to the Intercompany Subordination Agreement and (ii) Investments by any Obligor in a Subsidiary that is not an Obligor; provided that the total amount of Investments pursuant to this **clause (f)** shall not exceed $12,500,000 outstanding at any time (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(g) Permitted Hedging Agreements;

(h) Investments consisting of prepaid expenses, deposits or advances under commercial contracts for the purchase of assets or services, negotiable instruments held for collection or deposit, security deposits with utilities, landlords and other like Persons and deposits in connection with workers' compensation and similar deposits, in each case, made in the Ordinary Course, and other deposits and cash collateral constituting Permitted Liens;

(i) employee, officer and director loans, advances and guarantees in accordance with the Borrower's usual and customary practices with respect thereto (if permitted by applicable Laws) and non-cash loans to employees, officers, or directors relating to the purchase of Equity Interests of the Borrower pursuant to employee stock purchase plans or agreements, which in the aggregate shall not exceed $5,000,000 outstanding at any time (or the Equivalent Amount in other currencies) (or such greater amount as the Administrative Agent may consent in writing in its sole discretion);

(j) Investments received in connection with any Insolvency Proceedings in respect of any customers, suppliers or clients or in settlement of delinquent obligations of, and other disputes with, customers, suppliers or clients or upon the foreclosure with respect to any secured Investment or other transfer of title with respect to any secured Investment;

(k) the increase in value of any Investment otherwise permitted pursuant to this **Section 9.05**;

(l) in addition to the other Investments set forth in this **Section 9.03**, other Investments in an aggregate amount not to exceed $10,000,000 (or the Equivalent Amount in other currencies) (or such greater amount as the Administrative Agent may consent in writing in its sole discretion);

(m) Investments of any Person in existence at the time such Person becomes a Subsidiary; provided such Investment was not made in connection with or anticipation of such Person becoming a Subsidiary and any modification, replacement, renewal or extension thereof;

(n) Investments permitted under **Section 9.03** or Investments arising as a result of payments permitted by **Section 9.07**;

(o) Permitted Acquisitions, earnest money deposits in connection with Permitted Acquisitions, potential Permitted Acquisitions and Investments acquired as a result of a

Permitted Acquisition to the extent that such Investments were not made in contemplation of or in connection with such Permitted Acquisition and were in existence prior to the date of such Permitted Acquisition;

(p) Investments consisting of the non-cash portion of the sales consideration received by the Borrower or any of its Subsidiaries in connection with any Asset Sale permitted under **Section 9.09**;

(q) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the Ordinary Course;

(r) to the extent constituting Investments, Guarantees of Indebtedness, which Guarantees are permitted under **Section 9.01**;

(s) Investments consisting of Permitted Liens; and

(t) Investments in Joint Ventures, which except with the prior written consent of Administrative Agent shall not exceed $2,500,000 in the aggregate outstanding at any time (or the Equivalent Amount in other currencies) (or such greater amount as the Administrative Agent may consent in writing in its sole discretion); provided that no Joint Venture shall hold any Material Intellectual Property at any time.

Notwithstanding anything in this Agreement to the contrary, (i) the Borrower shall not, and shall not permit any of its Subsidiaries to (x) directly or indirectly transfer, by means of contribution, sale, assignment, lease or sublease, license or sublicense, or other disposition of any kind (including, for avoidance of doubt, as an Investment, Restricted Payment or Asset Sale), any Material Intellectual Property or Material Real Property other than (I) pursuant to Permitted Licenses, (II) as permitted pursuant to **Section 9.09(g)** or (y) permit any Person other than an Obligor to license or own any interest in any Material Intellectual Property or Material Real Property owned by such Obligor other than pursuant to (I) Permitted Licenses or (II) as permitted pursuant to **Section 9.09(g)**, and (ii) no Material Intellectual Property or Material Real Property shall be contributed as an Investment or distributed as a Restricted Payment to any Subsidiary other than an Obligor (other than pursuant to Permitted Licenses).

9.06 Restricted Payments. Such Obligor will not, and will not permit any of its Subsidiaries to, declare or make, or agree to pay or make, directly or indirectly, any Restricted Payment; provided that the following Restricted Payments shall be permitted so long as no Event of Default has occurred and is continuing or could reasonably be expected to occur or result from such Restricted Payment:

(a) dividends with respect to the Borrower's Equity Interests payable solely in shares of its Qualified Equity Interests (or the equivalent thereof);

(b) the Borrower's purchase, redemption, retirement, or other acquisition of shares of its Equity Interests with the proceeds received from a substantially concurrent issue of new shares of its Qualified Equity Interests;

(c) (i) each Subsidiary that is an Obligor may make Restricted Payments to any other Obligor, and (ii) each Subsidiary that is not an Obligor may make cash Restricted Payments to its equity holders generally; provided that the Borrower or its Subsidiary which owns the Equity Interests in such Subsidiary paying such dividend receives at least its proportional share thereof;

(d) so long as no Event of Default has occurred and is continuing or would occur or result from such Restricted Payment, any purchase, redemption, retirement or other acquisition of Equity Interests of the Borrower held by consultants, agents, officers, directors and employees or former consultants, agents, officers, directors or employees (or their transferees, estates, or beneficiaries under their estates) of the Borrower and its Subsidiaries not to exceed $2,000,000 (or the Equivalent Amount in other currencies) in the aggregate in any fiscal year (it being agreed that, to the extent constituting an Investment permitted by **Section 9.05(i)**, the amount of any Indebtedness of such Persons owing to the Borrower or any Subsidiary forgiven in connection with such Restricted Payment shall be excluded from any determination pursuant to this **clause (d)**); provided that the portion of such basket that is not used by the Borrower or its Subsidiaries in any fiscal year shall be carried forward and shall increase such basket for succeeding fiscal years;

(e) cashless repurchases of Equity Interests deemed to occur upon exercises of options and warrants or the settlement or vesting of other equity awards if such Equity Interests represent a portion of the exercise price of such options or warrants or similar equity incentive awards;

(f) cash payments made by the Borrower to redeem, purchase, repurchase or retire its obligations under options, warrants and other convertible securities issued by it in the nature of customary cash payments in lieu of fractional shares in accordance with the terms thereof;

(g) the Borrower may acquire (or withhold) its Equity Interests pursuant to any employee stock option or similar plan to pay withholding taxes for which the Borrower is liable in respect of a current or former officer, director, employee, member of management or consultant upon such grant or award (or upon vesting or exercise thereof) and the Borrower may make deemed repurchases in connection with the exercise of stock options;

(h) any payment of interest, principal or fees in respect of any Indebtedness owed by any Obligor or any of its Subsidiaries to any holder of any Equity Interests of any Obligor or any of its Subsidiaries, in each case to the extent permitted under **Section 9.07**;

(i) so long as no Default or Event of Default has occurred and is continuing (or could reasonably be expected to occur after giving effect to such Restricted Payment), other Restricted Payments in an aggregate amount not to exceed $1,000,000 (or the Equivalent Amount in other currencies) in any fiscal year; and

(j) exchanges, redemptions or conversions in whole or in part any of its Equity Interests for or into another class of its Equity Interests.

9.07 Payments of Indebtedness. Such Obligor will not, and will not permit any of its Subsidiaries to, make any payments in respect of any Indebtedness other than (i) payments of the Obligations, (ii) scheduled payments of other Indebtedness to the extent permitted pursuant to the terms, if any, of any applicable subordination or intercreditor agreement in respect of the

Obligations, (iii) intercompany indebtedness permitted under **Section 9.01**, and (iv) Indebtedness permitted to be incurred under **Sections 9.01(b), (c), (f), (g)(ii), (h)** (solely to the extent such Guarantee is for Permitted Indebtedness that may be repaid under this clause **(iv)**), **(i), (j), (k), (l), (m), (n), (o), (p),** and **(q)**.

9.08 Change in Fiscal Year. Such Obligor will not, and will not permit any of its Subsidiaries to, change the last day of its fiscal year from that in effect on the date hereof without the prior written consent of Administrative Agent, except to change the fiscal year of a Subsidiary acquired in connection with an Acquisition to conform its fiscal year to that of the Borrower.

9.09 Sales of Assets, Etc. Such Obligor will not, and will not permit any of its Subsidiaries to, sell, lease or sublease (as lessor or sub-lessor), sale and leaseback, assign, convey, exclusively license (in terms of geography or field of use), transfer, or otherwise dispose of any of its businesses, assets or property of any kind, whether real, personal, or mixed and whether tangible or intangible, whether now owned or hereafter acquired (including accounts receivable and Equity Interests of Subsidiaries), or forgive, release or compromise any amount owed to such Obligor or Subsidiary, in each case, in one transaction or series of transactions (any thereof, an "***Asset Sale***"), except:

(a) sales, transfers and other dispositions of receivables in connection with the compromise, settlement or collection thereof in the Ordinary Course;

(b) sales of inventory, including to end users (through wholesalers or other typical sales channels) or to distributors, in the Ordinary Course in an Arm's-Length Transaction;

(c) so long as no Event of Default has occurred and is continuing, the forgiveness, release or compromise of any amount owed to any Obligor or Subsidiary in the Ordinary Course;

(d) Permitted Licenses;

(e) transfers of assets, rights or property (i) among Obligors or (ii) from any Subsidiary that is not an Obligor to an Obligor or another Subsidiary that is not an Obligor;

(f) dispositions (including by way of abandonment or cancellation) of any equipment and other tangible property that is obsolete or worn out or no longer used or useful in the business disposed of in the Ordinary Course;

(g) (i) dispositions resulting from Casualty Events (and for the purposes of this **clause (g)**, the cap in the defined term "Casualty Events" shall not apply) and (ii) transfers of condemned property as a result of the exercise of "eminent domain" or other similar policies to the respective Governmental Authority or agency that has condemned the same (whether by deed in lieu of condemnation or otherwise);

(h) the unwinding of any Hedging Agreement permitted by **Section 9.05** pursuant to its terms;

(i) in connection with any transaction permitted under **Section 9.03**, **9.05**, **9.06** or **9.14**;

(j) Asset Sales identified in **Schedule 9.09**;

(k) so long as no Default or Event of Default has occurred and is continuing (or could reasonably be expected to occur after giving effect to such Asset Sale), in addition to the other Asset Sales set forth in this **Section 9.09**, other Asset Sales (other than with respect to Material Intellectual Property or Material Real Property) with a fair market value not in excess of $5,000,000 (or the Equivalent Amount in other currencies) in the aggregate in any fiscal year (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion);

(l) other Asset Sales (other than with respect to Material Intellectual Property or Material Real Property) not in excess of $5,000,000 (or the Equivalent Amount in other currencies) in the aggregate in any fiscal year (or such greater amount as the Administrative Agent may consent to in writing in its sole discretion) in which any Obligor or any Subsidiary will receive cash proceeds in an amount equal to no less than seventy-five percent (75%) of the total consideration (fixed or contingent) paid or payable to such Obligor or such Subsidiary, but only so long as, unless otherwise waived by Administrative Agent in its sole discretion, the net cash proceeds of such Asset Sale are utilized to repay or prepay, in whole or in part, Indebtedness under and in accordance with **Section 3.03(b)**;

(m) dispositions in the Ordinary Course consisting of the abandonment, lapse or cancellation of Intellectual Property (other than Material Intellectual Property) which, in the reasonable good faith determination of Borrower, are not material to the conduct of the business of Borrower or any of its Subsidiaries;

(n) dispositions of cash and Permitted Cash Equivalent Investments in the Ordinary Course or otherwise in transactions permitted hereunder;

(o) any sale or issuance of (i) the Equity Interests of any Subsidiary to any Obligor, (ii) the Equity Interests of any Subsidiary that is not an Obligor to any other Subsidiary that is not an Obligor, and (iii) the Equity Interests of any Subsidiary issued as qualifying shares under applicable Law; and

(p) to the extent constituting an Asset Sale, any Permitted Liens.

To the extent any Collateral is disposed of as expressly permitted by this **Section 9.09** to any Person that is not an Obligor, such Collateral shall be sold free and clear of the Liens created by the Loan Documents, and the Administrative Agent shall be authorized to take any actions deemed appropriate in order to effectuate the foregoing.

9.10 Transactions with Affiliates. Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into or permit to exist any transaction to sell, lease, license or otherwise transfer any assets to, or purchase, lease, license or otherwise acquire any assets from, or otherwise engage in any other transactions with, any of its Affiliates, unless such arrangement or transaction (i) is an Arm's-Length Transaction, (ii) is between or among (x) Obligors, (y) Subsidiaries of the Obligors that are not Obligors, (z) the Borrower, one or more Subsidiary Guarantors or their Subsidiaries that are not the Borrower or a Subsidiary Guarantor, on the one hand, and, on the other hand, the Borrower, one or more Subsidiary Guarantors or their

Subsidiaries that are the Borrower or a Subsidiary Guarantor (provided that, with respect to **clause (z)** only, the terms thereof are no less favorable than those that would be obtained in a comparable arm's-length transaction with a non-affiliated Person), (iii) is permitted under **Section 9.01, 9.03, 9.05, 9.06, 9.07** or **9.09**, (iv) constitutes customary compensation (including performance, discretionary, retention, relocation, transaction and other special bonuses and payment, severance payments and payments pursuant to employment agreements), other benefits (including retirement, health, stock option and other benefit plans, life insurance, disability insurance and other equity (or equity-linked) awards) and indemnification of, and other employment arrangements with, directors, officers, and employees of any Obligor or its Subsidiaries in the Ordinary Course, (v) constitutes payment of customary fees, reimbursement of expenses, and payment of indemnification to officers and directors and customary payment of insurance premiums on behalf of officers and directors by the Obligors or their Subsidiaries, in each case, in the Ordinary Course, (vi) are the transactions set forth on **Schedule 9.10** or any amendment to such transactions to the extent such an amendment is not adverse to the Lenders in any material respect, or (vii) is a transaction (with any series of related transactions being aggregated for the purposes of this clause (vii)) including consideration of less than $500,000.

9.11 Restrictive Agreements. Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into, incur or permit to exist any Restrictive Agreement other than (i) restrictions and conditions imposed by applicable Laws or by the Loan Documents, (ii) Restrictive Agreements listed on **Schedule 7.15** and to the extent such Restrictive Agreement is set forth in an agreement evidencing Indebtedness, are set forth in any agreement evidencing any Permitted Refinancing in respect thereof, so long as such restrictions are not (taken as a whole) materially less favorable to the Lenders than those in the original Indebtedness, (iii) limitations associated with Permitted Liens or any document or instrument governing any Permitted Lien, (iv) any documentation governing Indebtedness referenced in clause **(k)** of **Section 9.01** (or any Permitted Refinancing thereof), (v) customary provisions in leases, subleases, Permitted Licenses and other Contracts restricting the assignment thereof or restricting the assignment, pledge, transfer or sublease or sublicense of the property leased, licensed or otherwise the subject thereof; (vi) any restrictions or conditions set forth in any agreement in effect at any time any Person becomes a Subsidiary (but not any modification or amendment expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary; (vii) restrictions or conditions in any Indebtedness permitted pursuant to **Section 9.01** that is incurred or assumed by Subsidiaries that are not Obligors to the extent such restrictions or conditions are no more restrictive in any material respect than the restrictions and conditions in the Loan Documents; (viii) restrictions or conditions imposed by any agreement relating to purchase money Indebtedness and other secured Indebtedness or to leases, subleases and licenses permitted by this Agreement if such restrictions or conditions apply only to the property or assets securing such Indebtedness or the property leased, subleased or licensed; (ix) customary provisions in contracts for the disposition of any assets; provided that the restrictions in any such contract shall apply only to the assets or Subsidiary that is to be disposed of and such disposition is permitted hereunder; (x) customary provisions regarding confidentiality or restricting assignment, pledges or transfer of any Permitted License or any other agreement entered into in the Ordinary Course; (xi) customary provisions in joint venture agreements and other similar agreements applicable to Joint Ventures and applicable solely to such Joint Venture; and (xii) restrictions or encumbrances in any agreement in effect at the time any Person becomes a Subsidiary, so long as (x) such agreement was not entered into in contemplation of such Person

becoming a Subsidiary and (y) such restrictions or encumbrances do not extend beyond such Subsidiary or its assets.

9.12 Modifications and Terminations of Material Agreements and Organic Documents. Each Obligor will not, and will not permit any of its Subsidiaries to:

(a) waive, amend, terminate, replace or otherwise modify any term or provision of any Organic Document in any way or manner adverse to the interests of the Administrative Agent and the Lenders; or

(b) waive, amend, replace or otherwise modify any term or provision of any Material Agreement in a manner adverse to the rights and remedies of the Administrative Agent and the Lenders hereunder;

(c) waive, amend, replace or otherwise modify any term or provision of the Joint Product Development Agreement in a manner that results in any narrowing, limitation or other restriction on the licenses and other rights under Material Intellectual Property granted to each Obligor or any of its Subsidiaries pursuant to the Joint Product Development Agreement; provided that, for the avoidance of doubt, the foregoing shall not prohibit any Obligor from (i) replacing the Joint Product Development Agreement with another agreement that provides Establishment Labs S.A. with substantially similar rights to such Material Intellectual Property; or (ii) waiving, amending, replacing, terminating, or otherwise modifying the Joint Product Development Agreement with respect to any term or right that does not affect Establishment Labs S.A.'s rights to any Material Intellectual Property; or

(d) except as otherwise consented to in writing by the Administrative Agent, take or omit to take any action that results in the termination of, or permits any other Person to terminate, any Material Agreement or any rights in or to Material Intellectual Property or (y) take any action that permits any Material Agreement or any rights in or to Material Intellectual Property to be terminated by any counterparty thereto prior to its stated date of expiration.

9.13 Outbound Licenses. No Obligor shall, nor shall it permit any of its Subsidiaries to, enter into or become or remain bound by any outbound license, covenant not to sue or other grant of rights or immunities under Material Intellectual Property, except for Permitted Licenses.

9.14 Sales and Leasebacks. Except as disclosed on **Schedule 9.14**, except as otherwise consented to in writing by the Administrative Agent (such consent not to be unreasonably withheld), each Obligor will not, and will not permit any of its Subsidiaries to, become liable, directly or indirectly, with respect to any lease, whether an operating lease or a Capital Lease Obligation, of any property (whether real, personal, or mixed), whether now owned or hereafter acquired, (i) which such Person has sold or transferred or is to sell or transfer to any other Person and (ii) which such Obligor or Subsidiary intends to use for substantially the same purposes as property which has been or is to be sold or transferred.

9.15 Hazardous Material(a) . Each Obligor will not, and will not permit any of its Subsidiaries to, use, generate, manufacture, install, treat, release, store or dispose of any Hazardous Material, except as would not reasonably be expected to result in a Material Environmental Liability.

9.16 Accounting Changes. Such Obligor will not, and will not permit any of its Subsidiaries to, make any significant change in accounting treatment or reporting practices, except as required or permitted by GAAP or IFRS, as applicable, without the prior written consent of the Administrative Agent (such consent not to be unreasonably withheld or delayed).

9.17 Compliance with ERISA. No Obligor or any of its Subsidiaries shall cause or suffer to exist (i) any event that could reasonably be expected to result in the imposition of a Lien with respect to any Title IV Plan or Multiemployer Plan or (ii) any other ERISA Event that could, in the aggregate, reasonably be expected to result in a Material Adverse Effect.

9.18 Sanctions; Anti-Corruption Use of Proceeds.

(a) No Obligor nor any of its Subsidiaries or their respective agents shall (i) conduct any business or engage in any transaction or dealing with any Sanctioned Person in violation of Sanctions, including making or receiving any contribution of funds, goods or services to or for the benefit of any Sanctioned Person; (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to any Sanctions; or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in any applicable Sanctions, the Patriot Act or any other Anti-Terrorism Law.

(b) The Borrower will not, directly or, to the knowledge of the Borrower, indirectly, use the proceeds of the Loans, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person, (i) in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any applicable anti-corruption Law, or (ii) (A) for the purpose of funding any activities or business of or with any Sanctioned Person or any Designated Jurisdiction in violation of Sanctions or (B) in any other manner that would result in a violation of Sanctions by any party to this Agreement.

(c) This **Section 9.18** shall only apply to a party hereto, to the extent that it would not result in any violation of, conflict with or liability under (i) EU Regulation (EC) 2271/96, as last amended by EU Regulation (EC) 1100/2018, (ii) section 7 of the German Foreign Trade Regulation (*Außenwirtschaftsverordnung, AWV*) (in connection with section 4 of the German Foreign Trade Act (*Außenwirtschaftsgesetz, AWG*)) and/or (iii) any other similar antiboycott law or regulation, by such party.

9.19 COMI. Each Obligor which is organized under the laws of a member state of the European Union shall not cause or allow its centre of main interests (as that term is used in Article 3(1) of the EU Insolvency Regulation) to change in a manner which would be reasonably likely to be adverse to the interests of the Lenders.

SECTION 10.
FINANCIAL COVENANTS

10.01 Minimum Liquidity. The Obligors shall at all times maintain the Minimum Liquidity Amount in cash and/or Permitted Cash Equivalent Investments in one or more Controlled Accounts in the United States, free and clear of all Liens, other than Liens granted under the Loan

Documents in favor of the Administrative Agent and Liens permitted under **Section 9.02(f), 9.02(i), 9.02(l)** or **Section 9.02(t)**.

10.02 Minimum Gross Sales. Beginning with the fiscal quarter of the Borrower ending on September 30, 2022, and with respect to each subsequent fiscal quarter thereafter prior to the Minimum Gross Sales Covenant Termination Date, the Gross Sales of the Borrower and its Subsidiaries for the twelve (12) consecutive month period ending on the last day of such fiscal quarter shall exceed fifty percent (50%) of the Target Gross Sales for such quarter (the "***Minimum Gross Sales Covenant***").

SECTION 11.
EVENTS OF DEFAULT

11.01 Events of Default. Each of the following events shall constitute an "***Event of Default***":

(a) **Principal Payment Default**. The Borrower shall fail to pay any principal of the Loan, when and as the same shall become due and payable, whether at the due date thereof, at a date fixed for prepayment thereof or otherwise.

(b) **Other Payment Defaults**. Any Obligor shall fail to pay interest or any other Obligation (other than an amount referred to in **Section 11.01(a)**) when and as the same shall become due and payable, and such failure shall continue unremedied for a period of five (5) Business Days.

(c) **Representations and Warranties**. Any representation or warranty made or deemed made by or on behalf of any Obligor or any of its Subsidiaries in or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, or in any written report, certificate, financial statement or other document furnished pursuant to or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof, shall (i) have been incorrect or misleading when made or deemed made to the extent that such representation or warranty contains any materiality or Material Adverse Effect qualifier; or (ii) have been incorrect in any material respect when made or deemed made to the extent that such representation or warranty does not otherwise contain any materiality or Material Adverse Effect qualifier.

(d) **Certain Covenants**. Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in (i) **Section 8.01(a)**, **(b)** or **(c) and Section 8.11** (solely with respect to Material Subsidiaries), and such failure shall continue unremedied for a period of five (5) Business Days, (ii) **Section 8.02**, **Section 8.03** (solely as to the Borrower), **Section 8.17**, **Section 9** or **Section 10**; provided that notwithstanding this **Section 11.01(d)**, an Event of Default under **Section 10.02** is subject to **Section 11.04** and an Event of Default with respect to **Section 10.02** shall not occur until the Cure Expiration Date.

(e) **Other Covenants**. Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in this Agreement (other than those specified in **Section 11.01(a)**, **(b)** or **(d)**) or any other Loan Document, and, in the case of any failure that is capable of cure, such failure shall continue unremedied for a period of thirty (30) or more days.

(f) **Payment Default on Other Indebtedness**. Any Obligor or any of its Subsidiaries shall fail to make any payment of principal or interest (regardless of amount), due in respect of any Material Indebtedness, when and as the same shall become due and payable after giving effect to any applicable grace or cure period in respect thereof.

(g) **Other Defaults on Other Indebtedness**. Any material breach of, or "event of default" or similar event under, any Contract governing any Material Indebtedness shall occur and (i) the effect of which breach, "event of default" or similar event is to cause such Material Indebtedness becoming due prior to its scheduled maturity or (ii) enables or permits (with or without the giving of notice, the lapse of time or both) the holder or holders of such Material Indebtedness or any trustee or agent on its or their behalf to cause such Material Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity; provided that this **Section 11.01(g)** shall not apply to (x) secured Indebtedness that becomes due as a result of the voluntary sale or transfer of the property or assets securing such Material Indebtedness, (y) any conversion of any convertible Indebtedness or satisfaction of any condition giving rise to or permitting a conversion of any convertible Indebtedness; provided that the Borrower or the applicable Subsidiary has the right to settle any such Indebtedness into Equity Interests of the Borrower or such Subsidiary (and nominal cash payments in respect of fractional shares and cash payments in respect of accrued and unpaid interest) in accordance with the terms or conditions thereof and (z) with respect to any Material Indebtedness consisting of Hedging Agreements, termination events or equivalent events pursuant to the terms of such Hedging Agreements and not as a result of any event of default thereunder by any Obligor or any Subsidiary.

(h) **Insolvency, Bankruptcy, Etc**.

(i) Any Obligor or any of its Material Subsidiaries becomes insolvent, or generally does not or becomes unable to pay its debts or meet its liabilities as the same become due (means with respect to any German Guarantor is either unable to pay its debts as they fall due (*Zahlungsunfähigkeit*), or is over indebted (*Überschuldung*), or is threatened with insolvency (*drohende Zahlungsunfähigkeit*), or has commenced negotiations with any one or more of its creditors with a view to the general readjustment or rescheduling of its indebtedness or, for any of the reasons set out in Sections 17 to 19 (inclusive) of the German Insolvency Code (*Insolvenzordnung*)), or admits in writing its inability to pay its debts generally, or declares any general moratorium on its indebtedness, or proposes a compromise or arrangement or deed of company arrangement between it and any class of its creditors. In furtherance of the foregoing, in respect of a French Guarantor, (a) a French Guarantor is or becomes in a *cessation des paiements* within the meaning of Article L. 631-1 of the French Commercial Code (*Code de commerce*) or encounters difficulties that it is not able to overcome within the meaning of Article L. 620-1 of the French Commercial Code (*Code de commerce*), or becomes insolvent under any applicable insolvency Law, or (b) a moratorium is declared in respect of any indebtedness of a French Guarantor, or a French Guarantor is subject to alert procedure (*procédure d'alerte*) by its statutory auditors in accordance with Articles L. 234-1, L. 234-2 or L. 612-3 of the French Commercial Code (*Code de commerce*).

(ii) Any Obligor or any of its Material Subsidiaries commits an act of bankruptcy or makes an assignment of its property for the general benefit of its creditors or makes a proposal (or files a notice of its intention to do so).

(iii) Any Obligor or any of its Material Subsidiaries institutes any proceeding seeking to adjudicate it an insolvent, or seeking liquidation, dissolution, winding-up, reorganization, examinership, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), or composition of it or its debts or any other relief, under any Law, whether U.S. or non-U.S., now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, examinership, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity, or files an answer admitting the material allegations of a petition filed against it in any such proceeding. In furtherance of the foregoing, in respect of a French Guarantor, (a) any corporate action is taken to authorize, approve or initiate (as applicable), or any legal proceeding is commenced by a French Guarantor in relation to, (x) the suspension of payments, a moratorium of all or any indebtedness, dissolution, the opening of proceedings for *sauvegarde* (including, for the avoidance of doubt, *sauvegarde accélérée*), *redressement judiciaire* or *liquidation judiciaire* or reorganization (in the context of a *mandat ad hoc* or of a *conciliation* or otherwise) of a French Guarantor, or (y) the appointment of a liquidator, receiver, administrator, administrative receiver (*administrateur séquestre*), temporary administrator, *mandataire ad-hoc*, *conciliateur* or other Person exercising similar functions in respect of a French Guarantor or in respect of all or any of their respective assets, except in relation to the appointment of a liquidator in case of an amicable dissolution (*liquidation amiable*) of a French Guarantor, (b) a French Guarantor commences proceedings for the appointment of a *mandataire ad hoc* or the opening of a procedure of *conciliation* in accordance with Articles L. 611-3 to L. 611-15 of the French Commercial Code (*Code de commerce*), (c) a judgment opening proceedings for *sauvegarde* (including, for the avoidance of doubt, *sauvegarde accélérée*), *redressement judiciaire* or *liquidation judiciaire* or ordering a *cession totale ou partielle de l'entreprise* is rendered in relation to a French Guarantor in accordance with Articles L. 620-1 to L.670-8 of the French Commercial Code (*Code de commerce*), or (d) any procedure, judgment or step is taken, which has effects that are substantially the same as those referred to in paragraphs (a) through (c) above.

(iv) Any Obligor or any of its Material Subsidiaries applies for the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, examiner, trustee, liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property.

(v) Any Obligor or any of its Material Subsidiaries takes any action, corporate or otherwise, to approve, effect, consent to or authorize any of the actions described in this **Section 11.01(h)**, or otherwise acts in furtherance thereof or fails to act in a timely and appropriate manner in defense thereof.

(vi) Any petition is filed, application made or other proceeding instituted against or in respect of any Obligor or any of its Material Subsidiaries:

(A) seeking to adjudicate it as insolvent;

(B) seeking a receiving order against it;

(C) seeking liquidation, dissolution, winding-up, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, examinership, stay of proceedings of creditors generally (or any class of creditors), deed of company arrangement or composition of it or its debts or any other relief under any Law, whether U.S. or non-U.S., now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity; or

(D) seeking the entry of an order for relief or the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, examiner, sequestrator, conservator, custodian, administrator, trustee, liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property, and such petition, application or proceeding continues undismissed, or unstayed and in effect, for a period of forty-five (45) days after the institution thereof; provided that if an order, decree or judgment is granted or entered (whether or not subject to appeal) against such Obligor or such Subsidiary thereunder in the interim, such grace period will cease to apply; provided, further, if such Obligor or Material Subsidiary files an answer admitting the material allegations of a petition filed against it in any such proceeding, such grace period will cease to apply.

(vii) Any other event occurs which, under the Laws of any applicable jurisdiction, has an effect equivalent to any of the events referred to in this **Section 11.01(h)**.

(i) **Judgments**. One or more final judgments for the payment of money in an aggregate amount in excess of $5,000,000 (or the Equivalent Amount in other currencies) (to the extent not fully covered (other than to the extent of customary deductibles) by insurance pursuant to which the insurer has not denied coverage) shall be rendered against any Obligor or any of its Subsidiaries or any combination thereof and the same shall remain undischarged for a period of forty-five (45) consecutive calendar days during which execution shall not be effectively stayed or bonded pending appeal, or any action shall be legally taken by a judgment creditor to attach or levy upon any assets of any Obligor to enforce any such judgment.

(j) **ERISA**. An ERISA Event shall have occurred that when taken together with all other ERISA Events that have occurred, could reasonably be expected to result in liability of the Borrower and its Subsidiaries in an aggregate amount in excess of $5,000,000 (or the Equivalent Amount in other currencies).

(k) **Change of Control**. A Change of Control shall have occurred unless concurrently with the consummation thereof the Commitments are terminated and the Obligations (other than inchoate indemnification and reimbursement obligations for which no claim has been asserted), including, for the avoidance of doubt, any applicable Yield Protection Premium and the Exit Fee, are paid in full.

(l) **Regulatory Matters, Etc.** If any of the following occurs: (i) the FDA or any other Regulatory Authority initiates enforcement action against, or issues a warning letter with respect to, any Obligor, the Motiva Implants and/or the Products, or any manufacturing facilities related to the foregoing that (x) causes any Obligor to discontinue or withdraw, or could reasonably be

expected to cause any Obligor to discontinue or withdraw, marketing or sales of the Motiva Implants and/or the Products or causes a delay in the manufacture or sale of the Motiva Implants and/or the Products, and (y) could reasonably be expected to result in a Material Adverse Effect, or (ii) a recall of the Motiva Implants and/or the Products that could reasonably be expected to result in a Material Adverse Effect; provided that Administrative Agent shall have provided three (3) calendar days written notice to the Borrower before exercising any right or remedy or causing a Default or Event of Default to occur with respect to this **Section 11.01(l)**, whereby during such time, Administrative Agent shall make itself available to discuss in good faith any proposed solution to such Material Adverse Effect, and the Borrower may take such action otherwise permitted under the Loan Documents (i) as required so that the event or circumstance that is the basis for such Material Adverse Effect no longer exists (to the extent curable), (ii) to show evidence that no Material Adverse Effect has occurred, (iii) to provide a plan detailing how it will mitigate the effect of such event or circumstance that, based on such plan, in the foreseeable future will provide the Obligors (taken as a whole) the ability to overcome such Material Adverse Effect or (iv) to establish that the Obligors (taken as a whole) remain able to pay the Obligations, when and as the same shall become due and payable hereunder in the ordinary course, which in each case, at such time such evidence is shown and plans are provided, the Administrative Agent shall promptly re-determine in good faith whether an Event of Default still exists with respect to this **Section 11.01(l)**.

(m) **Impairment of Security, Etc.** Subject in all respects to any applicable post-closing periods and certain other time periods and exceptions under the Loan Documents for any Obligor or Subsidiary to take perfection actions, if any of the following events occurs: (i) Any Lien created by any of the Security Documents shall at any time (except as expressly permitted by the terms of any Loan Document) not constitute a valid and perfected Lien on the applicable Collateral having a value in excess of $2,500,000 in the aggregate in favor of the Secured Parties, free and clear of all other Liens (other than Permitted Liens) except due to the action or inaction of the Administrative Agent, (ii) except for expiration in accordance with its terms, any of the Security Documents or any Guarantee of any of the Obligations (including that contained in **Section 13**) shall for whatever reason cease to be in full force and effect, (iii) any Obligor shall, directly or indirectly, contest in any manner such effectiveness, validity, binding nature or enforceability of any such Lien or any Loan Document, or (iv) any injunction, whether temporary or permanent, shall be rendered against any Obligor and not be effectively stayed pending appeal, which injunction prevents the Obligors from conducting it business in the Ordinary Course for more than thirty (30) calendar days and after the termination of such thirty (30) day period, the existence of such circumstances could reasonably be expected to result in a Material Adverse Effect.

(n) **Strike-off**. Any action is taken to strike-off the Borrower from the Register of Companies maintained by the BVI Registrar.

11.02 Remedies.

(a) **Defaults Other Than Bankruptcy Defaults**. Upon the occurrence of any Event of Default, then, and in every such event (other than an Event of Default described in **Section 11.01(h)**), and at any time thereafter during the continuance of such event, the Administrative Agent may, by notice to the Borrower, declare the Loans then outstanding to be due and payable in whole (or in part, in which case any principal not so declared to be due and payable may

thereafter be declared to be due and payable), and thereupon the principal of the Loans so declared to be due and payable, together with accrued interest thereon and all fees and other Obligations, including any applicable Yield Protection Premium and the Exit Fee, shall become due and payable immediately, without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

(b) **Bankruptcy Defaults**. In case of an Event of Default described in **Section 11.01(h)**, the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, including any applicable Yield Protection Premium and the Exit Fee, shall automatically become due and payable immediately, without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

11.03 Additional Remedies. If an Event of Default has occurred and is continuing, if any Obligor shall be in default under a Material Agreement, the Administrative Agent shall have the right (but not the obligation) to cause the default or defaults under such Material Agreement to be remedied (including without limitation by paying any unpaid amount thereunder) and otherwise exercise any and all rights of such Obligor, as the case may be, thereunder, as may be necessary to prevent or cure any default. Without limiting the foregoing, upon any such default, if an Event of Default has occurred and is continuing, each Obligor shall promptly execute, acknowledge and deliver to the Administrative Agent such instruments as may reasonably be required of such Obligor to permit the Administrative Agent to cure any default under the applicable Material Agreement or permit the Administrative Agent to take such other action required to enable the Administrative Agent to cure or remedy the matter in default and preserve the interests of the Administrative Agent. Any amounts paid by the Administrative Agent pursuant to this **Section 11.03** shall be payable in accordance with **Section 14.03(a)**, shall accrue interest at the Default Rate if not paid when due, and shall constitute "Obligations." The Administrative Agent and the Lenders agree that in connection with any foreclosure or other exercise of rights under this Agreement or any other Loan Document with respect to Intellectual Property, the rights of the non-Affiliate licensees under Permitted Licenses will not be terminated, limited or otherwise adversely affected so long as no default exists under the Permitted License that would permit the licensor to terminate such Permitted License (commonly known as a non-disturbance); provided that the Administrative Agent shall be entitled to exercise any rights of the Obligors under such licenses, including termination rights, upon the exercise of remedies during an Event of Default.

11.04 Minimum Gross Sales Covenant Cure.

(a) Notwithstanding anything to the contrary contained in **Section 11.02**, in the event the Obligors fail to comply with the Minimum Gross Sales Covenant, during the period from the end of the relevant fiscal quarter until the expiration of the fifteenth (15^{th}) Business Day subsequent to the date the financial statements are required to be delivered pursuant to **Section 8.01(a)** or **8.01(b)** (the "***Cure Expiration Date***"), the Obligors shall have the right to make a Gross Sales Cure Payment and neither the Administrative Agent nor any Lender shall exercise the right to accelerate the Loans or terminate the Commitments and no Secured Party shall exercise any right to foreclose on or take possession of the Collateral or exercise any other remedy pursuant to this **Section 11**, the other Loan Documents or applicable Law prior to the Cure Expiration Date solely on the basis of an Event of Default having occurred and continuing under **Section 10.02**; provided that such payment shall be made, at the Borrower's option, with either cash on hand or cash raised from the

issuance or sale of common Equity Interests (or other equity having terms reasonably acceptable to the Administrative Agent) in the Borrower for cash (the "***Minimum Gross Sales Cure Right***"). Upon the Administrative Agent's receipt of the applicable Gross Sales Cure Payment, the Obligors shall then be in compliance with the requirements of the Minimum Gross Sales Covenant, and the Obligors shall be deemed to have satisfied the requirements of the Minimum Gross Sales Covenant as of the relevant date of determination with the same effect as though there had been no failure to comply therewith at such date, and the applicable breach of the Minimum Gross Sales Covenant and any related Default that had occurred shall be deemed cured for the purposes of this Agreement. Any Gross Sales Cure Payment shall be applied to the prepayment of all outstanding Obligations, which shall include the Yield Protection Premium, if applicable and the Exit Fee. Notwithstanding anything else in this Agreement, the Obligors may not exercise a Cure Right more than four (4) times over the life of the Loans or more than two (2) times in any twelve (12) month period.

(b) Upon the Administrative Agent's receipt of a notice from the Borrower that the Obligors intend to exercise the Minimum Gross Sales Cure Right (a "***Notice of Intent to Cure Gross Sales Covenant***"), until the earlier of (i) Administrative Agent's receipt of the applicable Gross Sales Cure Payment and (ii) the Cure Expiration Date to which such Notice of Intent to Cure Gross Sales Covenant relates, no Lender shall be required to extend any credit pursuant to its Commitment during such period. If within such fifteen (15) Business Day period, the Majority Lenders decline the exercise by the Borrower of the Minimum Gross Sales Cure Right by written notice to the Administrative Agent and the Borrower to that effect, then the Borrower shall be deemed to have satisfied the requirements of the Minimum Gross Sales Covenant without making such Gross Sales Cure Payment as of the relevant date of determination with the same effect as though there had been no failure to comply therewith at such date, and the applicable breach of the Minimum Gross Sales Covenant and any related Default that had occurred shall be deemed cured for the purposes of this Agreement.

11.05 Payment of Yield Protection Premium and Exit Fee. Notwithstanding anything in this Agreement to the contrary, the Yield Protection Premium and the Exit Fee shall automatically be due and payable at any time the Obligations become due and payable prior to the Maturity Date in accordance with the terms hereof as though such Indebtedness was voluntarily prepaid and shall constitute part of the Obligations, whether due to acceleration pursuant to the terms of this Agreement (in which case it shall be due immediately, upon the giving of notice to Borrower in accordance with **Section 11.02(a)**, or automatically, in accordance with **Section 11.02(b)**), by operation of law or otherwise (including, without limitation, on account of any bankruptcy filing), in view of the impracticability and extreme difficulty of ascertaining the actual amount of damages to the Lenders or profits lost by the Lenders as a result of such acceleration, and by mutual agreement of the parties as to a reasonable estimation and calculation of the lost profits or damages of the Lenders as a result thereof. Any Yield Protection Premium or Exit Fee payable pursuant to this Agreement shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination, acceleration or prepayment and each Obligor agrees that such Yield Protection Premium or Exit Fee is reasonable under the circumstances currently existing. The Yield Protection Premium and Exit Fee shall also be payable in the event the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means or the Obligations are reinstated pursuant to Section 1124 of the Bankruptcy Code. If the Yield Protection Premium and/or becomes due and

payable pursuant to this Agreement, such Yield Protection Premium and/or Exit Fee shall be deemed to be principal of the Loans and Obligations under this Agreement and interest shall accrue on the full principal amount of the Loans (including the Yield Protection Premium or Exit Fee, as applicable) from and after the applicable triggering event. In the event the Yield Protection Premium and/or Exit Fee is determined not to be due and payable by order of any court of competent jurisdiction, including, without limitation, by operation of the Bankruptcy Code, despite such a triggering event having occurred, such Yield Protection Premium and Exit Fee, as applicable, shall nonetheless constitute Obligations under this Agreement for all purposes hereunder. **EACH OBLIGOR HEREBY WAIVES THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE YIELD PROTECTION PREMIUM OR EXIT FEE AND ANY DEFENSE TO PAYMENT, WHETHER SUCH DEFENSE MAY BE BASED IN PUBLIC POLICY, AMBIGUITY, OR OTHERWISE.** The Obligors, the Administrative Agent and the Lenders acknowledge and agree that any Yield Protection Premium and the Exit Fee due and payable in accordance with this Agreement shall not constitute unmatured interest, whether under Section 5.02(b)(3) of the Bankruptcy Code or otherwise. Each Obligor further acknowledges and agrees, and waives any argument to the contrary, that payment of such amount does not constitute a penalty or an otherwise unenforceable or invalid obligation. Each Obligor expressly agrees that (i) the Yield Protection Premium and Exit Fee are each reasonable and each is the product of an arm's-length transaction between sophisticated business people, ably represented by counsel, (ii) the Yield Protection Premium and Exit Fee shall be payable notwithstanding the then prevailing market rates at the time payment is made, (iii) there has been a course of conduct between the Lenders and the Obligors giving specific consideration in this transaction for such agreement to pay the Yield Protection Premium and Exit Fee, (iv) the Obligors shall be estopped hereafter from claiming differently than as agreed to in this **Section 11.05**, (v) their agreement to pay the Yield Protection Premium and Exit Fee is a material inducement to the Lenders to make the Loans, and (vi) the Yield Protection Premium and Exit Fee represent a good faith, reasonable estimate and calculation of the lost profits, losses or other damages of the Lenders and that it would be impractical and extremely difficult to ascertain the actual amount of damages to the Lenders or profits lost by the Lenders as a result of such event.

SECTION 12.
THE ADMINISTRATIVE AGENT

12.01 Appointment and Duties. Subject in all cases to clause (c) below:

(a) **Appointment of the Administrative Agent**. Each of the Lenders hereby irrevocably appoints Oaktree Fund Administration, LLC (together with any successor Administrative Agent pursuant to **Section 12.09**) as the Administrative Agent hereunder and authorizes the Administrative Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from any Obligor or any of its Subsidiaries, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to the Administrative Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto. Except as expressly set forth herein, the provisions of this **Section 12** (other than as expressly provided herein) are solely for the benefit of the Administrative Agent and the Lenders, and no Obligor or any Affiliate thereof shall have rights as a third-party beneficiary of any such provisions. Each of the Lenders hereby releases the Administrative Agent

acting also as collateral agent to the extent possible from any restrictions on representing several persons and self-dealing applicable to it under any applicable Law, in particular pursuant to Section 181 of the German Civil Code (*Bürgerliches Gesetzbuch*).

(b) **Appointment in relation to the Belgian Security Documents**. For the purposes of the Belgian Security Documents, each Secured Party:

(i) appoints the Administrative Agent as its representative in accordance with (A) Article 5 of the Belgian Act of 15 December 2004 on financial collateral arrangements and several tax dispositions in relation to security collateral arrangements and loans of financial instruments; and (B) Article 3 of Book III, Title XVII of the Belgian Civil Code, which appointment is hereby accepted; and

(ii) agrees that the Administrative Agent shall not be severally and jointly liable with the other Secured Parties.

~~(e~~(c) **Appointment in relation to the French Security Documents**. For the purposes of the French Security Documents, each Secured Party (other than the Administrative Agent) hereby irrevocably and unconditionally appoints the Administrative Agent to act, for so long as any of the French Security Documents are outstanding, as *agent des sûretés* (security agent) in accordance with Articles 2488-6 to 2488-12 of the French Civil Code (*Code civil*), and in such capacity to obtain, hold, register, manage and enforce any such French Security Document in the Administrative Agent's own name for the benefit of (*en son nom propre au profit des*) the Secured Parties, it being expressly acknowledged and agreed that in such capacity, the Administrative Agent will be the title holder (*titulaire*) of such security and Guarantees and that in such respect, the Administrative Agent shall enjoy all of the rights and prerogatives of an *agent des sûretés* designated in accordance with Articles 2488-6 to 2488-12 of the French Civil Code (*Code civil*). The Administrative Agent hereby confirms its acceptance of the appointment referred to in this **Section 12.01(c)**.

(d) **Duties as Collateral and Disbursing Agent**. Without limiting the generality of **Section 12.01(a)**, the Administrative Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any proceeding described in **Section 11.01(h)** or any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Secured Party is hereby authorized to make such payment to the Administrative Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of the Secured Parties with respect to any Obligation in any proceeding described in **Section 11.01(h)** or any other bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Secured Party), (iii) act as collateral agent for each Secured Party for purposes of acquiring, holding, enforcing and perfecting all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to the Administrative Agent and the other Secured Parties with respect to the

Collateral, whether under the Loan Documents, applicable Laws or otherwise, (vii) enter into non-disturbance agreements and similar agreements and (viii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided that the Administrative Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for the Administrative Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by a Obligor with, and cash and Permitted Cash Equivalent Investments held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to the Administrative Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed.

(~~d~~e) **Limited Duties**. The Lenders and the Obligors hereby each acknowledge and agree that the Administrative Agent (i) has undertaken its role hereunder purely as an accommodation to the parties hereto and the Transactions, (ii) is receiving no compensation for undertaking such role and (iii) subject only to the notice provisions set forth in **Section 12.09**, may resign from such role at any time for any reason or no reason whatsoever. Without limiting the foregoing, the parties hereto further acknowledge and agree that under the Loan Documents, the Administrative Agent (i) is acting solely on behalf of the Lenders (except to the limited extent provided in **Section 12.11**), with duties that are entirely administrative in nature, notwithstanding the use of the defined term "the Administrative Agent", the terms "agent", "administrative agent" and "collateral agent" and similar terms in any Loan Document to refer to the Administrative Agent, which terms are used for title purposes only, (ii) is not assuming any duty or obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Secured Party and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document (fiduciary or otherwise), in each case, regardless of whether a Default has occurred and is continuing, and each Lender hereby waives and agrees not to assert any claim against the Administrative Agent based on the roles, duties and legal relationships expressly disclaimed in this **clause (c)**. Without in any way limiting the foregoing, the Administrative Agent shall not, except as expressly set forth in this Agreement and in the other Loan Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to any Obligor or any of its Affiliates that is communicated to or obtained by the Person serving as the Administrative Agent or any of its Affiliates in any capacity.

12.02 Binding Effect. Each Lender agrees that (i) any action taken by the Administrative Agent or the Majority Lenders (or, if expressly required hereby, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by the Administrative Agent in reliance upon the instructions of the Majority Lenders (or, where so required, such greater proportion) and (iii) the exercise by the Administrative Agent or the Majority Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Secured Parties.

12.03 Use of Discretion.

(a) **No Action without Instructions**. The Administrative Agent shall not be required to exercise any discretion or take, or to omit to take, any action, including with respect to enforcement or collection, except (subject to **clause (b)** below) any action it is required to take or omit to take (i) under any Loan Document or (ii) pursuant to written instructions from the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders).

(b) **Right Not to Follow Certain Instructions**. Notwithstanding **Section 12.03(a)** or any other term or provision of this **Section 12**, the Administrative Agent shall not be required to take, or to omit to take, any action (i) unless, upon demand, the Administrative Agent receives an indemnification satisfactory to it from the Lenders (or, to the extent applicable and acceptable to the Administrative Agent, any other Secured Party) against all liabilities that, by reason of such action or omission, may be imposed on, incurred by or asserted against the Administrative Agent or any Related Party thereof or (ii) that is, in the opinion of the Administrative Agent, in its sole and absolute discretion, contrary to any Loan Document, Law or the best interests of the Administrative Agent or any of its Affiliates or Related Parties, including, for the avoidance of doubt, any action that may be in violation of the automatic stay in connection with any Insolvency Proceeding.

12.04 Delegation of Rights and Duties. The Administrative Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Secured Party). The Administrative Agent and any such Person may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. Any such Person and its Related Parties shall benefit from this **Section 12** to the extent provided by the Administrative Agent; provided, however, that the exculpatory provisions of this **Section 12** shall apply to any such sub-agent and to the Related Parties of the Administrative Agent and of any such sub-agent, and shall apply to their respective activities in connection with their activities as Administrative Agent. The Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and non-appealable judgment that the Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agents.

12.05 Reliance and Liability.

(a) The Administrative Agent may, without incurring any liability hereunder, (i) consult with any of its Related Parties and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, any Obligor) and (ii) rely and act upon any notice, request, certificate, consent, statement, instrument, document or other writing (including and electronic message, Internet or intranet website posting or other distribution), telephone message or conversation or oral conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. In determining compliance with any condition hereunder to the making of a Loan that by its terms must be fulfilled to the satisfaction of a Lender, the Administrative Agent may presume that such condition is satisfactory to such Lender unless the Administrative Agent shall have received written notice to the contrary from such Lender prior to the making of such Loan.

(b) Neither the Administrative Agent nor any of its Related Parties shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and the Borrower hereby waive and shall not assert (and the Borrower shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting primarily from the fraudulent conduct or behavior of the Administrative Agent or, as the case may be, such Related Party (each as determined in a final, non-appealable judgment or order by a court of competent jurisdiction) in connection with the duties expressly set forth herein. Without limiting the foregoing, the Administrative Agent:

(i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of, or with the consent of, the Majority Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Administrative Agent shall believe in good faith to be necessary, under the circumstances as provided in **Section 14.04**) or for the actions or omissions of any of its Related Parties selected with reasonable care (other than employees, officers and directors of the Administrative Agent, when acting on behalf of the Administrative Agent);

(ii) shall not be responsible to any Secured Party for the (a) validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document, or (b) due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document;

(iii) makes no warranty or representation, and shall not be responsible, to any Secured Party for, and shall not have any duty to ascertain or inquire into, any statement, document, information, certificate, report, representation or warranty made or furnished by or on behalf of any Related Party, in or in connection with any Loan Document or any transaction contemplated therein, whether or not transmitted by the Administrative Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by the Administrative Agent in connection with the Loan Documents, including, for the avoidance of doubt, the satisfaction of any condition set forth in **Section 6** of this Agreement or elsewhere herein (other than to confirm receipt of items expressly required to be delivered to the Administrative Agent); and

(iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document or whether any condition set forth in any Loan Document is satisfied or waived, including, without limiting the generality of the foregoing, as to the financial condition of any Obligor or as to the existence or continuation or possible occurrence or continuation of any Default or Event of Default and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from the Borrower, any Lender describing such Default or Event of Default clearly labeled "notice of default" (in which case the Administrative Agent shall promptly give notice of such receipt to all Lenders);

and, for each of the items set forth in **clauses (i)** through **(iv)** above, each Lender and the Borrower hereby waives and agrees not to assert (and the Borrower shall cause each other Obligor to waive

and agree not to assert) any right, claim or cause of action it might have against the Administrative Agent based thereon.

12.06 Administrative Agent Individually. The Administrative Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, accept deposits from, act as the financial advisor for or in any other advisory capacity for, or engage in any kind of business with, any Obligor or Affiliate thereof as though it were not acting as the Administrative Agent and may receive separate fees and other payments therefor. To the extent the Administrative Agent or any of its Affiliates makes any Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Majority Lender", and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, the Administrative Agent or such Affiliate, as the case may be, in its individual capacity as Lender or as one of the Majority Lenders, respectively.

12.07 Lender Credit Decision. Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent, any Lender or any of their Related Parties or upon any document (including the Disclosure Documents) solely or in part because such document was transmitted by the Administrative Agent or any of its Related Parties, conducted its own independent investigation of the financial condition and affairs of each Obligor and has made and continues to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate.

12.08 Expenses; Indemnities.

(a) Each Lender agrees to reimburse the Administrative Agent and each of its Related Parties (to the extent not reimbursed by any Obligor) promptly upon demand for such Lender's Proportionate Share of any costs and expenses (including fees, charges and disbursements of financial, legal and other advisors and Other Taxes paid in the name of, or on behalf of, any Obligor) that may be incurred by the Administrative Agent or any of its Related Parties in connection with the preparation, syndication, execution, delivery, administration, modification, consent, waiver or enforcement (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding or otherwise) of, or legal advice in respect of its rights or responsibilities under, any Loan Document.

(b) Each Lender further agrees to indemnify the Administrative Agent (or any sub-agent thereof) and any Related Parties of the Administrative Agent (or any such sub-agent) (to the extent not paid by any Obligor), from and against such Lender's aggregate Proportionate Share of the liabilities (including taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to on or for the account of any Lender) that may be imposed on, incurred by or asserted against the Administrative Agent (or any sub-agent thereof) or any Related Parties of the Administrative Agent (or any such sub-agent) in any matter relating to or arising out of, in connection with or as a result of any Loan Document, any related document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by the Administrative Agent (or any sub-

agent thereof) or any Related Parties of the Administrative Agent (or any such sub-agent) under or with respect to any of the foregoing; provided that no Lender shall be liable to the Administrative Agent (or any sub-agent thereof) or any Related Parties of the Administrative Agent (or any such sub-agent) to the extent such liability has resulted primarily from the gross negligence or willful misconduct of the Administrative Agent (or any sub-agent thereof) or, as the case may be, such Related Party of the Administrative Agent (or any sub-agent thereof), as determined by a court of competent jurisdiction in a final non-appealable judgment or order.

(c) The Lenders agree to indemnify the Administrative Agent for any loss it may suffer as a result of the registration of incorrect information regarding the Collateral in the Belgian National Pledge Register.

12.09 Resignation of the Administrative Agent.

(a) At any time upon not less than thirty (30) days prior written notice to the Lenders and the Borrower, the Administrative Agent may resign as the "the Administrative Agent" hereunder (in the sole and absolute discretion of the Administrative Agent). If the Administrative Agent delivers any such notice, the Majority Lenders shall have the right (subject to the consent of the Borrower, which shall not be unreasonably withheld or, if an Event of Default has occurred and is continuing, required), to appoint a successor, which shall be (i) a Lender holding at least thirty percent (30%) of the outstanding principal amount of the Loans or any Affiliate thereof or (ii) any other financial institution consented to by the Borrower (provided that the consent of the Borrower shall not be required to the extent a payment or bankruptcy Event of Default has occurred and is continuing). If any amount payable under this Agreement by an Obligor established in France becomes not deductible from that Obligor's taxable income for French tax purposes by reason of that amount (i) being paid or accrued to an Agent incorporated or acting through an office situated in a Non-Cooperative Jurisdiction or (ii) paid to an account opened in the name of that Administrative Agent in a financial institution situated in a Non-Cooperative Jurisdiction, the Administrative Agent and the Lenders shall (at the request of the Borrower) use commercially reasonable efforts to (x) designate a new facility office of the Administrative Agent that is not situated in a Non-Cooperative Jurisdiction, (y) replace the relevant bank account of the Administrative Agent by a bank account opened in a financial institution that is not situated in a Non-Cooperative Jurisdiction, or (z) failing to achieve (x) or (y), replace the Administrative Agent. The Borrower hereby agrees to pay all reasonable costs and expenses incurred by the Administrative Agent or the Lenders in connection with any such designation or replacement completed at the request of the Borrower. If a successor Administrative Agent has not been appointed on or before the effectiveness of the resignation of the resigning Administrative Agent (or such earlier date as shall be agreed by the Majority Lenders) (the "***Resignation Effective Date***"), then the resigning Administrative Agent may (but shall not be obligated to), on behalf of the Lenders, appoint any Person reasonably chosen by it as the successor Administrative Agent meeting the qualifications set forth above; provided that in no event shall any such successor Administrative Agent be a Defaulting Lender. Whether or not a successor has been appointed, such resignation shall become effective on the Resignation Effective Date.

(b) Effective from the Resignation Effective Date, (i) the resigning Administrative Agent shall be discharged from its duties and obligations under the Loan Documents to the extent set forth in the applicable resignation notice, (ii) the Majority Lenders shall assume and perform

all of the duties of the Administrative Agent until a successor Administrative Agent shall have accepted a valid appointment hereunder, (iii) the resigning Administrative Agent and its Related Parties shall no longer have the benefit of any provision of any Loan Document other than with respect to (x) any actions taken or omitted to be taken while such resigning Administrative Agent was, or because the Administrative Agent had been, validly acting as the Administrative Agent under the Loan Documents or (y) any continuing duties such resigning Administrative Agent will continue to perform, and (iv) subject to its rights under **Section 12.04**, the resigning Administrative Agent shall take such action as may be reasonably necessary to assign to the successor Administrative Agent its rights as the Administrative Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as the Administrative Agent, a successor Administrative Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the resigning Administrative Agent under the Loan Documents.

12.10 Release of Collateral or Guarantors. Each Lender hereby consents to the release and hereby directs the Administrative Agent to release, and the Administrative Agent hereby agrees, (or, in the case of **Section 12.10(b)**, release or subordinate) the following:

(a) any Subsidiary of the Borrower from its guaranty of any Obligation of any Obligor (i) if such Subsidiary ceases to be a Subsidiary of such Obligor as a result of a transaction permitted under and in accordance with the Loan Documents (including pursuant to a waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to Guaranty any Obligations pursuant to **Section 8.11(a)** or (ii) upon (x) termination of the Commitments and (y) payment and satisfaction in full of all Loans and all other Obligations that the Administrative Agent has been notified in writing are then due and payable (other than inchoate indemnification and expense reimbursement obligations for which no claim has been made); and

(b) any Lien held by the Administrative Agent for the benefit of the Secured Parties against (i) any Collateral that is disposed of by an Obligor as a result of a transaction permitted under and in accordance with the Loan Documents (including pursuant to a valid waiver or consent), (ii) any property subject to a Lien described in **Section 9.02(c)** or **(j)**, and (iii) all of the Collateral and all Obligors, upon (x) termination of the Commitments and (y) payment and satisfaction in full of all Loans and all other Obligations that the Administrative Agent has been notified in writing are then due and payable (other than inchoate indemnification and expense reimbursement obligations for which no claim has been made).

Each Lender hereby directs the Administrative Agent, and the Administrative Agent hereby agrees, upon receipt of reasonable advance notice from the Borrower, to execute and deliver or file such documents and to perform other actions reasonably necessary to release the guarantees and Liens when and as directed in this **Section 12.10** and deliver to the Borrower, at the expense of the Borrower, any portion of such Collateral so released pursuant to this **Section 12.10** that is in possession of the Administrative Agent. In addition, in connection with any Permitted Licenses, each Lender hereby authorizes Administrative Agent to, and at the request of the Borrower, the Administrative Agent shall, negotiate and enter into a non-disturbance agreement and other similar agreements in form and substance reasonably satisfactory to Administrative Agent.

Notwithstanding the foregoing or anything to the contrary herein, (i) the release of any Obligor from its guaranty of any Obligations under this **Section 12.10** or otherwise hereunder shall only

be permitted if any such permitted transaction or series of related transactions is not consummated for the primary purpose of effecting a release of such Obligor from its Obligations under the Loan Documents in accordance with the terms hereof, and (ii) the Administrative Agent may not effect a release of any Obligor that ceases to be an Obligor due solely to a disposition of Equity Interests in (or issuance of Equity Interests by) such Obligor, unless in the case of this clause (ii) the transaction related to such release is a disposition of Equity Interests for fair market value to an unaffiliated third party and for a bona fide primary business purpose.

12.11 Additional Secured Parties. The benefit of the provisions of the Loan Documents directly relating to the Collateral or any Lien granted thereunder shall extend to and be available to any Secured Party that is not a Lender as long as, by accepting such benefits, such Secured Party agrees, as among the Administrative Agent and all other Secured Parties, that such Secured Party is bound by (and, if requested by the Administrative Agent, shall confirm such agreement in a writing in form and substance acceptable to the Administrative Agent) this **Section 12** and the decisions and actions of the Administrative Agent and the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders) to the same extent a Lender is bound; provided that, notwithstanding the foregoing, (i) such Secured Party shall be bound by **Section 12.08** only to the extent of liabilities, costs and expenses with respect to or otherwise relating to the Collateral held for the benefit of such Secured Party, in which case the obligations of such Secured Party thereunder shall not be limited by any concept of Proportionate Share or similar concept, (ii) each of the Administrative Agent and each Lender shall be entitled to act at its sole discretion, without regard to the interest of such Secured Party, regardless of whether any Obligation to such Secured Party thereafter remains outstanding, is deprived of the benefit of the Collateral, becomes unsecured or is otherwise affected or put in jeopardy thereby, and without any duty or liability to such Secured Party or any such Obligation and (iii) such Secured Party shall not have any right to be notified of, consent to, direct, require or be heard with respect to, any action taken or omitted in respect of the Collateral or under any Loan Document.

~~**12.12 [Reserved]**~~**12.12 Parallel Debt**.

(a) Each Obligor hereby irrevocably and unconditionally undertakes to pay to the Administrative Agent as creditor in its own right and not as a representative of the Lenders or other Secured Parties by way of an abstract acknowledgment of debt (*abstraktes Schuldanerkenntnis*) amounts equal to any amounts owing from time to time by that Obligor to each of the Lenders and other Secured Parties under each of the Loan Documents as and when those amounts are due for payment.

(b) Each Obligor and the Administrative Agent acknowledges that the obligations of each Obligor under paragraph (a) above are several and are separate and independent from, and shall not in any way limit or affect, the corresponding obligations of that Obligor to any Lender or other Secured Party under any Loan Document (its "***Corresponding Debt***") nor shall the amounts for which each Obligor is liable under paragraph (a) above (its "***Parallel Debt***") be limited or affected in any way by its Corresponding Debt, provided that:

(i) the Administrative Agent shall not demand payment with regard to the Parallel Debt of any Obligor to the extent that such Obligor's Corresponding Debt has been irrevocably paid or (in the case of guarantee obligations) discharged; and

(ii) a Lender or other Secured Party shall not demand payment with regard to the Corresponding Debt of any Obligor to the extent that such Obligor's Parallel Debt has been irrevocably paid or (in the case of guarantee obligations) discharged.

(c) The Administrative Agent acts in its own name and not as a trustee and its claims in respect of the Parallel Debt shall not be held on trust. The security interest granted under the Security Documents to the Administrative Agent to secure the Parallel Debt is granted to the Administrative Agent in its capacity as creditor of the Parallel Debt.

(d) All monies received or recovered by the Administrative Agent pursuant to this **Section 12.12**, and all amounts received or recovered by the Administrative Agent from or by the enforcement of any security interest granted to secure the Parallel Debt, shall be applied in accordance with this Agreement.

(e) Without limiting or affecting the Administrative Agent's rights against the Obligors (whether under this **Section 12.12** or under any other provision of the Loan Documents), each Obligor acknowledges that:

(i) nothing in this **Section 12.12** shall impose any obligation on the Administrative Agent to advance any sum to any Obligor or otherwise under any Loan Document (except in any capacity as a Lender); and

(ii) for the purpose of any vote taken under any Loan Document, the Administrative Agent shall not be regarded as having any participation or Commitment (other than those which it has or may have as a Lender).

12.13 Agent May File Proofs of Claim. In case of the pendency of any Insolvency Proceeding or any other judicial proceeding relating to any Obligor, the Administrative Agent (irrespective of whether the principal of any Loan shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Administrative Agent shall have made any demand on the Borrower or any other Obligor) shall be entitled and empowered (but not obligated) by intervention or such proceeding or otherwise:

(a) to file and prove a claim for the whole amount of the principal and interest owing and unpaid in respect of the Loans and all other Obligations that are owing and unpaid and to file such other documents as may be necessary or advisable in order to have the claims of the Lenders and the Administrative Agent (including any claim for the reasonable compensation, expenses, disbursements and advances of the Lenders and the Administrative Agent and their respective agents and counsel and all other amounts due the Lenders and the Administrative Agent under **Section 14.03**) allowed in such judicial proceeding; and

(b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, assignee, trustee, liquidator, sequestrator, examiner or other similar official in any such judicial proceeding is hereby authorized by each Lender to make such payments to the Administrative Agent and, in the event that the Administrative Agent shall consent to the making of such payments directly to the Lenders, to pay to the Administrative Agent any

amount due for the reasonable compensation, expenses, disbursements and advances of the Administrative Agent and its agents and counsel, and any other amounts due to the Administrative Agent under **Section 14.03**.

12.14 Acknowledgements of Lenders.

(a) If the Administrative Agent notifies a Lender, or any Person who has received funds on behalf of a Lender (any such Lender or other recipient, a "***Payment Recipient***"), that the Administrative Agent has determined in its reasonable discretion (whether or not after receipt of any notice under immediately succeeding **clause (b)**) that any funds received by such Payment Recipient from the Administrative Agent or any of its Affiliates were erroneously transmitted to, or otherwise erroneously or mistakenly received by, such Payment Recipient (whether or not known to such Lender or other Payment Recipient on its behalf) (any such funds, whether received as a payment, prepayment or repayment of principal, interest, fees, distribution or otherwise, individually and collectively, an "***Erroneous Payment***") and demands the return of such Erroneous Payment (or a portion thereof), such Erroneous Payment shall at all times remain the property of the Administrative Agent, and such Lender shall (or, with respect to any Payment Recipient who received such funds on its behalf, shall cause such Payment Recipient to) promptly, but in no event later than five Qatari Business Days thereafter, return to the Administrative Agent the amount of any such Erroneous Payment (or portion thereof) as to which such a demand was made, in same day funds (in the currency so received), together with interest thereon in respect of each day from and including the date such Erroneous Payment (or portion thereof) was received by such Payment Recipient to the date such amount is repaid to the Administrative Agent in same day funds at the greater of the Federal Funds Effective Rate and a rate determined by the Administrative Agent in accordance with banking industry rules on interbank compensation from time to time in effect. A notice of the Administrative Agent to any Payment Recipient under this **clause (a)** shall be conclusive, absent manifest error. Notwithstanding the foregoing, without limiting any other rights or remedies (whether at law or in equity), the Administrative Agent may not make any demand under this **clause (a)** with respect to an Erroneous Payment unless such demand is made within five (5) Business Days of the date of receipt of such Erroneous Payment by the applicable Payment Recipient.

(b) Without limiting immediately preceding **clause (a)**, each Lender, or any Person who has received funds on behalf of a Lender, hereby further agrees that if it receives a payment, prepayment or repayment (whether received as a payment, prepayment or repayment of principal, interest, fees, distribution or otherwise) from the Administrative Agent (or any of its Affiliates) (x) that is in a different amount than, or on a different date from, that specified in a notice of payment, prepayment or repayment sent by the Administrative Agent (or any of its Affiliates) with respect to such payment, prepayment or repayment, (y) that was not preceded or accompanied by a notice of payment, prepayment or repayment sent by the Administrative Agent (or any of its Affiliates) or (z) that such Lender or other such recipient otherwise becomes aware was transmitted, or received, in error or by mistake (in whole or in part), in each case: (i) (A) in the case of immediately preceding clauses (x) or (y), an error shall be presumed to have been made (absent written confirmation from the Administrative Agent to the contrary) or (B) an error has been made (in the case of immediately preceding **clause (z)**), in each case, with respect to such payment, prepayment or repayment; and (ii) such Lender shall (and shall cause any other recipient that receives funds on its respective behalf to) promptly (and, in all events, within one (1) Business Day of its knowledge

such error) use commercially reasonable efforts to notify the Administrative Agent of its receipt of such payment, prepayment or repayment, the details thereof (in reasonable detail) and that it is so notifying the Administrative Agent pursuant to this **Section 12.14(b)(ii)**.

(c) Each Lender hereby authorizes the Administrative Agent to set off, net and apply any and all amounts at any time owing to such Lender under any Loan Document, or otherwise payable or distributable by the Administrative Agent to such Lender under any Loan Document with respect to any payment of principal, interest, fees or other amounts, against any amount that the Administrative Agent has demanded to be returned under the preceding **clause (a)** above.

(d) In the event that an Erroneous Payment (or portion thereof) is not recovered by the Administrative Agent for any reason, after demand therefor by the Administrative Agent in accordance with the preceding **clause (a)** above, from any Lender that has received such Erroneous Payment (or portion thereof) (and/or from any Payment Recipient who received such Erroneous Payment (or portion thereof) on its respective behalf) (such unrecovered amount, an "***Erroneous Payment Return Deficiency***"), upon the Administrative Agent's notice to such Lender at any time, (i) such Lender shall be deemed to have assigned its Loans (but not its Commitments) with respect to which such Erroneous Payment was made (the "***Erroneous Payment Impacted Loans***") in an amount equal to the Erroneous Payment Return Deficiency (or such lesser amount as the Administrative Agent may specify) (such assignment of the Loans (but not Commitments) of the Erroneous Payment Impacted Loans, the "***Erroneous Payment Deficiency Assignment***") at par plus any accrued and unpaid interest (with the assignment fee to be waived by the Administrative Agent in such instance), and is hereby (together with the Borrower) deemed to execute and deliver an Assignment and Assumption with respect to such Erroneous Payment Deficiency Assignment, and such Lender shall deliver any Notes evidencing such Loans to the Borrower or the Administrative Agent, (ii) the Administrative Agent as the assignee Lender shall be deemed to have acquired the Erroneous Payment Deficiency Assignment, (iii) upon such deemed acquisition, the Administrative Agent as the assignee Lender shall become a Lender hereunder with respect to such Erroneous Payment Deficiency Assignment and the assigning Lender shall cease to be a Lender, as applicable, hereunder with respect to such Erroneous Payment Deficiency Assignment, excluding, for the avoidance of doubt, its obligations under the indemnification provisions of this Agreement and its Commitments which shall survive as to such assigning Lender and (iv) the Administrative Agent may reflect in the Register its ownership interest in the Loans subject to the Erroneous Payment Deficiency Assignment. The Administrative Agent may, in its discretion, sell any Loans acquired pursuant to an Erroneous Payment Deficiency Assignment and upon receipt of the proceeds of such sale, the Erroneous Payment Return Deficiency owing by the applicable Lender shall be reduced by the net proceeds of the sale of such Loan (or portion thereof), and the Administrative Agent shall retain all other rights, remedies and claims against such Lender (and/or against any recipient that receives funds on its respective behalf). For the avoidance of doubt, no Erroneous Payment Deficiency Assignment will reduce the Commitments of any Lender and such Commitments shall remain available in accordance with the terms of this Agreement. In addition, each party hereto agrees that, except to the extent that the Administrative Agent has sold a Loan (or portion thereof) acquired pursuant to an Erroneous Payment Deficiency Assignment, and irrespective of whether the Administrative Agent may be equitably subrogated, the Administrative Agent shall be contractually subrogated to all the rights and interests of the applicable Lender under the Loan Documents with respect to each Erroneous Payment Return Deficiency.

(e) The parties hereto agree that an Erroneous Payment shall not pay, prepay, repay, discharge or otherwise satisfy any Obligations owed by the Borrower or any other Obligor except, in each case, to the extent such Erroneous Payment is, and solely with respect to the amount of such Erroneous Payment that is, comprised of funds received by the Administrative Agent from the Borrower or any other Obligor for the purpose of making such Erroneous Payment.

(f) To the extent permitted by applicable law, no Payment Recipient shall assert any right or claim to an Erroneous Payment, and hereby waives, and is deemed to waive, any claim, counterclaim, defense or right of set-off or recoupment with respect to any demand, claim or counterclaim by the Administrative Agent for the return of any Erroneous Payment received, including waiver of any defense based on "discharge for value" or any similar doctrine.

(g) Each party's obligations, agreements and waivers under this **Section 12.14(g)** shall survive the resignation or replacement of the Administrative Agent, any transfer of rights or obligations by, or the replacement of, a Lender, the termination of the Commitments and/or the repayment, satisfaction or discharge of all Obligations (or any portion thereof) under any Loan Document.

SECTION 13.
GUARANTY

13.01 The Guaranty. The Guarantors hereby unconditionally jointly and severally guarantee to the Administrative Agent and the Lenders, and their successors and assigns, the full and punctual payment in full or performance (whether at stated maturity, by acceleration or otherwise) of the Obligations, including (i) principal of and interest on the Loans, (ii) all fees and other amounts and Obligations from time to time owing to the Administrative Agent and the Lenders by the Borrower and each other Obligor under this Agreement or under any other Loan Document, in each case strictly in accordance with the terms hereof and thereof and (iii) the punctual and faithful performance, keeping, observance and fulfillment by the Borrower and Guarantors of all the agreements, conditions, covenants and obligations of the Borrower and Guarantors contained in the Loan Documents (such obligations being herein collectively called the "***Guaranteed Obligations***"). The Guarantors hereby further jointly and severally agree that if the Borrower or any other Obligor shall fail to pay any amount in full when due or perform any such obligation (whether at stated maturity, by acceleration or otherwise), the Guarantors will promptly pay the same or perform such obligation at the place and in the manner specified herein or in the relevant Loan Document, as the case may be, without any demand or notice whatsoever, and that in the case of any extension of time of payment or performance or renewal of any of the Guaranteed Obligations, the same will be promptly paid in full or performed when due (whether at extended maturity, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

13.02 Obligations Unconditional. The obligations of the Guarantors under **Section 13.01** shall constitute a guaranty of payment and performance and not of collection and are absolute and unconditional, joint and several, irrespective of the value, genuineness, validity, regularity or enforceability of the Guaranteed Obligations under this Agreement or any other agreement or instrument referred to herein, or any substitution, release or exchange of any other guarantee of or security for any of the Guaranteed Obligations, and, to the fullest extent permitted by all applicable Laws, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or

equitable discharge or defense of a surety or guarantor, it being the intent of this **Section 13.02** that the obligations of the Guarantors hereunder shall be absolute and unconditional, joint and several, under any and all circumstances. Without limiting the generality of the foregoing, but subject to Section 14.04, it is agreed that the occurrence of any one or more of the following shall not alter or impair the liability of the Guarantors hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to the Guarantors, the time for any performance of or compliance with any of the Guaranteed Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of this Agreement or any other agreement or instrument referred to herein shall be done or omitted;

(c) the maturity of any of the Guaranteed Obligations shall be accelerated, or any of the Guaranteed Obligations shall be extended, modified, supplemented or amended in any respect, or any right under this Agreement or any other agreement or instrument referred to herein shall be waived or any other guarantee of any of the Guaranteed Obligations or any security therefor shall be released or exchanged in whole or in part or otherwise dealt with;

(d) any lien or security interest granted to, or in favor of, the Secured Parties as security for any of the Guaranteed Obligations shall fail to be perfected or preserved;

(e) any modification or amendment of or supplement to this Agreement or any other Loan Document, including any such amendment which may increase the amount of, or the interest rates applicable to, any of the Guaranteed Obligations guaranteed hereby;

(f) any change in the corporate, partnership, limited liability company or other existence, structure or ownership of the Borrower, any Guarantor or any other guarantor of any of the Guaranteed Obligations, or any Insolvency Proceeding or other similar proceeding affecting the Borrower, any Guarantor or any other guarantor of the Guaranteed Obligations, or any of their respective assets, or any resulting release or discharge of any obligation of the Borrower, any Guarantor or any other guarantor of any of the Guaranteed Obligations (other than the satisfaction of the Termination Conditions);

(g) the existence of any claim, setoff or other rights which any Guarantor may have at any time against the Borrower, any other Guarantor or any other guarantor of any of the Guaranteed Obligations, the Administrative Agent, any Secured Party or any other Person, whether in connection herewith or in connection with any unrelated transactions; provided that, notwithstanding any other provisions in this Guaranty, nothing in this Guaranty shall prevent the assertion of any such claim by separate suit or compulsory counterclaim;

(h) the unenforceability or invalidity of the Guaranteed Obligations or any part thereof or the lack of genuineness, enforceability or validity of any agreement relating thereto or with respect to the Collateral, if any, securing the Guaranteed Obligations or any part thereof, or any other invalidity or unenforceability relating to or against the Borrower, any Guarantor or any other guarantor of any of the Guaranteed Obligations, for any reason, related to this Agreement or any other Loan Document, or any provision of applicable Law, decree, order or regulation of any

jurisdiction purporting to prohibit the payment of any of the Guaranteed Obligations by the Borrower, any Guarantor or any other guarantor of the Guaranteed Obligations;

(i) the disallowance, under any state or federal bankruptcy, insolvency or similar law, of all or any portion of the claims of the Secured Parties or the Administrative Agent for repayment of all or any part of the Guaranteed Obligations;

(j) the failure of any other guarantor to sign or become party to this Agreement or any amendment, change, or reaffirmation hereof;

(k) any release, surrender, compromise, settlement, waiver, subordination or modification, with or without consideration, of any Collateral securing the Guaranteed Obligations or any part thereof, any other guaranties with respect to the Guaranteed Obligations or any part thereof, or any other obligation of any person or entity with respect to the Guaranteed Obligations or any part thereof, or any nonperfection or invalidity of any direct or indirect security for the Guaranteed Obligations; or

(l) any other act or omission to act or delay of any kind by the Borrower, such Guarantor, any other guarantor of the Guaranteed Obligations, the Administrative Agent, any Secured Party or any other Person or any other circumstance whatsoever which might, but for the provisions of this **Section 13.02**, constitute a legal or equitable discharge of any Guarantor's obligations hereunder (other than the satisfaction of the Termination Conditions).

The Guarantors hereby expressly waive diligence, presentment, demand of payment, protest and all notices whatsoever (except if such notice is specifically required to be given to such Guarantor under this Guaranty or under the other Loan Documents), and any requirement that the Administrative Agent or any Lender exhaust any right, power or remedy or proceed against the Borrower or any other Guarantor under this Agreement or any other agreement or instrument referred to herein, or against any other Person under any other guarantee of, or security for, any of the Guaranteed Obligations.

13.03 Discharge Only Upon Payment in Full.13.04 Subject to any prior release herefrom of any Guarantor by the Administrative Agent in accordance with (and pursuant to authority granted to the Administrative Agent under) the terms of this Agreement, each Guarantor's obligations hereunder shall remain in full force and effect until all of the Guaranteed Obligations shall have been paid in full in cash (other than inchoate indemnification and expense reimbursement obligations for which no claim has been made), and all other financing arrangements among the Borrower or any Guarantor and the Secured Parties under or in connection with this Agreement and each other Loan Document shall have terminated (herein, the "***Termination Conditions***"), and until the prior and complete satisfaction of the Termination Conditions all of the rights and remedies under this Guaranty and the other Loan Documents shall survive. Notwithstanding the foregoing, the Administrative Agent hereby agrees to release any Subsidiary of the Borrower from its guaranty of any Obligation of any Obligor if all of the Equity Interests in such Subsidiary owned by any Obligor or any of its Subsidiaries are disposed of as a result of a transaction permitted under and in accordance with the Loan Documents (including pursuant to a waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guarantee any Obligations pursuant to **Section 8.12(a)**.

13.04 Additional Waivers; General Waivers.

(a) *Additional Waivers.* Notwithstanding anything herein to the contrary, each of the Guarantors hereby absolutely, unconditionally, knowingly, and expressly waives:

(i) any right it may have to revoke this Guaranty as to future indebtedness or notice of acceptance hereof;

(ii) (A) notice of acceptance hereof; (B) notice of any other financial accommodations made or maintained under the Loan Documents or the creation or existence of any Guaranteed Obligations; (C) notice of the amount of the Guaranteed Obligations, subject, however, to each Guarantor's right to make inquiry of the Administrative Agent and the Secured Parties to ascertain the amount of the Guaranteed Obligations at any reasonable time; (D) notice of any adverse change in the financial condition of the Borrower or of any other fact that might increase such Guarantor's risk hereunder; (E) notice of presentment for payment, demand, protest, and notice thereof as to any instruments among the Loan Documents; (F) notice of any Event of Default; and (G) all other notices (except if such notice is specifically required to be given to such Guarantor under this Guaranty or under the other Loan Documents) and demands to which each Guarantor might otherwise be entitled;

(iii) its right, if any, to require the Administrative Agent and the Secured Parties to institute suit against, or to exhaust any rights and remedies which the Administrative Agent and the Secured Parties now have or may hereafter have against, any other guarantor of the Guaranteed Obligations or any third party, or against any Collateral provided by such other guarantors or any third party; and each Guarantor further waives any defense arising by reason of any disability or other defense (other than the defense that the Guaranteed Obligations shall have been fully and finally performed and indefeasibly paid) of any other guarantor of the Guaranteed Obligations or by reason of the cessation from any cause whatsoever of the liability of any other guarantor of the Guaranteed Obligations in respect thereof;

(iv) (A) any rights to assert against the Administrative Agent and the Secured Parties any defense (legal or equitable), set-off, counterclaim, or claim which such Guarantor may now or at any time hereafter have against any other guarantor of the Guaranteed Obligations or any third party liable to the Administrative Agent and the Secured Parties; (B) any defense, set-off, counterclaim or claim, of any kind or nature, arising directly or indirectly from the present or future lack of perfection, sufficiency, validity or enforceability of the Guaranteed Obligations or any security therefor; (C) any defense such Guarantor has to performance hereunder, and any right such Guarantor has to be exonerated, arising by reason of: (1) the impairment or suspension of the Administrative Agent's and the Secured Parties' rights or remedies against any other guarantor of the Guaranteed Obligations; (2) the alteration by the Administrative Agent and the Secured Parties of the Guaranteed Obligations; (3) any discharge of the obligations of any other guarantor of the Guaranteed Obligations to the Administrative Agent and the Secured Parties by operation of law as a result of the Administrative Agent's and the Secured Parties' intervention or omission (other than upon satisfaction of the Termination Conditions); or (4) the acceptance by the Administrative Agent and the Secured Parties of anything in partial satisfaction of the Guaranteed Obligations; and (D) the benefit of any statute of limitations affecting such Guarantor's liability hereunder or the enforcement thereof, and any act which shall defer or delay the operation of any statute of

limitations applicable to the Guaranteed Obligations shall similarly operate to defer or delay the operation of such statute of limitations applicable to such Guarantor's liability hereunder; and

(v) any defense arising by reason of or deriving from (A) any claim or defense based upon an election of remedies by the Administrative Agent and the other Secured Parties; or (B) any election by the Administrative Agent and the other Secured Parties under any provision of any state or federal bankruptcy, insolvency or similar law to limit the amount of, or any Collateral securing, its claim against the Guarantors.

(b) *General Waivers.* Each Guarantor irrevocably waives, to the fullest extent permitted by Law, any notice not provided for herein or in the other Loan Documents.

(c) *Brazilian Guarantors.* For the avoidance of doubt and notwithstanding the fact that the Guaranteed Obligations of each Brazilian Guarantor under this Agreement are governed by the Laws of the State of New York, each Brazilian Guarantor hereby irrevocably and unconditionally waives the benefits of Articles 827, 829, 830, 834, 835, 837, 838 and 839 of Law No. 10,406, of January 10, 2002 and Articles 130 and 794 of Law No. 10,105, of March 16, 2015.

13.05 Reinstatement. The obligations of the Guarantors under this **Section 13** shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of the Borrower in respect of the Guaranteed Obligations is at any time rescinded, annulled, avoided, set aside, invalidated, declared to be fraudulent or must be otherwise restored or repaid by any holder of any of the Guaranteed Obligations, whether as a result of any proceedings in bankruptcy or reorganization, equitable cause or otherwise, and the Guarantors jointly and severally agree that they will indemnify the Secured Parties on demand for all reasonable costs and expenses (including fees of counsel) incurred by such Persons in connection with such rescission, repayment or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any state or federal bankruptcy, insolvency or similar law. The provisions of this **Section 13.05** shall survive termination of this Guaranty.

13.06 Subrogation. The Guarantors hereby jointly and severally agree that, until the prior and complete satisfaction of all Termination Conditions, they (i) shall have no right of subrogation with respect to the Guaranteed Obligations and (ii) waive any right to enforce any remedy which the Secured Parties or the Administrative Agent now have or may hereafter have against the Borrower, any endorser or any other guarantor of all or any part of the Guaranteed Obligations or any other Person, and each Guarantor waives any benefit of, and any right to participate in, any security or Collateral that may from time to time be given to the Secured Parties and the Administrative Agent to secure the payment or performance of all or any part of the Guaranteed Obligations or any other liability of the Borrower to the Secured Parties. Should any Guarantor have the right, notwithstanding the foregoing, to exercise its subrogation rights prior to complete satisfaction of the Termination Conditions, each Guarantor hereby expressly and irrevocably (A) subordinates any and all rights at law or in equity to subrogation, reimbursement, exoneration, contribution, indemnification or set-off that such Guarantor may have prior to the complete satisfaction of the Termination Conditions, and (B) waives any and all defenses available to a surety, guarantor or accommodation co-obligor until all Termination Conditions are satisfied in full. Each Guarantor acknowledges and agrees that this subordination is intended to benefit the

Administrative Agent and the Secured Parties and shall not limit or otherwise affect such Guarantor's liability hereunder or the enforceability of this Guaranty, and that the Administrative Agent, the Secured Parties and their respective successors and assigns are intended third party beneficiaries of the waivers and agreements set forth in this **Section 13.06**.

13.07 Remedies. The Guarantors jointly and severally agree that, as between the Guarantors, on one hand, and the Administrative Agent and the Lenders, on the other hand, the obligations of the Borrower under this Agreement and under the other Loan Documents may be declared to be forthwith due and payable as provided in **Section 11** (and shall be deemed to have become automatically due and payable in the circumstances provided in **Section 11**) for purposes of **Section 13.01** notwithstanding any stay, injunction or other prohibition, including any such stay upon an Insolvency Proceeding, preventing such declaration (or such obligations from becoming automatically due and payable) as against the Borrower and that, in the event of such declaration (or such obligations being deemed to have become automatically due and payable), such obligations (whether or not due and payable by the Borrower) shall forthwith become due and payable by the Guarantors for purposes of **Section 13.01**.

13.08 Instrument for the Payment of Money. Each Guarantor hereby acknowledges that the guarantee in this **Section 13** constitutes an instrument for the payment of money, and consents and agrees that the Administrative Agent and the Lenders, at their sole option, in the event of a dispute by such Guarantor in the payment of any moneys due hereunder, shall have the right to proceed by motion for summary judgment in lieu of complaint pursuant to N.Y. Civ. Prac. L&R § 3213.

13.09 Continuing Guarantee. The guarantee in this **Section 13** is a continuing guarantee, and shall apply to all Guaranteed Obligations whenever arising.

13.10 Contribution with Respect to Guaranteed Obligations.

(a) To the extent that any Guarantor shall make a payment under this Guaranty (a "***Guarantor Payment***") which, taking into account all other Guarantor Payments then previously or concurrently made by any other Guarantor, exceeds the amount which otherwise would have been paid by or attributable to such Guarantor if each Guarantor had paid the aggregate Guaranteed Obligations satisfied by such Guarantor Payment in the same proportion as such Guarantor's Allocable Amount (as determined immediately prior to such Guarantor Payment) bore to the aggregate Allocable Amounts of each of the Guarantors as determined immediately prior to the making of such Guarantor Payment, *then*, following the prior and complete satisfaction of the Termination Conditions, such Guarantor shall be entitled to receive contribution and indemnification payments from, and be reimbursed by, each other Guarantor for the amount of such excess, *pro rata* based upon their respective Allocable Amounts in effect immediately prior to such Guarantor Payment.

(b) As of any date of determination, the "***Allocable Amount***" of any Guarantor shall be equal to the maximum amount of the claim which could then be recovered from such Guarantor under this Agreement without rendering such claim voidable or avoidable under any state or federal bankruptcy, insolvency or similar law or other applicable Law.

(c) This **Section 13.10** is intended only to define the relative rights of the Guarantors, and nothing set forth in this **Section 13.10** is intended to or shall impair the obligations of the Guarantors, jointly and severally, to pay any amounts as and when the same shall become due and payable in accordance with the terms of this Agreement.

(d) The parties hereto acknowledge that the rights of contribution and indemnification hereunder shall constitute assets of the Guarantor or Guarantors to which such contribution and indemnification is owing.

(e) The rights of the indemnifying Guarantors against other Guarantors under this **Section 13.10** shall be exercisable only upon the prior and complete satisfaction of the Termination Conditions.

13.11 General Limitations on Guarantee Obligations. In any action or proceeding involving any provincial, territorial or state corporate law, or any state or federal bankruptcy, insolvency, reorganization or other law affecting the rights of creditors generally, if the obligations of any Guarantor under **Section 13.01** would otherwise be held or determined to be void, invalid or unenforceable, or subordinated to the claims of any other creditors, on account of the amount of its liability under **Section 13.01**, then, notwithstanding any other provision hereof to the contrary, the amount of such liability shall, without any further action by such Guarantor, the Administrative Agent, any Lender or any other Person, be automatically limited and reduced to the highest amount that is valid and enforceable and not subordinated to the claims of other creditors as determined in such action or proceeding.

13.12 Limitations Applicable to Belgian Obligors.

(a) The total liability of a Belgian Obligor for the Obligations of any other Obligor (other than its Subsidiaries) under the Loan Documents shall at all times be limited to an amount (without double counting) not exceeding the sum of:

(i) the aggregate of all principal amounts, either directly or through one or more other Obligors (through intra-group loans or otherwise and whether retained for its own purposes or on-lent) made available to such Belgian Obligor (or its direct or indirect Subsidiaries) under any intra-group arrangement (including through the subscription of debt instruments) using proceeds made available pursuant to this Agreement; *plus*

(ii) ninety-five percent (95%) of such Belgian Obligor's own net assets (*netto actief/actif net*) (as determined in accordance with article 5:142 or 7:212 of the Belgian Code of Companies and Associations (as applicable) and accounting principles generally accepted in Belgium and ignoring the Guaranty of such Belgian Obligor) as shown by its most recent audited unconsolidated annual financial statements at the date on which the demand is made on it.

(b) No Belgian Obligor shall be liable for the Obligations of any other Obligor under the Loan Documents to the extent that such liability would result in such guarantee constituting unlawful financial assistance within the meaning of article 5:152 or 7:227 of the Belgian Code of Companies and Associations (as applicable), or any equivalent and applicable provisions in any relevant jurisdiction.

13.13 German Limitations on Guarantee Obligations.

(a) In this **Section 13.13**:

"***Auditors' Determination***" shall have the meaning ascribed to that term in paragraph (e) below.

"***Enforcement Notice***" shall have the meaning ascribed to that term in paragraph (d) below.

"***German Guarantor***" means any Guarantor incorporated in Germany as (x) a limited liability company (*Gesellschaft mit beschränkter Haftung - GmbH*) (a "***German GmbH Guarantor***") or (y) a limited partnership (*Kommanditgesellschaft*) with a limited liability company as general partner (a "***German GmbH & Co. KG Guarantor***") in relation to whom the Secured Parties (or the Administrative Agent) intend to demand payment under the Guaranty.

"***Guaranteed Obligor***" shall have the meaning ascribed to that term in paragraph (b) below.

"***Management Determination***" shall have the meaning ascribed to that term in paragraph (d) below.

"***Net Assets***" means the relevant company's assets (Section 266 para.(2) A, B, C, D and E German Commercial Code (*Handelsgesetzbuch*)), less the aggregate of its liabilities (Section 266 para. (3) B (but disregarding any accruals (*Rückstellungen*) in respect of a potential enforcement of the Guaranty), C, D and E German Commercial Code), the amount of profits (*Gewinne*) not available for distribution to its shareholders in accordance with sections 253 para. 6, 268 para. 8 and 272 para. 5 German Commercial Code and the amount of its stated share capital (*Stammkapital*).

(b) Each Secured Party agrees not to enforce the Guaranty if and to the extent that Guaranty secures any liability of an Obligor which is an Affiliate of a German Guarantor (other than that German Guarantor's wholly-owned Subsidiaries) (the "***Guaranteed Obligor***") and if and to the extent that a payment under the Guaranty would cause that German Guarantor's (or, in the case of a German GmbH & Co. KG Guarantor, its general partners') or any of its direct or indirect holding company's (in form of a German GmbH or GmbH & Co. KG which is not a relevant Obligor) Net Assets (determined pursuant to paragraphs (c), (d) and/or (e) below) to be reduced below zero, or further reduced if already below zero.

(c) For the purposes of the calculation of the Net Assets the following balance sheet items shall be adjusted as follows:

(i) the amount of any increase of the stated share capital (*Erhöhungen des Stammkapitals*) of the relevant German Guarantor after the date hereof that has been effected without the prior written consent of the Administrative Agent, shall be deducted from the stated share capital; and

(ii) contractual liabilities incurred by the relevant German Guarantor in negligent or willful violation of the Loan Documents shall be disregarded.

(d) The relevant German Guarantor shall deliver to the Secured Parties (or the Administrative Agent), within 30 Business Days after receipt from the Administrative Agent of a notice stating that the Administrative Agent intends to demand payment under the Guaranty (the "***Enforcement Notice***"), its up-to-date balance sheet, or in the case of a German GmbH & Co. KG Guarantor its and its general partner's balance sheet, together with a detailed calculation of the amount of its Net Assets taking into account the adjustments set forth in paragraph (c) above (the "***Management Determination***"). The Management Determination shall be prepared as of the date of receipt of the Enforcement Notice.

(e) Following the Administrative Agent's receipt of the Management Determination, upon request by the Administrative Agent (acting reasonably), the relevant German Guarantor shall deliver to the Secured Parties (or the Administrative Agent) within 30 Business Days of such request its up-to-date balance sheet, or in the case of a German GmbH & Co. KG Guarantor its and its general partner's balance sheet, drawn-up by its auditor together with a detailed calculation of the amount of the Net Assets taking into account the adjustments set forth in paragraph (c) above (the "***Auditors' Determination***"). Such balance sheet and Auditors' Determination shall be prepared in accordance with the accounting principles as consistently applied. The Auditors' Determination shall be prepared as of the date of receipt of the Enforcement Notice.

(f) The Administrative Agent shall be entitled to demand payment under the Guaranty in an amount which would, in accordance with the Management Determination or, if applicable and taking into account any previous enforcement in accordance with the Management Determination, the Auditors' Determination, not cause the German Guarantor's Net Assets, or in the case of a German GmbH & Co. KG Guarantor, its general partner's Net Assets, to be reduced below zero or further reduced if already below zero. If and to the extent that the Net Assets as determined by the Auditors' Determination are lower than the amount enforced (i) in accordance with the Management Determination or (ii) without regard to the Management and/or Auditors' Determination, the Administrative Agent shall release to the relevant German Guarantor (or in case of a German GmbH & Co. KG Guarantor to its general partner) such excess enforcement proceeds.

(g) The restriction under paragraph (b) above shall not apply:

(i) to the extent that the Guaranty secures (A) any Loans that are on-lent, actually disbursed to the relevant German Guarantor or any of its Subsidiaries and not repaid or (B) any guarantees issued under this Agreement for the benefit of the relevant German Guarantor or any of its Subsidiaries which are not returned, in each case if and to the extent that the relevant German Guarantor is able to set-off its recourse claims (if any) against the loan obligation in respect of the amounts on-lent to it;

(ii) if the relevant German Guarantor (as dominated entity) is subject to a domination and/or profit transfer agreement (*Beherrschungs- und/oder Gewinnabführungsvertrag*) (a "***DPTA***") with the Guaranteed Obligor, whether directly or indirectly through a chain of DPTAs between each company and its shareholder (or in case of a

German GmbH & Co. KG Guarantor between its general partner and its shareholder) and has a fully recoverable compensation claim (*Verlustausgleichsanspruch*) pursuant to Section 302 German Stock Corporation Act against its dominating entity; or

(iii) if and to extent the relevant German Guarantor has on the date of enforcement of the Guaranty a fully recoverable indemnity or claim for refund ("*vollwertiger Gegenleistungs- oder Rückgewähranspruch*") against its shareholder or the Guaranteed Obligor.

13.14 French Guarantee Limitations.

(a) Notwithstanding any provision to the contrary in the Loan Documents, in the case of each French Guarantor, the liabilities of each French Guarantor under the Loan Documents (including, without limitation, this **Section 13**) shall at all times be limited to the payment obligations of any other Obligor guaranteed by such French Guarantor and:

(i) in the case that such Obligor is a direct or indirect Subsidiary of that French Guarantor, shall:

(A) in relation to any amount due by that Obligor as Borrower, not be limited and shall therefore cover all amounts due by that Obligor as Borrower; and

(B) in relation to any amount due by that Obligor as Guarantor, be limited as set out in paragraph (a)(ii) below; and

(ii) in the case that such Obligor is not a direct or indirect Subsidiary of that French Guarantor, shall not exceed the amount equal to the aggregate of all amounts borrowed directly (as Borrower) or indirectly (by way of intra-group loans or advances directly or indirectly from any other Borrower) by such other Obligor under this Agreement to the extent directly or indirectly on-lent by such Obligor to that French Guarantor or its direct or indirect Subsidiaries and which is outstanding on the date on which the guarantee is enforced against that French Guarantor (the "***Maximum Guaranteed Amount***"); it being specified that any payment made by such French Guarantor under this **Section 13** in respect of the obligations of any other Obligor shall reduce *pro tanto* the outstanding amount of the intra-group loans or advances (if any) due by such French Guarantor or its direct or indirect Subsidiaries to that other Obligor under the intra-group loans or advances referred to above. For the avoidance of doubt, any payment made by a French Guarantor under this **Section 13.14(a)(ii)** shall reduce the Maximum Guaranteed Amount proportionally.

(b) Notwithstanding any other provision of this **Section 13**, no French Guarantor shall guarantee or secure liabilities under the Loan Documents (and in particular under this **Section 13**) which would result in such French Guarantor not complying with French financial assistance rules as set out in Article L. 225-216 of the French Commercial Code (*Code de commerce*) and/or would constitute a misuse of corporate assets (*abus de biens sociaux*) within the meaning of Articles L. 241-3, L. 242-6 and L. 244-1 of the French Commercial Code (*Code de commerce*) and/or would constitute a breach of trust (*abus de confiance*) within the meaning of Article 314-1 of the French Penal Code (*Code pénal*), and/or would infringe Articles L. 511-5 and L. 511-7 of the French Monetary and Financial Code (*Code monétaire et financier*) or any other Laws or regulations having the same effect, as interpreted by French courts.

(c) It is acknowledged that no French Guarantor is acting jointly and severally with the other Guarantors and no French Guarantor shall therefore be considered as a "*caution solidaire*" and as a "*co-débiteur solidaire*" within the meaning of Article 1318 of the French Civil Code (*Code civil*) as to their obligations pursuant to the guarantee given in accordance with this **Section 13**.

(d) For the purpose of this **Section 13.14**, "Subsidiary" means, in relation to any company, another company which is controlled by it within the meaning of Article L. 233-3 of the French Commercial Code (*Code de commerce*).

(e) Notwithstanding any provision to the contrary in this Agreement, the representations made in **Section 7** (*Representations and warranties*) by a French Guarantor shall be made for itself and for each of its Subsidiaries only and the undertakings made in **Sections 8** (*Affirmative covenants*) and **9** (*Negative covenants*) by a French Guarantor shall be made for itself and for each of its Subsidiaries only.

13.15 Spanish Guarantee Limitations. Notwithstanding the foregoing and any other provisions of this Agreement, the obligations and liabilities of any Obligor incorporated in Spain ("***Spanish Obligor***") shall (1) not extend to lending funds or guaranteeing the borrowing of (or giving any kind of financial assistance with respect to) any funds under the Loan Documents, to the extent that the same are used for the purposes of (A) acquiring quota shares (*participaciones sociales*) representing the share capital of such Spanish Obligor or quota shares (*participaciones sociales*) or shares (*acciones*) representing the share capital of a company of the same group as such Spanish Obligor, or (B) refinancing a previous debt incurred for the acquisition of quota shares (*participaciones sociales*) representing the share capital of such Spanish Obligor or shares (*acciones*) or quota shares (*participaciones sociales*) representing the share capital of a company of the same group of such Spanish Obligor and (2) be deemed not to be undertaken or incurred by such Spanish Obligor to the extent that the same would constitute unlawful financial assistance within the meaning of Article 143 or Article 150 of the Spanish Companies Law.

13.16 Italian Guarantee Limitations.

(a) In this **Section 13.16**:

"***Acquisition Utilization***" means any loan, the proceeds of which are applied towards, either directly or indirectly, the financing or re-financing of the acquisition of, or the subscription for, shares in the Italian Guarantor and/or any entity of which the Italian Guarantor is a direct or indirect subsidiary.

"***Italian Guarantor***" means a Guarantor incorporated under the laws of the Republic of Italy.

"***Maximum Rate***" means the maximum rate permitted by Law No. 108 of 7 March 1996 of Italy, as subsequently amended and supplemented.

(b) Notwithstanding any provision to the contrary herein or in the other Loan Documents and subject to **Section 13.16(c)** below, the obligations of each Italian Guarantor under this **Section 13** in respect of the obligations of any Obligor which is not a Subsidiary of such Italian Guarantor, shall not exceed, at any time, an amount equal to the greater of:

(i) the aggregate principal amount of the Loans at any time made available to and/or drawn by such Italian Guarantor (or any of its direct or indirect Subsidiaries pursuant to article 2359 of the Italian Civil Code) as Borrower under this Agreement (to the extent it is still outstanding as at that time); and

(ii) the aggregate principal amount of any intercompany loans (or other financial support in any form, such term, for the avoidance of doubt not including equity contribution) made available to and/or drawn by such Italian Guarantor (or any of its direct or indirect Subsidiaries pursuant to article 2359 of the Italian Civil Code) by any Obligor out of the proceeds of any utilisation under this Agreement and not yet repaid (in whole or in part), as resulting from time to time from the latest financial statements (*bilancio di esercizio*) duly approved by the shareholders meeting of such Italian Guarantor and/or any of its direct or indirect subsidiaries pursuant to article 2359, paragraph 1, numbers 1 and/or 2, of the Italian Civil Code, as the case may be.

(c) In any event, pursuant to article 1938 of the Italian Civil Code, the maximum amount that any Italian Guarantor may be required to pay in respect of its obligations as Guarantor under this Agreement shall not exceed $337,500,000 (or its equivalent in any other currency) (being determined as the amount equal to 150% of the aggregate amount of the Commitments as of the Closing Date), provided that the Parties agree that the amount actually secured from time to time shall in any case be determined within the limitation set forth in **Section 13.16(b)** above.

(d) Notwithstanding any provision to the contrary herein or in the other Loan Documents:

(i) if at any time any remuneration in excess of the Maximum Rate is provided for herein and/or in any other Loan Documents, then in such event the remuneration payable by any Italian Guarantor in respect of the amounts due pursuant to this Section shall not exceed the Maximum Rate;

(ii) the obligations of each Italian Guarantor under the Loan Documents shall not include, and shall not extend to any Acquisition Utilization (or portion thereof) where this would constitute an unlawful financial assistance pursuant to articles 2358 and 2474 of the Italian Civil Code;

(iii) in order to comply with the mandatory provisions of Italian law, interest applicable to amounts due by the Italian Guarantor as guarantor under this Agreement shall contractually not accrue on any interest (compounding), unless within the limits of article 1283 of the Italian Civil Code and/or, where applicable, article 120 of the Italian Banking Law and, in any case, to the extent permitted under Italian law.

SECTION 14.
MISCELLANEOUS

14.01 No Waiver.

(a) No failure on the part of the Administrative Agent or the Lenders to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under

any Loan Document shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under any Loan Document preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

(b) Each party hereto hereby acknowledges that the provisions of Article 1195 of the French Civil Code (*Code civil*) shall not apply to it with respect to its obligations under the Loan Documents and that it shall not be entitled to make any claim under Article 1195 of the French Civil Code (*Code civil*).

14.02 Notices.

(a) All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Agreement) or in the other Loan Documents shall be given or made in writing (including by telecopy or email) delivered, if to the Borrower, another Obligor, the Administrative Agent or any Lender, to its address specified on the signature pages hereto or its Guarantee Assumption Agreement, as the case may be, or at such other address as shall be designated by such party in a written notice to the other parties. Except as otherwise provided in this Agreement or therein, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

(b) Notwithstanding anything in this **Section 14.02** to the contrary, any notice, request, instruction, direction or other communication provided for herein and addressed to a QIA Lender (a "***QIA Lender Notice***") shall be effective only if such QIA Lender Notice is (a) delivered either personally by hand or by an international courier service providing delivery service in Qatar to the address of such QIA Lender set forth in this Agreement under the signature pages hereto and, in each case (b) confirmed by email to such QIA Lender's email addresses listed under the signature pages hereto; provided that (i) all such email addresses listed under the signature pages hereto for copy are copied and (ii) a "failed delivery" message is not received by the sender from such QIA Lender's primary email addresses listed under the signature pages hereto. Delivery shall be deemed effective only if completed by 1:30 p.m. on a day in which banks are open for business in Qatar (a "***Qatari Business Day***") or on the following Qatari Business Day if completed later.

14.03 Expenses, Indemnification, Etc.

(a) **Expenses**. Each Obligor, jointly and severally, agrees to pay or reimburse within ten (10) Business Days of receipt of a reasonably detailed invoice (i) the Administrative Agent and the Lenders and their respective Affiliates for all of their reasonable and documented out-of-pocket costs and expenses (including the reasonable and documented out-of-pocket fees, expenses, charges and disbursements of Sullivan & Cromwell LLP, counsel to the Administrative Agent and the Lenders, the fees (if necessary) of a single firm of local counsel, a single firm of regulatory counsel, and any additional counsel necessary as a result of any conflicts for both of the Administrative Agent and the Lenders in each relevant material jurisdiction, and any sales, goods

and services or other similar Taxes applicable thereto, and reasonable and documented printing, reproduction, document delivery, communication and travel costs) in connection with (x) the negotiation, preparation, execution and delivery of this Agreement and the other Loan Documents and the making of the Loans (exclusive of post-closing costs), (y) post-closing costs (including, without limitation, costs of the administration of this Agreement and the other Loan Documents) and (z) the negotiation or preparation of any modification, supplement or waiver of any of the terms of this Agreement or any of the other Loan Documents (whether or not consummated); provided, that, in the case of such expenses on the Closing Date, the amount of such expenses obligated to be paid by the Obligors shall be net of any amounts previously paid by the Borrower to the Administrative Agent or any Lender as a deposit against such fees, costs and expenses and (ii) each of the Administrative Agent and the Lenders for all of their reasonable and documented out-of-pocket costs and expenses (including the reasonable and documented fees and expenses of any legal counsel) in connection with the enforcement, exercise or protection of their rights in connection with this Agreement and the other Loan Documents, including their rights under this **Section 14.03**, or in connection with the Loans made hereunder, including such reasonable and documented out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Loans and in connection with any enforcement or collection proceedings resulting from the occurrence of an Event of Default.

(b) **Indemnification**. Each Obligor, jointly and severally, hereby indemnifies the Administrative Agent (and any sub-agent thereof), the Lenders and their respective Affiliates, directors, officers, employees, attorneys, agents, advisors and controlling parties (each, an "***Indemnified Party***") from and against, and agrees to hold them harmless against, any and all Claims and Losses of any kind including reasonable and documented out-of-pocket fees and disbursements of any counsel for each Indemnified Party (limited to, at most, two legal counsels in each relevant jurisdiction, one for each of (A) the Administrative Agent and the Lenders that are not QIA Lenders and (B) the QIA Lenders), that may be incurred by or asserted or awarded against any Indemnified Party, in each case arising out of or in connection with or relating to (i) this Agreement or any of the other Loan Documents or the Transactions, (ii) any use made or proposed to be made with the proceeds of the Loans, (ii) any actual or alleged presence or release of Hazardous Materials on or from any property owned or operated by any Obligor or any of its Subsidiaries, or (iv) any actual or prospective claim, investigation, litigation or proceeding relating to any of the foregoing, whether based on contract, tort, or any other theory, whether or not such investigation, litigation or proceeding is brought by any Obligor, any of its Subsidiaries, shareholders or creditors, an Indemnified Party or any other Person, or an Indemnified Party is otherwise a party thereto, and whether or not any of the conditions precedent set forth in **Section 6** are satisfied or the other transactions contemplated by this Agreement are consummated, except to the extent such Claim or Loss is (i) found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted from such Indemnified Party's gross negligence or willful misconduct or (ii) is determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from a claim brought by any Obligor against an Indemnified Party for material breach in bad faith or reckless disregard of such Indemnified Party's obligations hereunder or under any other Loan Document. No Obligor shall assert any claim against any Indemnified Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the Transactions or the actual or proposed use of the proceeds of the Loans. None of the Administrative Agent and the Lenders shall assert any claim against any Obligor, their Subsidiaries and Affiliates

and their respective directors, officers, employees, attorneys, agents, advisors and controlling parties, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the Transactions or the actual or proposed use of the proceeds of the Loans. Notwithstanding the foregoing in this **Section 14.03(b)**, the Obligors shall not be liable for any settlement of any proceeding effected without the Obligors' consent (which consent shall not be unreasonably withheld, delayed or conditioned), but if settled with the Obligors' written consent, or if there is a judgment against an Indemnified Party in any such proceeding, the Obligors shall indemnify and hold harmless each Indemnified Party to the extent and in the manner set forth above. The Obligors shall not, without the prior written consent of an Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), effect any settlement of any pending or threatened proceeding against such Indemnified Party in respect of which indemnity could have been sought hereunder by such Indemnified Party unless (a) such settlement includes an unconditional release of such Indemnified Party from all liability or claims that are the subject matter of, or arise out of, such proceeding and (b) such settlement does not include any statement as to, or any admission of fault, culpability, wrongdoing or a failure to act by or on behalf of such Indemnified Party. This Section shall not apply with respect to (x) Taxes other than Taxes relating to a non-Tax Claim or Loss governed by this **Section 14.03(a)** and (y) yield protection matters covered by **Section 5.01**, which shall be governed exclusively by **Section 5.01**.

14.04 Amendments, Etc. Except as otherwise expressly provided in this Agreement, any provision of this Agreement and any other Loan Document may be modified or supplemented only by an instrument in writing signed by the Borrower, the Administrative Agent, the Majority Lenders, and solely in the case of amendments to Section 13, the Subsidiary Guarantors; provided that:

(a) any such modification or supplement that is disproportionately adverse to any Lender as compared to other Lenders or subjects any Lender to any additional obligation shall not be effective without the consent of such affected Lender;

(b) the consent of all of the Lenders shall be required to:

(i) amend, modify, discharge, terminate or waive any of the terms of this Agreement or any other Loan Document (including by modifying any defined term used therein or any provision referenced therein) if such amendment, modification, discharge, termination or waiver would increase the amount of the Loans or Commitment, reduce the fees payable hereunder, reduce interest rates or other amounts payable with respect to the Loans, extend any date fixed for payment of principal (it being understood that the waiver of any prepayment of Loans shall not constitute an extension of any date fixed for payment of principal), interest or other amounts payable relating to the Loans, extend the repayment dates of the Loans, modify the Commitments, modify the definition of "Proportionate Share" or extend the Commitment Termination Date; provided, for the avoidance of doubt, that any waiver or amendment relating to an Event of Default or Default arising out of a breach or prospective breach of the Minimum Gross Sales Covenant shall only require the consent of the Majority Lenders;

(ii) amend, modify, discharge, terminate or waive any Security Document or Guarantee if the effect is to release all or substantially all of the Collateral, or to release all or

substantially all of the value of the Guarantee, subject thereto other than pursuant to the terms hereof or thereof; or

(iii) amend this **Section 14.04** or the definition of "Majority Lenders".

Notwithstanding anything to the contrary herein, (A) the Administrative Agent and the Borrower may amend or modify this Agreement and any other Loan Document (1) to cure any factual or typographical error, omission, defect or inconsistency therein, (2) to grant a new Lien for the benefit of the Lenders, extend an additional Lien over additional property for the benefit of the Lenders or join additional Persons as Obligors, or (3) in connection with the implementation of the requirements of **Section 8.17(g)** and (B) no Defaulting Lender shall have any right to approve or disapprove any amendment, waiver or consent hereunder (and any amendment, waiver or consent which by its terms requires the consent of all Lenders or each affected Lender may be effected with the consent of the applicable Lenders other than Defaulting Lenders), except that (x) the Commitment of any Defaulting Lender may not be increased or extended without the consent of such Lender and (y) any waiver, amendment or modification requiring the consent of all Lenders or each affected Lender that by its terms affects any Defaulting Lender more adversely than other affected Lenders shall require the consent of such Defaulting Lender.

14.05 Successors and Assigns.

(a) **General**. The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the parties hereto or thereto and their respective successors and assigns permitted hereby or thereby, except that no Obligor may assign or otherwise transfer any of its rights or obligations hereunder (except in connection with an event permitted under **Section 9.03**) without the prior written consent of each Lender. Any Lender may assign or otherwise transfer any of its rights or obligations hereunder or under any of the other Loan Documents to an assignee in accordance with the provisions of **Section 14.05(b)**, (ii) by way of participation in accordance with the provisions of **Section 14.05(e)**, or (iii) by way of pledge or assignment of a security interest subject to the restrictions of **Section 14.05(f)**. Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, Participants to the extent provided in **Section 14.05(e)** and, to the extent expressly contemplated hereby, the Indemnified Parties) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) **Assignments by Lender**. Any Lender may at any time assign to any Person that is not a Disqualified Lender or Defaulting Lender (or, if an Event of Default has occurred and is continuing, to any Person that is not a Defaulting Lender) all or a portion of its rights and obligations under this Agreement (including all or a portion of the Loans at the time owing to it) and the other Loan Documents; provided that no such assignment shall be made to any Obligor, any Affiliate of any Obligor, any employees or directors of any Obligor at any time and no such assignment shall be made without the prior written consent of the Administrative Agent, not to be unreasonably withheld, conditioned or delayed; provided that no such assignment shall be made without the prior written consent of the Borrower, not to be unreasonably withheld, conditioned or delayed, unless (x) an Event of Default has occurred and is continuing at the time of such assignment or (y) such assignment is to (A) a Lender or an Affiliate of a Lender or such Lender's or Affiliate's managed funds or accounts or (B) an Approved Lender; provided that,

notwithstanding the above, the assignee shall not be incorporated, domiciled or acting through a lending office in a Non-Cooperative Jurisdiction without the prior consent of the Borrower; provided, further that the Borrower shall be deemed to have consented to any such assignment unless it shall object thereto by written notice to the Administrative Agent within five (5) Business Days after having received written notice thereof. Subject to the recording thereof by the Administrative Agent pursuant to **Section 14.05(d)**, and to receipt by the Administrative Agent of a processing and recordation fee in the amount of $3,500 (provided that the Administrative Agent may, in its sole discretion, elect to waive such processing and recordation fee in the case of any assignment) from and after the date such Assignment and Assumption is recorded in the Register, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of the Lender under this Agreement and the other Loan Documents, and correspondingly the assigning Lender shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of the Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) and the other Loan Documents but shall continue to be entitled to the benefits of **Section 5** and **Section 14.03**. Any assignment or transfer by the Lender of rights or obligations under this Agreement that does not comply with this **Section 14.05(b)** shall be treated for purposes of this Agreement as a sale by such Lender of a participation in such rights and obligations in accordance with **Section 14.05(e)**. If an assignee is not a Lender, the assignee shall provide the Administrative Agent with all "know your customer" documents requested by the Administrative Agent pursuant to anti-money laundering rules and regulations.

(c) **Amendments to Loan Documents**. Each of the Administrative Agent, the Lenders and the Obligors agrees to enter into such amendments to the Loan Documents, and such additional Security Documents and other instruments and agreements, in each case in form and substance reasonably acceptable to the Administrative Agent, the Lenders and the Obligors, as shall reasonably be necessary to implement and give effect to any assignment made under this **Section 14.05**.

(d) **Register**. The Administrative Agent, acting solely for this purpose as a non-fiduciary agent of the Borrower, shall maintain at one of its offices in the United States a copy of each Assignment and Assumption delivered to it and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts of (and stated interest on) the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "***Register***"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. In addition, the Administrative Agent shall maintain on the Register information regarding the designation, and revocation of designation, of any Lender as a Defaulting Lender. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior written notice. Notwithstanding anything to the contrary, any assignment of any Loan shall be effective only upon appropriate entries with respect thereto being made in the Register.

(e) **Participations**. Any Lender may at any time, without the consent of, or notice to, the Borrower, sell participations to any Person (other than a natural person, a Defaulting Lender or any Obligor or any of its Affiliates or Subsidiaries) (each, a "***Participant***") in all or a portion of the Lender's rights and/or obligations under this Agreement (including all or a portion of the Commitment and/or the Loans owing to it); provided that (i) such Lender's obligations under this Agreement and the other Loan Documents shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of such obligations and (iii) the Borrower shall continue to deal solely and directly with such Lender in connection therewith. Any agreement or instrument pursuant to which any Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce the Loan Documents and to approve any amendment, modification or waiver of any provision of the Loan Documents; provided that such agreement or instrument may provide that such Lender will not, without the consent of the Participant, agree to any amendment, modification or waiver that would (i) increase or extend the term of such Lender's Commitment (it being understood and agreed that a waiver of any condition precedent set forth in **Section 6.02** or of any Default or Event of Default or a mandatory reduction in Commitments is not considered an increase of any Commitment), (ii) extend the date fixed for the payment of principal (excluding mandatory prepayments) of or interest on the Loans or any portion of any fee hereunder payable to the Participant, (iii) reduce the amount of any such payment of principal, or (iv) reduce the rate at which interest is payable thereon to a level below the rate at which the Participant is entitled to receive such interest (other than a waiver of default interest). Subject to **Section 14.05(f)**, the Borrower agrees that each Participant shall be entitled to the benefits of **Section 5.01** or **5.03** (subject to the requirements and limitations therein, including the requirements under **Section 5.03(f)** (it being understood that the documentation required under **Section 5.03(f)** shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to **Section 14.05(b)**; provided that such Participant (i) shall not be entitled to such benefits unless such Participant agrees, for the benefit of the Borrower, to comply with the documentation requirements of **Section 5.03(f)(v)** as if it were a Lender and complies with such requirements, (ii) agrees to be subject to the provisions of **Section 5.04** as if it were an assignee under **Section 14.05(b)** and (iii) shall not be entitled to receive any greater payment under **Section 5.01** or **5.03**, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in Law that occurs after the Participant acquired the applicable participation. To the extent permitted by Law, each Participant also shall be entitled to the benefits of **Section 4.03(a)** as though it were a Lender. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each Participant and the principal amounts of (and stated interest on) each Participant's interest in the Loans or other obligations under the Loan Documents (the "***Participant Register***"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any Participant or any information relating to a Participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the

Administrative Agent (in its capacity as Administrative Agent) shall have no responsibility for maintaining a Participant Register.

(f) **Limitations on Rights of Participants**. A Participant shall not be entitled to receive any greater payment under **Sections 5.01** or **5.03** than such Lender would have been entitled to receive with respect to the participation sold to such Participant, unless the sale of the participation to such Participant is made with the Borrower's prior written consent.

(g) **Certain Pledges**. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under the Loan Documents to secure obligations of such Lender, including any pledge or assignment to secure obligations to a Federal Reserve Bank; provided that no such pledge or assignment shall release such Lender from any of its obligations hereunder or substitute any such pledgee or assignee for such Lender as a party hereto.

(h) **Certain Additional Payments**. In connection with any assignment of rights and obligations of any Defaulting Lender hereunder, no such assignment shall be effective unless and until, in addition to the other conditions thereto set forth herein, the parties to the assignment shall make such additional payments to the Administrative Agent in an aggregate amount sufficient, upon distribution thereof as appropriate (which may be outright payment, purchases by the assignee of participations or subparticipations, or other compensating actions, including funding, with the consent of the Borrower and the Administrative Agent, the applicable Proportionate Share of Loans previously requested but not funded by the Defaulting Lender, to each of which the applicable assignee and assignor hereby irrevocably consent), to (x) pay and satisfy in full all payment liabilities then owed by such Defaulting Lender to the Administrative Agent or any Lender hereunder (and interest accrued thereon) and (y) acquire (and fund as appropriate) its full Proportionate Share of all Loans. Notwithstanding the foregoing, in the event that any assignment of rights and obligations of any Defaulting Lender hereunder shall become effective under applicable Law without compliance with the provisions of this paragraph, then the assignee of such interest shall be deemed to be a Defaulting Lender for all purposes of this Agreement until such compliance occurs.

(i) **Preservation of Collateral**. The benefit of the Collateral and of the Security Documents shall automatically transfer to any assignee or transferee (by way of novation or otherwise) of part or all of the obligations expressed to be secured by the Collateral. For the purpose of ~~article~~Article 1278 and ~~article~~Article 1281 of the Belgian Civil Code and Article 1334 of the French Civil Code (*Code civil*) (and, to the extent applicable, any similar provisions of foreign law), the Administrative Agent, the other Secured Parties and each of the Obligors hereby expressly reserve the preservation of the Collateral and of the Security Documents in case of assignment, novation, amendment or any other transfer or change of the obligations expressed to be secured by the Collateral (including, without limitation, an extension of the term or an increase of the amount of such obligations or the granting of additional credit) or of any change of any of the parties to this Agreement or any other Loan Document. A transfer by way of novation under this **Section 14.05(i)** is also a novation (*novation*) within the meaning of Articles 1329 *et seq.* of the French Civil Code (*Code civil*). Any Person who becomes a Lender may (at its own cost), in case of a transfer of rights and obligations, or an assignment of rights by an existing Lender hereunder and in accordance with the terms of this Agreement, if it considers it necessary to make such transfer or assignment effective as against a French Obligor, at its own costs arrange for the

assignment agreement or the transfer certificate to be notified to or acknowledged by the relevant French Obligor by registered letter with acknowledgement of receipt, in accordance with article 1324 of the French Civil Code (*Code civil*) or any other applicable provision of any applicable law.

(j) **Waiver of priority**. Any person who becomes a Lender expressly waives any priority of ranking that they may have in connection with the Loan Documents pursuant to article 4 of the Belgian Act of 3 August 2012 on various measures to facilitate the mobilisation of receivables in the financial sector.

14.06 Survival. The obligations of the Borrower under **Sections 5.01**, **5.03**, **14.03**, **14.05**, **14.06**, **14.09**, **14.10**, **14.11**, **14.12**, **14.13** and **14.14** and the obligations of the Guarantors under **Section 13** (solely to the extent guaranteeing any of the obligations under the foregoing Sections) shall survive the repayment of the Obligations and the termination of the Commitments and, in the case of the Lenders' assignment of any interest in the Commitments or the Loans hereunder, shall survive, in the case of any event or circumstance that occurred prior to the effective date of such assignment, the making of such assignment, notwithstanding that the Lenders may cease to be "Lenders" hereunder. In addition, each representation and warranty made, or deemed to be made by a Borrowing Notice, herein or pursuant hereto shall survive the making of such representation and warranty.

14.07 Captions. The table of contents and captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Agreement.

14.08 Counterparts, Effectiveness. This Agreement may be executed in any number of counterparts (including electronic imaging means), all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart. Delivery of an executed signature page of this Agreement by electronic transmission (*e.g.*, "pdf" or "tif" format) shall be effective as delivery of a manually executed counterpart hereof. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

14.09 Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply.

14.10 Jurisdiction, Service of Process and Venue.

(a) **Submission to Jurisdiction**. Each party hereby irrevocably and unconditionally agrees that it will not commence any action, litigation or proceeding of any kind or description, whether in law or equity, whether in contract or tort or otherwise, against such other party in any way relating to this Agreement or any Loan Document (unless indicated otherwise in the relevant Loan Document) or the transactions relating hereto or thereto, in any forum other than the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and each of the parties hereto irrevocably and unconditionally submits to the exclusive jurisdiction of such courts and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by applicable Law, in such federal court. Each of the parties hereto agrees that a final judgment in any such action, litigation or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(b) **Service of Process**. Each party hereto irrevocably consents to service of process in the manner provided for notices in **Section 14.02**. As an alternative method of service, each Obligor (other than any Obligor organized or formed in the United States or Brazil) also irrevocably appoints Neeta Toprani, General Counsel (the "***Process Agent***") with a mailing address on the date hereof at 1187 Coast Village Road Suite 1-402 Santa Barbara, CA 93108, as its agent to receive on behalf of such Obligor and its property service of copies of any process, summons, notice or document in any such action, litigation or proceeding. Such service may be made by mailing or delivering a copy of such process to such Obligor in care of the Process Agent (with a copy (which shall not constitute notice) to be delivered to O'Melveny & Myers LLP, Two Embarcadero Center, 28th Floor, San Francisco, California 94111, Attention: Jennifer Taylor, jtaylor@omm.com; provided that failure to deliver such copy shall not make any service under this **Section 14.10(b)** ineffective), and each Obligor hereby irrevocably authorizes and directs the Process Agent to accept such service on its behalf. Each Obligor irrevocably consents and agrees that service of any process, summons, notice or document in any such action, litigation or proceeding shall automatically be deemed effective upon such Obligor upon the earlier of (x) in the case of a document sent by overnight mail, one Business Day following the mailing of such document to the foregoing address, (y) in the case of a document sent by first class mail, three Business Days following the mailing of such document to the foregoing address and (z) the receipt by the Process Agent of such document. Each Obligor covenants and agrees that it shall maintain its appointment of the Process Agent and shall keep the Administrative Agent advised of the identity and location of the Process Agent; provided, that if at any time the Process Agent is no longer employed by the Borrower, each Obligor shall appoint a successor Process Agent with the same mailing address, which Process Agent shall be an officer of the Borrower acceptable to the Administrative Agent. If no successor Process Agent is appointed in accordance herewith, each Obligor irrevocably consents and agrees that service sent to the above mailing address shall nonetheless be effective as set forth herein. Nothing in this Agreement will affect the right of any party hereto to serve process in any other manner permitted by applicable Law. With respect to the Brazilian Guarantors, service of process has to be made *via* letters rogatory, as provided for in Law No. 10,105, of March 16, 2015.

(c) **Waiver of Venue, Etc**. Each party hereto irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement or any other Loan Document

and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which such party is or may be subject, by suit upon judgment.

14.11 Waiver of Jury Trial. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

14.12 Waiver of Immunity. To the extent that any Obligor may be or become entitled to claim for itself or its property or revenues any immunity on the ground of sovereignty or the like from suit, court jurisdiction, attachment prior to judgment, attachment in aid of execution of a judgment or execution of a judgment, and to the extent that in any such jurisdiction there may be attributed such an immunity (whether or not claimed), such Obligor hereby irrevocably agrees not to claim and hereby irrevocably waives such immunity with respect to its obligations under this Agreement and the other Loan Documents.

14.13 Entire Agreement. This Agreement and the other Loan Documents constitute the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof, including any confidentiality (or similar) agreements and any letters of intent. EACH OBLIGOR ACKNOWLEDGES, REPRESENTS AND WARRANTS THAT IN DECIDING TO ENTER INTO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS OR IN TAKING OR NOT TAKING ANY ACTION HEREUNDER OR THEREUNDER, IT HAS NOT RELIED, AND WILL NOT RELY, ON ANY STATEMENT, REPRESENTATION, WARRANTY, COVENANT, AGREEMENT OR UNDERSTANDING, WHETHER WRITTEN OR ORAL, OF OR WITH ADMINISTRATIVE AGENT OR THE LENDERS OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS.

14.14 Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof. Without limiting the foregoing provisions of this **Section 14.14**, if and to the extent that the enforceability of any provisions in this Agreement relating to Defaulting Lenders shall be limited by the Bankruptcy Code, or any other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, examinership, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief Laws of the United States or other applicable jurisdictions from time to time in effect, as determined in good faith by the Administrative Agent, then such provisions shall be deemed to be in effect only to the extent not so limited.

14.15 No Fiduciary Relationship. The Borrower acknowledges that the Administrative Agent and the Lenders have no fiduciary relationship with, or fiduciary duty to, the Borrower arising out of or in connection with this Agreement or the other Loan Documents, and the relationship between

the Lenders and the Borrower is solely that of creditor and debtor. This Agreement and the other Loan Documents do not create a joint venture among the parties.

14.16 Confidentiality.

(a) The Administrative Agent and each Lender agree to keep confidential, and not disclose to any Person all non-public information provided to them by or on behalf of any Obligor pursuant to this Agreement that is designated by such Obligor as confidential in accordance with its customary procedures for handling its own confidential information; provided that nothing herein shall prevent the Administrative Agent or any Lender from disclosing any such information (i) to the Administrative Agent, any other Lender, any Affiliate of a Lender or subject to an agreement to comply with the provisions of this Section, any assignee permitted under **Section 14.05(b)**, (ii) subject to an agreement to comply with the provisions of this Section, to any actual or prospective direct or indirect counterparty to any Hedging Agreement (or any professional advisor to such counterparty), (iii) to its employees, officers, directors or agents (provided that such Persons were informed of the confidential nature of such confidential information and instructed to keep such information confidential), or its attorneys, accountants, trustees and other professional advisors or those of any of its affiliates (provided that such Persons were informed of the confidential nature of such confidential information and instructed to keep such information confidential or are otherwise subject to professional obligations to maintain the confidentiality of such confidential information) (collectively, its "***Related Parties***"), (iv) upon the request or demand of any Governmental Authority or any Regulatory Authority purporting to have jurisdiction over such Person or its Related Parties (including any self-regulatory authority, such as the National Association of Insurance Commissioners), (v) in response to any order of any court or other Governmental Authority or as may otherwise be required pursuant to any Law, (vi) if requested or required to do so in connection with any litigation or similar proceeding, (vii) that has been publicly disclosed (other than as a result of a disclosure in violation of this **Section 14.16**), (viii) to the National Association of Insurance Commissioners or any similar organization or any nationally recognized rating agency that requires access to information about a Lender's investment portfolio in connection with ratings issued with respect to such Lender, (ix) in connection with the exercise of any remedy hereunder or under any other Loan Document, (x) on a confidential basis to (A) any rating agency in connection with rating the Borrower or its Subsidiaries or the Loans or (B) the CUSIP Service Bureau or any similar agency in connection with the issuance and monitoring of CUSIP numbers of other market identifiers with respect to the Loans or (xi) to any other party hereto; provided that, in the case of disclosure pursuant to **clause (iv), (v)** and **(vi)** above, the Administrative Agent or applicable Lender, as applicable, shall promptly provide notice to the Borrower to the extent reasonable and not prohibited by Law or any applicable Governmental Authority.

(b) Notwithstanding any provision of this Agreement otherwise requiring any QIA Lender to provide any information or documents to any Loan Party or any third party, such QIA Lender shall be entitled to withhold, edit, redact and/or otherwise limit disclosure of any such information or documents on the grounds of national security and/or financial or economic sensitivity and such QIA Lender shall have no liability whatsoever and shall be free and harmless from any claims whatsoever for exercising its rights pursuant to this **Section 14.16(b)**.

14.17 Interest Rate Limitation. Notwithstanding anything herein to the contrary, if at any time the interest rate applicable to any Loan, together with all fees, charges and other amounts that are treated as interest on such Loan under applicable Law (collectively, "***charges***"), shall exceed the maximum lawful rate (the "***Maximum Rate***") that may be contracted for, charged, taken, received or reserved by the Administrative Agent and the Lender holding such Loan in accordance with applicable Law, the rate of interest payable in respect of such Loan hereunder, together with all charges payable in respect thereof, shall be limited to the Maximum Rate. To the extent lawful, the interest and charges that would have been paid in respect of such Loan but were not paid as a result of the operation of this Section shall be cumulated and the interest and charges payable to such Lender in respect of other Loans or periods shall be increased (but not above the amount collectible at the Maximum Rate therefor) until such cumulated amount, together with interest thereon at the Federal Funds Effective Rate for each day to the date of repayment, shall have been received by such Lender. Any amount collected by such Lender that exceeds the maximum amount collectible at the Maximum Rate shall be applied to the reduction of the principal balance of such Loan so that at no time shall the interest and charges paid or payable in respect of such Loan exceed the maximum amount collectible at the Maximum Rate.

14.18 Judgment Currency.

(a) If, for the purposes of obtaining judgment in any court, it is necessary to convert a sum due hereunder in Dollars into another currency, the parties hereto agree, to the fullest extent permitted by Law, that the rate of exchange used shall be that at which, in accordance with normal banking procedures, the Administrative Agent could purchase Dollars with such other currency at the buying spot rate of exchange in the New York foreign exchange market on the Business Day immediately preceding that on which any such judgment, or any relevant part thereof, is given.

(b) The obligations of the Obligors in respect of any sum due to the Administrative Agent hereunder and under the other Loan Documents shall, notwithstanding any judgment in a currency other than Dollars, be discharged only to the extent that on the Business Day following receipt by the Administrative Agent of any sum adjudged to be so due in such other currency the Administrative Agent may, in accordance with normal banking procedures, purchase Dollars with such other currency. If the amount of Dollars so purchased is less than the sum originally due to the Administrative Agent in Dollars, the Borrower agrees, to the fullest extent that it may effectively do so, as a separate obligation and notwithstanding any such judgment, to indemnify the Administrative Agent against such loss. If the amount of Dollars so purchased exceeds the sum originally due to the Administrative Agent in Dollars, the Administrative Agent shall remit such excess to the Borrower.

14.19 USA PATRIOT Act. The Administrative Agent and the Lenders hereby notify the Obligors that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "***Patriot Act***"), they are required to obtain, verify and record information that identifies the Obligors, which information includes the name and address of each Obligor and other information that will allow such Person to identify such Obligor in accordance with the Patriot Act.

14.20 Acknowledgement and Consent to Bail-In of Affected Financial Institutions. Notwithstanding anything to the contrary in any Loan Document or in any other agreement,

arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Affected Financial Institution arising under any Loan Document, to the extent such liability is unsecured, may be subject to the Write-Down and Conversion Powers of the applicable Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by:

(a) the application of any Write-Down and Conversion Powers by the applicable Resolution Authority to any such liabilities arising hereunder which may be payable to it by any party hereto that is an EEA Financial Institution; and

(b) the effects of any Bail-In Action on any such liability, including, if applicable:

(i) a reduction in full or in part or cancellation of any such liability;

(ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such Affected Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Loan Document; or

(iii) the variation of the terms of such liability in connection with the exercise of the Write-Down and Conversion Powers of any the applicable Resolution Authority.

14.21 Certain ERISA Matters.

(a) Each Person that becomes party hereto after the date hereof as a Lender (x) represents and warrants, as of the date such Person became a Lender party hereto, to, and (y) covenants, from the date such Person became a Lender party hereto to the date such Person ceases being a Lender party hereto, for the benefit of, the Administrative Agent and its Affiliates, and not, for the avoidance of doubt, to or for the benefit of Obligors, that at least one of the following is and will be true:

(i) such Lender is not using "plan assets" (within the meaning of Section 3(42) of ERISA or otherwise) of one or more Employee Benefit Plans with respect to such Lender's entrance into, participation in, administration of and performance of the Loans, the Notes or this Agreement;

(ii) the transaction exemption set forth in one or more PTEs, such as PTE 84-14 (a class exemption for certain transactions determined by independent qualified professional asset managers), PTE 95-60 (a class exemption for certain transactions involving insurance company general accounts), PTE 90-1 (a class exemption for certain transactions involving insurance company pooled separate accounts), PTE 91-38 (a class exemption for certain transactions involving bank collective investment funds) or PTE 96-23 (a class exemption for certain transactions determined by in-house asset managers), is applicable with respect to such Lender's entrance into, participation in, administration of and performance of the Loans, the Notes and this Agreement;

(iii) (A) such Lender is an investment fund managed by a "Qualified Professional Asset Manager" (within the meaning of Part VI of PTE 84-14), (B) such Qualified Professional Asset Manager made the investment decision on behalf of such Lender to enter into, participate in, administer and perform the Loans, the Notes and this Agreement, (C) the entrance into, participation in, administration of and performance of the Loans, the Notes and this Agreement satisfies the requirements of sub-sections (b) through (g) of Part I of PTE 84- 14 and (D) to the best knowledge of such Lender, the requirements of subsection (a) of Part I of PTE 84-14 are satisfied with respect to such Lender's entrance into, participation in, administration of and performance of the Loans, the Notes and this Agreement; or

(iv) such other representation, warranty and covenant as may be agreed in writing between the Administrative Agent, in its sole discretion, and such Lender.

In addition, unless either (1) sub-clause (i) in the immediately preceding clause (a) is true with respect to a Lender making the representation in clause (a) or (2) a Lender making the representation in clause (a) has provided another representation, warranty and covenant in accordance with sub-clause (iv) in the immediately preceding clause (a), such Lender further (x) represents and warrants, as of the date such Person became a Lender party hereto, to, and (y) covenants, from the date such Person became a Lender party hereto to the date such Person ceases being a Lender party hereto, for the benefit of, the Administrative Agent and its Affiliates, and not, for the avoidance of doubt, to or for the benefit of the Borrower, that none of the Administrative Agent or its Affiliates is a fiduciary with respect to the assets of such Lender involved in such Lender's entrance into, participation in, administration of and performance of the Loans, the Notes and this Agreement (including in connection with the reservation or exercise of any rights by the Administrative Agent under this Agreement, any other Loan Documents or any documents related hereto or thereto).

[Signature Pages Follow]

Annex B

Schedule 8.11(a)

Requirements with respect to the French Material Subsidiary

In application of Schedule 8.17(g) and Sections 6.01 and 8.11(a) hereto, within sixty (60) days as from the Closing Date, the Borrower shall and/or shall cause the French Material Subsidiary to satisfy the following requirements:

(i) Enter into and deliver to the Administrative Agent the Guarantee Assumption Agreement in the form attached hereto as Exhibit D;

(ii) Enter into and deliver to the Administrative Agent the Accession Agreement in the form attached to the Security Agreement as Exhibit A;

(iii) Execute and deliver to the Administrative Agent, a copy of each French Security Document (in a form and substance reasonably satisfactory to the Administrative Agent);

(iv) Deliver to the Administrative Agent a copy of the resolutions of the French Material Subsidiary's sole shareholder (in a form and substance reasonably satisfactory to the Administrative Agent) (x) authorizing the execution, delivery and performance of the Transactions and of each Loan Document to which the French Material Subsidiary is party, and confirming that such execution, delivery and performance are compliant with the French Material Subsidiary's corporate interest and purpose, and (y) authorizing a specified Person(s) to sign such Loan Documents and any documents to be delivered by the French Material Subsidiary pursuant thereto;

(v) Deliver to the Administrative Agent (x) if applicable, a copy of an incumbency certificate or power of attorney authorizing the Person(s) specified in the resolutions referred to under paragraph (iv) above to sign any Loan Documents on behalf and in the name of the French Material Subsidiary, and (y) a specimen signature of such Person(s);

(vi) Deliver to the Administrative Agent an electronic copy of an excerpt of the trade and companies register (*extrait K-bis*) in relation to the French Material Subsidiary issued by the *Greffe* of the *Tribunal de Commerce* of the French Material Subsidiary's place of incorporation and dated no earlier than fifteen (15) Business Days prior to the date of its delivery to the Administrative Agent;

(vii) Deliver to the Administrative Agent an electronic version of a certified true copy of the French Material Subsidiary's up-to-date articles of association (*statuts*) issued by the *Greffe* of the *Tribunal de Commerce* of the French Material Subsidiary's place of incorporation;

(viii) Deliver to the Administrative Agent an electronic copy of the French Material Subsidiary's statement of charges and encumbrances (*état des privilèges et nantissements*) issued by the *Greffe* of the *Tribunal de Commerce* of the French Material

Subsidiary's place of incorporation and dated no earlier than fifteen (15) Business Days prior to the date of its delivery to the Administrative Agent;

(ix) Deliver to the Administrative Agent an electronic copy of the French Material Subsidiary's insolvency certificate (*certificat de non-faillite*) issued by the *Greffe* of the *Tribunal de Commerce* of the French Material Subsidiary's place of incorporation and dated no earlier than fifteen (15) Business Days prior to the date of its delivery to the Administrative Agent;

(x) Deliver to the Administrative Agent a copy of a certificate, duly executed by a Responsible Officer of the French Material Subsidiary, certifying as to the following:

a. each document specified under paragraphs (v) to (ix) above, as attached thereto, is correct, complete, valid and in full force and effect;

b. that attached thereto are true and complete copies of the resolutions of the French Material Subsidiary's sole shareholder referred to under paragraph (iv) above, and that such resolutions have not been modified, rescinded or amended and are in full force and effect; and

c. that the entry into by the French Material Subsidiary to any Loan Documents and the related Guaranty would not cause any guarantee or similar limit binding on the French Material Subsidiary to be exceeded;

(xi) Deliver to the Administrative Agent a customary legal opinion on powers and capacity of the French Material Subsidiary to execute the Loan Documents to which the French Material Subsidiary is party, duly executed by Baker & McKenzie A.A.R.P.I., French law counsel to the Borrower and the French Material Subsidiary.

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
JEN-Vault AG	Switzerland
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

* European Distribution Center Motiva BV owns 99% of Establishment Labs Brasil Produtos Para Saude Ltda., with 1% owned by a local Brazilian party.
** European Distribution Center Motiva BV owns 100% of Motiva Nordica AB.
*** Establishment Labs Holdings Inc. and Establishment Labs, S.A. own 95% and 5%, 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 this Registration Statement of Establishment Labs Holdings Inc. on Form S-3ASR (File No. 333-271418) and S-8 (File Nos. 333-254283, 333-237219, 333-230419, 333-226340, 333-263149 and 333-270196) of our report dated March 4, 2024 with respect to our audits of the consolidated financial statements of Establishment Labs Holdings, Inc. as of December 31, 2023 and 2022 and for the years ended and our report dated March 4, 2024 with respect to our audit of internal control over financial reporting of Establishment Labs Holdings Inc. as of December 31, 2023 appearing in the Annual Report on Form 10-K of Establishment Labs Holdings Inc. for the year ended December 31, 2023.

Our report on the effectiveness of internal control over financial reporting expressed an adverse opinion because of the existence of a material weakness.

/s/ Marcum LLP

Marcum LLP

Ronil Chandra, CPA
Los Angeles, CA
March 4, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Juan José Chacón Quirós, 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: March 4, 2024

/s/ Juan José Chacón Quirós
Juan José Chacón Quirós
Chief Executive Officer and Director
(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: March 4, 2024

/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), Juan José Chacón Quirós, 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, 2023, 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: March 4, 2024

/s/ Juan José Chacón Quirós
Juan José Chacón Quirós

Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 4, 2024

/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.
Policy Regarding the Recoupment of Certain Compensation Payments

As Adopted by the Board of Directors Effective as of August 9, 2023

In the event Establishment Labs Holdings Inc. (the "Company") is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws (including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company shall recover reasonably promptly the amount of any erroneously awarded Incentive-Based Compensation from each Covered Individual unless an exception (set forth below) applies.

Incentive-Based Compensation shall be considered "erroneously awarded" under this policy to the extent such Incentive-Based Compensation (1) is received by the Covered Individual on or after October 2, 2023 (the effective date of Rule 5608 of The Nasdaq Stock Market LLC ("Nasdaq") listing rules) and while the Company has a class of securities listed on a national securities exchange or a national securities association, (2) is received by the Covered Individual during the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement (and any transition period applicable to a change in the Company's fiscal year as required by Nasdaq listing rules), and (3) the amount of such received Incentive-Based Compensation exceeds the amount of the Incentive-Based Compensation that would have been received by the Covered Individual had it been determined based on the restated financial results (with such Incentive-Based Compensation computed in each case without regard to any taxes paid). For purposes of this policy, the date that the Company is required to prepare the accounting restatement is the earlier to occur of (A) the date the Company's Board of Directors (the "Board"), or a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such accounting restatement, or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare such accounting restatement.

For purposes of this policy, Incentive-Based Compensation is considered "received" by a Covered Individual in the Company's fiscal period during which the Financial Reporting Measure applicable to the Incentive-Based Compensation is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that fiscal period. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the amount of erroneously awarded compensation will be determined by the Compensation Committee of the Board (the "Committee") based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received. The Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq as required by Nasdaq listing rules. If the

erroneously awarded Incentive-Based Compensation consists of shares (including share-denominated equity awards) or options that are still held by the Covered Individual at the time of recovery, the recoverable amount is the number of shares or options received in excess of the number of shares or options that would have been received based on the accounting restatement (or the value of that excess number). If the options have been exercised but the underlying shares have not been sold, the recoverable amount is the number of shares underlying the excess options based on the restatement (or the value thereof). If the shares have been sold, the recoverable amount is the proceeds that were received in connection with the sale of the excess number of shares. Amounts credited under plans (other than tax-qualified plans for which the exception set forth below applies) based on erroneously awarded Incentive-Based Compensation and any accrued earnings thereon are also recoverable under this policy.

The Company shall not be required under this policy to recover erroneously awarded Incentive-Based Compensation if the Committee has made a determination that recovery would be impracticable and any of the following conditions are met: (1) after making a reasonable attempt to recover such erroneously awarded Incentive-Based Compensation, the Committee determines that the direct expense paid to a third party to assist in enforcing this policy would exceed the amount to be recovered (documentation evidencing the reasonable attempt to recover the erroneously awarded Incentive-Based Compensation must be maintained and provided to Nasdaq as required by Nasdaq listing rules), or (2) the recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Internal Revenue Code Section 401(a)(13) or Internal Revenue Code Section 411(a) and the regulations thereunder.

For purposes of this policy, the following definitions will apply:

- "Covered Individual" means any current or former officer of the Company who is or was subject to Section 16 of the Securities Exchange Act of 1934, as amended, at any time during the applicable performance period for the relevant Incentive-Based Compensation, regardless of whether such individual continues to hold such position or continues to be employed by the Company or any of its subsidiaries.

- "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

- "Financial Reporting Measures" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures (including, for purposes of this policy, stock price and total shareholder return). A Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the Securities and Exchange Commission.

This policy is intended to comply with the requirements of Rule 10D-1 promulgated by the Securities and Exchange Commission and the related listing rules of Nasdaq, and the terms hereof shall be construed consistent with that intent. This policy does not limit any other remedies the Company may have available to it in the circumstances, which may include, without limitation, dismissing an employee or initiating other disciplinary procedures. This policy supersedes and replaces any other policy adopted by the Company prior to the date hereof regarding the recoupment of incentive compensation. However, the provisions of this policy are in addition to (and not in lieu of) any rights to repayment the Company may have under Section 304 of the Sarbanes-Oxley Act of 2002 (applicable to the Chief Executive Officer and Chief Financial Officer only) and other applicable laws. The Company shall not indemnify any Covered Individual against the loss of erroneously-awarded Incentive-Based Compensation that is recovered by the Company pursuant to this policy.

The Committee shall have the sole authority to construe and interpret this policy and to make all determinations required to be made pursuant to this policy. Any such construction, interpretation or determination by the Committee shall be final and binding.

The Committee may revise this policy from time to time.