# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

# FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2020

**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** | **Not applicable** |
|---|---|
| State or Other Jurisdiction of Incorporation or Organization | I.R.S. Employer Identification No. |
| **Building B15 and 25<br>Coyol Free Zone<br>Alajuela<br>Costa Rica** | **Not applicable** |
| Address of Principal Executive Offices | Zip Code |

**+506 2434 2400**
Registrant's Telephone Number, Including Area Code

**Not applicable**
Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

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

| Title of each class | Trading symbol | Name of each exchange on which registered |
|---|---|---|
| Common Shares, No Par Value | ESTA | The NASDAQ Capital Market |

The number of the registrant's common shares outstanding as of August 6, 2020 was 23,367,033.

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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 and MotivaImagine, 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 TM symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names.

## SPECIAL NOTE ABOUT 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 (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, anticipated trends in our business (including the impact of the COVID-19 outbreak), 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, and some will inevitably prove to be incorrect. 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 under the sections contained in this Form 10-Q entitled “Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk,” and “Part II, Item 1A. Risk Factors”, and our other filings with the Securities and Exchange Commission. The risks included in those documents 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 are based on known results and trends at the time they are made, to anticipate future results or trends.

**ESTABLISHMENT LABS HOLDINGS INC.**
**Condensed Consolidated Balance Sheets**
**(In thousands, except share data)**

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (Unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash | $ 86,382 | $ 37,655 |
| Accounts receivable, net of allowance for doubtful accounts of $1,954 and $1,026 | 17,142 | 22,767 |
| Inventory, net | 29,057 | 28,660 |
| Prepaid expenses and other current assets | 3,841 | 6,757 |
| Total current assets | 136,422 | 95,839 |
| Long-term assets: | | |
| Property and equipment, net of accumulated depreciation | 16,085 | 16,418 |
| Goodwill | 465 | 465 |
| Intangible assets, net of accumulated amortization | 3,480 | 3,441 |
| Other non-current assets | 360 | 368 |
| Total assets | $ 156,812 | $ 116,531 |
| **Liabilities and shareholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 8,293 | $ 10,366 |
| Accrued liabilities | 10,517 | 10,677 |
| Other liabilities, short term | 1,742 | 2,199 |
| Total current liabilities | 20,552 | 23,242 |
| Long-term liabilities: | | |
| Note payable, Madryn, net of debt discount and issuance costs | 48,939 | 48,142 |
| Madryn put option | 3,509 | 3,072 |
| Other liabilities, long term | 2,026 | 2,461 |
| Total liabilities | 75,026 | 76,917 |
| Commitments and contingencies (Note 7) | | |
| Shareholders' equity: | | |
| Common shares - zero par value, unlimited amount authorized; 23,762,787 and 21,057,040 shares issued at June 30, 2020 and December 31, 2019, respectively; 23,354,717 and 20,648,970 shares outstanding at June 30, 2020 and December 31, 2019, respectively | 211,932 | 147,688 |
| Additional paid-in-capital | 24,338 | 21,214 |
| Treasury shares, at cost, 408,070 shares held at June 30, 2020 and December 31, 2019 | (2,854) | (2,854) |
| Accumulated deficit | (155,355) | (127,125) |
| Accumulated other comprehensive income | 3,725 | 691 |
| Total shareholders' equity | 81,786 | 39,614 |
| Total liabilities and shareholders' equity | $ 156,812 | $ 116,531 |

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

**ESTABLISHMENT LABS HOLDINGS INC.**

**Condensed Consolidated Statements of Operations**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue | $ 10,474 | $ 21,684 | $ 34,955 | $ 42,462 |
| Cost of revenue | 3,240 | 8,672 | 12,243 | 18,198 |
| Gross profit | 7,234 | 13,012 | 22,712 | 24,264 |
| Operating expenses: | | | | |
| Sales, general and administrative | 14,438 | 18,394 | 33,422 | 34,450 |
| Research and development | 2,399 | 4,001 | 6,598 | 7,585 |
| Total operating expenses | 16,837 | 22,395 | 40,020 | 42,035 |
| Loss from operations | (9,603) | (9,383) | (17,308) | (17,771) |
| Interest income | 2 | 4 | 10 | 10 |
| Interest expense | (2,130) | (2,521) | (4,276) | (4,763) |
| Change in fair value of derivative instruments | 1,492 | 2,640 | (437) | 2,608 |
| Change in fair value of contingent consideration | (141) | 137 | 299 | 362 |
| Other expense, net | 103 | 118 | (6,093) | (186) |
| Loss before income taxes | (10,277) | (9,005) | (27,805) | (19,740) |
| Provision for income taxes | (194) | (35) | (425) | (79) |
| Net loss | $ (10,471) | $ (9,040) | $ (28,230) | $ (19,819) |
| | | | | |
| Basic and diluted net loss per share | $ (0.45) | $ (0.44) | $ (1.23) | $ (0.97) |
| Weighted average outstanding shares used for basic and diluted net loss per share | 23,482,031 | 20,448,643 | 22,969,162 | 20,407,912 |

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

**ESTABLISHMENT LABS HOLDINGS INC.**
**Condensed Consolidated Statements of Comprehensive Income (Loss)**
**(In thousands)**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Net loss | $ (10,471) | $ (9,040) | $ (28,230) | $ (19,819) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation gain (loss) | 213 | (154) | 3,034 | (87) |
| Other comprehensive gain (loss) | 213 | (154) | 3,034 | (87) |
| Comprehensive loss | $ (10,258) | $ (9,194) | $ (25,196) | $ (19,906) |

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

**ESTABLISHMENT LABS HOLDINGS INC.**

**Condensed Consolidated Statement of Shareholders' Equity**
**(Unaudited) (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, 2020** | **21,057,040** | **$ 147,688** | **(408,070)** | **$ (2,854)** | **$ 21,214** | **$ (127,125)** | **$ 691** | **$ 39,614** |
| Issuance of common stock, net of underwriters' discount and issuance costs | 2,628,571 | 63,855 | — | — | — | — | — | 63,855 |
| Stock option exercises | 39,723 | 181 | — | — | — | — | — | 181 |
| Share-based compensation | 11,062 | 11 | — | — | 1,618 | — | — | 1,629 |
| Shares withheld to cover income tax obligation upon vesting of restricted stock | (1,383) | (1) | — | — | (33) | — | — | (34) |
| Foreign currency translation gain | — | — | — | — | — | — | 2,821 | 2,821 |
| Net loss | — | — | — | — | — | (17,759) | — | (17,759) |
| **Balance at March 31, 2020** | **23,735,013** | **211,734** | **(408,070)** | **(2,854)** | **22,799** | **(144,884)** | **3,512** | **90,307** |
| Stock option exercises | 22,734 | 193 | — | — | — | — | — | 193 |
| Share-based compensation | 5,802 | 6 | — | — | 1,551 | — | — | 1,557 |
| Shares withheld to cover income tax obligation upon vesting of restricted stock | (762) | (1) | — | — | (12) | — | — | (13) |
| Foreign currency translation gain | — | — | — | — | — | — | 213 | 213 |
| Net loss | — | — | — | — | — | (10,471) | — | (10,471) |
| **Balance at June 30, 2020** | **23,762,787** | **$ 211,932** | **(408,070)** | **$ (2,854)** | **$ 24,338** | **$ (155,355)** | **$ 3,725** | **$ 81,786** |

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

**ESTABLISHMENT LABS HOLDINGS INC.**

**Condensed Consolidated Statement of Shareholders' Equity**
**(Unaudited) (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, 2019** | **20,672,025** | **$ 145,709** | **(408,070)** | **$ (2,854)** | **$ 15,156** | **$ (88,975)** | **$ 449** | **$ 69,485** |
| Issuance of shares in an asset acquisition | 12,404 | 337 | — | — | — | — | — | 337 |
| Stock option exercises | 5,941 | 84 | — | — | — | — | — | 84 |
| Warrant exercises | 70,567 | 113 | — | — | (57) | — | — | 56 |
| Share-based compensation | 45,394 | 45 | — | — | 1,791 | — | — | 1,836 |
| Shares withheld to cover income tax obligation upon vesting of restricted stock | (2,528) | (3) | — | — | (53) | — | — | (56) |
| Foreign currency translation gain | — | — | — | — | — | — | 67 | 67 |
| Net loss | — | — | — | — | — | (10,779) | — | (10,779) |
| **Balance at March 31, 2019** | **20,803,803** | **146,285** | **(408,070)** | **(2,854)** | **16,837** | **(99,754)** | **516** | **61,030** |
| Stock option exercises | 22,289 | 92 | — | — | — | — | — | 92 |
| Warrant exercises | 16,754 | 16 | — | — | (16) | — | — | — |
| Share-based compensation | 41,024 | 41 | — | — | 1,853 | — | — | 1,894 |
| Shares withheld to cover income tax obligation upon vesting of restricted stock | (1,451) | (1) | — | — | (34) | — | — | (35) |
| Foreign currency translation loss | — | — | — | — | — | — | (154) | (154) |
| Net loss | — | — | — | — | — | (9,040) | — | (9,040) |
| **Balance at June 30, 2019** | **20,882,419** | **$ 146,433** | **(408,070)** | **$ (2,854)** | **$ 18,640** | **$ (108,794)** | **$ 362** | **$ 53,787** |

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

**ESTABLISHMENT LABS HOLDINGS INC.**

**Condensed Consolidated Statements of Cash Flows**
**(In thousands)**
**(Unaudited)**

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Cash flows from operating activities: | | |
| Net loss | $ (28,230) | $ (19,819) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,629 | 1,416 |
| Provision for doubtful accounts | 971 | (17) |
| Provision for inventory obsolescence | 564 | (22) |
| Share-based compensation | 3,186 | 3,730 |
| Loss from disposal of property and equipment | 114 | 24 |
| Unrealized foreign currency loss, net | 5,647 | 67 |
| Change in fair value of derivative instruments | 437 | (2,608) |
| Change in fair value of contingent consideration | (299) | (362) |
| Amortization of debt discount | 797 | 1,731 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 4,150 | (3,715) |
| Inventory | (3,235) | (725) |
| Prepaid expenses and other current assets | 2,667 | (234) |
| Other assets | 4 | (56) |
| Accounts payable | (1,289) | 2,413 |
| Accrued liabilities | (5) | 2,709 |
| Other liabilities | (5) | 407 |
| Net cash used in operating activities | (12,897) | (15,061) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (1,290) | (4,882) |
| Cash used in asset acquisition | (497) | (767) |
| Cost incurred for intangible assets | (495) | (17) |
| Net cash used in investing activities | (2,282) | (5,666) |
| Cash flows from financing activities: | | |
| Repayments on capital leases | (139) | (185) |
| Proceeds from issuance of common shares, net of underwriters' discount and issuance costs | 63,855 | — |
| Proceeds from stock option exercises | 374 | 176 |
| Proceeds from warrant exercises | — | 58 |
| Tax payments related to shares withheld upon vesting of restricted stock | (48) | (91) |
| Net cash provided by (used in) financing activities | 64,042 | (42) |
| Effect of exchange rate changes on cash | (136) | — |
| Net (decrease)/increase in cash | 48,727 | (20,769) |
| Cash at beginning of period | 37,655 | 52,639 |
| Cash at end of period | $ 86,382 | $ 31,870 |
| | | |
| Supplemental disclosures: | | |
| Cash paid for interest | $ 3,464 | $ 2,724 |
| Cash paid for income taxes | $ 2 | $ 146 |

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

**ESTABLISHMENT LABS HOLDINGS INC.**

**Condensed Consolidated Statements of Cash Flows**
**(In thousands)**
**(Unaudited)**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2020** | **2019** |
| Supplemental disclosures of non-cash investing and financing activities: | | |
| Unpaid balance for property and equipment | $ 327 | $ 622 |
| Assets acquired under capital leases | $ — | $ 69 |
| Equity consideration in an asset acquisition | $ — | $ 337 |
| Inventory acquired in an asset acquisition | $ — | $ 1,257 |
| Consideration payable related to asset acquisition | $ 779 | $ 1,277 |

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

**ESTABLISHMENT LABS HOLDINGS, INC.**

**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

## 1. Formation and Business of the Company

***Formation and Business of the Company***

Establishment Labs Holdings Inc. and its wholly owned subsidiaries (collectively "the Company", "we", "us", or "our") 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 June 30, 2020, 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 BVBA), 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. 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. 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 products in the United States. The Company received approval for an investigational device exemption, or IDE, from the FDA in March 2018 to initiate a clinical trial in the United States for its Motiva Implants. In August 2019, we completed all patient surgeries for the IDE aesthetic cohorts, which include primary augmentation and revision. As of June 30, 2020, we are continuing to enroll subjects in the remaining reconstruction cohorts.

The Company has been expanding its global operations through a series of acquisitions and establishing wholly-owned subsidiaries. In November 2015, the Company purchased certain assets from Magna Equities I, LLC and established its wholly-owned subsidiary, JAMM Technologies, Inc., in the United States. In January 2016, the Company purchased a distribution company in Brazil to support the application to sell its products in Brazil. In March 2016, the Company purchased a storage and distribution company in Belgium to support its continued growth in Europe. In September 2016, the Company purchased a distribution company in France, and it also established a wholly-owned subsidiary in Switzerland. In November 2017, the Company acquired certain assets from Femiline AB and established its wholly-owned subsidiary in Sweden, Motiva Nordica AB. During 2018, the Company established wholly-owned subsidiaries in the United Kingdom and Italy and purchased certain assets from Menke Med GmbH, Motiva Matrix Spain, S.L. and Belle Health Ltd. In 2019, the Company purchased certain assets from AFS Medical GMBH and established wholly-owned subsidiaries in Austria, Spain and Germany. In 2020, the Company established a wholly-owned subsidiary in Argentina.

## 2. Summary of Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2020 as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's audited consolidated financial statements as of December 31, 2019 and 2018 and for the years then ended. Below are those policies with current period updates.

***Basis of Presentation and Consolidation***

The accompanying condensed 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, for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the years ended

**ESTABLISHMENT LABS HOLDINGS, INC.**

**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

December 31, 2019 and 2018 presented in the Company's Form 10-K filed on March 16, 2020, with the U.S. Securities and Exchange Commission.

The condensed consolidated financial statements include the Company's accounts and those of its wholly owned subsidiaries as of June 30, 2020 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.

***Unaudited Interim Condensed Consolidated Financial Information***

The accompanying interim condensed consolidated financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019, and the related interim information contained within the notes to the condensed consolidated financial statements, are unaudited. The unaudited interim condensed consolidated financial statements have been prepared in accordance with GAAP and on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to state fairly the Company's financial position as of June 30, 2020, and the results of its operations and cash flows for the six months ended June 30, 2020 and 2019. Such adjustments are of a normal and recurring nature. The results for the six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the full fiscal year 2020, or for any future period.

***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 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.

For the six months ended June 30, 2020 and 2019, Brazil accounted for 9.6% and 16.1% of consolidated revenue and no other individual country exceeded 10% of consolidated revenue, on a ship-to destination basis.

The Company's long-lived assets located in Costa Rica represented the majority of the total long-lived assets as of June 30, 2020 and December 31, 2019.

***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 condensed consolidated financial statements and accompanying notes. Significant accounting estimates and management judgments reflected in the condensed consolidated financial statements include items such as accounts receivable valuation and allowances, inventory valuation and allowances, valuation of acquired intangible assets, valuation of derivatives, estimation of assets' useful lives 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.

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 participates, the Company uses a combination of distributors and makes 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.

During the six months ended June 30, 2020 and 2019, no customers accounted for more than 10% of the Company's revenue. Substantially all of the Company's revenues are derived from the sale of Motiva Implants. One customer accounted for 13.0% and another customer accounted for 11.5% of the Company's trade accounts receivable balance as of June 30, 2020. One customer accounted for 10.2% of the Company's trade accounts receivable balance as of December 31, 2019.

The Company relies on NuSil Technology, LLC, or NuSil, as the sole supplier of medical-grade silicone used in Motiva Implants. During the six months ended June 30, 2020 and 2019, the Company had purchases of $8.1 million, or 67.4% of total purchases, and $8.1 million, or 62.1% of total purchases, respectively, from NuSil. As of June 30, 2020 and December 31, 2019, the Company had an outstanding balance owed to this vendor of $2.0 million and $2.7 million, respectively.

The Company's 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, 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, 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 was denied clearance, clearance was delayed, or the Company was unable to maintain its existing clearances, these developments could have a material adverse impact on the Company.

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic which has spread globally, including locations where the Company does business. The full extent of the outbreak, related business and travel restrictions and changes to behavior intended to reduce its spread are uncertain and continues to evolve globally. Therefore, the full extent to which COVID-19 may impact the

Company's results of operations, liquidity or financial position is uncertain. This outbreak has already had a material disruption on the operations of the Company and its suppliers and customers. Management continues to monitor the impact that the COVID-19 pandemic is having on the Company, the breast aesthetics and reconstruction market and the economies in which the Company operates. The Company anticipates that its future results of operations, including the results for 2020, will be materially impacted by the COVID-19 outbreak, but, at this time, does not currently expect that the impact from the COVID-19 outbreak will have a material effect on the Company's liquidity or financial position. However, given the speed and frequency of continuously evolving developments with respect to this pandemic, the Company cannot reasonably estimate the magnitude of the impact to the results of its operations. To the extent that the Company's customers continue to be materially and adversely impacted by the COVID-19 outbreak, this could materially interrupt the Company's business operations.

***Cash***

The Company's cash consists of cash maintained in checking and interest-bearing accounts. The Company accounts for financial instruments with original maturities of three months or less at the date of purchase as cash equivalents. The Company held no cash equivalents as of June 30, 2020 and December 31, 2019.

***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. An inventory reserve of $0.9 million and $0.3 million has been recorded as of June 30, 2020 and December 31, 2019, respectively.

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

***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 three months ended June 30, 2020 and 2019, shipping and handling costs were $0.6 million and $0.7 million, respectively. For each of the six months ended June 30, 2020 and 2019, shipping and handling costs were $1.4 million.

***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.

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Appropriate reserves are established for anticipated sales returns based on historical experience, recent gross sales and any notification of pending returns. 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 within fifteen days after the original sale and records estimated sales returns as a reduction of sales in the same period revenue is recognized. Sales return provisions are calculated based upon historical experience with actual 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 June 30, 2020 and December 31, 2019, an allowance of $24,000 and $36,000 was recorded for product returns, respectively.

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.

Revenue was generated in these primary geographic markets:

| | Six Months Ended June 30, | | Three Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (in thousands) | | | |
| Europe | $ 15,932 | $ 18,687 | $ 6,153 | $ 9,280 |
| Latin America | 8,508 | 12,184 | 1,366 | 6,017 |
| Asia-Pacific/Middle East | 10,350 | 11,222 | 2,880 | 6,276 |
| Other | 165 | 369 | 75 | 111 |
| | $ 34,955 | $ 42,462 | $ 10,474 | $ 21,684 |

The Company has a limited warranty for the shelf life of the product, 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 are 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 condensed 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 FDA 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.

Following the exercise of its option to purchase its manufacturing facility in June 2019, the Company depreciates the owned building 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 is 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 and trademarks and 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 year ended December 31, 2019, there was no impairment of goodwill or intangible assets based on the qualitative assessments performed by the Company. As of June 30, 2020, the Company determined that the economic impact of the global COVID-19 pandemic constituted a triggering event which would indicate that the acquired intangible asset values may not be recoverable. During the six months ended June 30, 2020, 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 year ended December 31, 2019 or the six months ended June 30, 2020.

***Debt and Embedded Derivatives***

The Company applies the accounting standards for derivatives and hedging 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 6).

The Company uses option pricing valuation models to determine the fair value of embedded derivatives and records any change in fair value as a component of other income or expense in the condensed consolidated statements of operations (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 condensed 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 condensed 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 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 in fiscal 2019 and for the six months ended June 30, 2020.

***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 (loss)" as equity in the condensed 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

condensed consolidated statement of operations. For the six months ended June 30, 2020, foreign currency transaction loss amounted to $5.8 million as compared to a foreign currency transaction loss of $0.3 million for the six months ended June 30, 2019.

***Comprehensive Income (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 stock-based awards in accordance with the provisions of ASC 718, *Stock Compensation*. Stock-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 that the Company 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 share warrants, share options and non-vested restricted stock outstanding under the Company's equity plan are potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for periods where the Company reported a net loss because including the dilutive securities would be anti-dilutive.

***Recent Accounting Standards***

Periodically, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, 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. Under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. The Company will remain an emerging growth company until the earliest of (1) the last day of its first fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

The following recent accounting pronouncements issued by the FASB, could have a material effect on our financial statements:

*Recently Issued Accounting Standards*

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU modifies the disclosure requirements for fair value measurements. The modifications removed the following disclosure requirements: (i) the amount of, and reasons for, transfers between Level 1 and Level 2 of the fair value hierarchy; (ii) the policy for timing of transfers between levels; and (iii) the valuation processes for Level 3 fair value measurements. This ASU added the following disclosure requirements: (i) the changes in unrealized gains and losses for the period included in other

comprehensive income ("OCI") for recurring Level 3 fair value measurements held at the end of the reporting period; and (ii) the range and weighted average of significant observable inputs used to develop Level 3 fair value measurements. This update is effective for non-public entities for annual and interim periods beginning after December 15, 2020, with early adoption permitted. As the requirements of this literature are disclosure only, ASU 2018-13 will not impact our financial condition or results of operations.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This ASU replaces the impairment methodology in current GAAP, which delays recognition of credit losses until it is probable a loss has been incurred, with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. For non-public business entities and emerging growth companies the standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently assessing the impact the adoption of ASU 2016-13 will have on its consolidated financial statements and footnote disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840 *Leases*. The standard is effective for non-public business entities and emerging growth companies for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021. Early adoption is permitted. The Company is currently assessing the impact the adoption of ASC 842 will have on its consolidated financial statements and footnote disclosures.

## 3. Balance Sheet Accounts

***Inventory, Net***

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Raw materials | $ 6,510 | $ 5,506 |
| Work in process | 1,265 | 1,200 |
| Finished goods | 21,282 | 21,954 |
| | $ 29,057 | $ 28,660 |

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***Property and Equipment, Net***

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Machinery and equipment | $ 8,450 | $ 8,045 |
| Building improvements | 6,456 | 6,443 |
| Furniture and fixtures | 3,820 | 3,614 |
| Building | 2,472 | 2,472 |
| Leasehold improvements | 1,978 | 2,101 |
| Land | 802 | 802 |
| Vehicles | 464 | 463 |
| Construction in Process | 113 | — |
| Total | 24,555 | 23,940 |
| Less: Accumulated depreciation and amortization | (8,470) | (7,522) |
| | $ 16,085 | $ 16,418 |

For the three months ended June 30, 2020 and 2019, depreciation and amortization expense related to property and equipment was $0.6 million and $0.7 million, respectively. For the six months ended June 30, 2020 and 2019, depreciation and amortization expense related to property and equipment was $1.2 million and $1.3 million, respectively.

The Company entered into capital leases relating to equipment and vehicles and recorded the fair value of the lease payments on the initial contract date and is amortizing the assets over the term of the leases. As of each of June 30, 2020 and December 31, 2019, the gross asset value for capital lease assets was $1.5 million. Depreciation expense for assets under capital leases was $21,000 for each of the three months ended June 30, 2020 and 2019. Depreciation expense for assets under capital leases was $42,000 for each of the six months ended June 30, 2020 and 2019.

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***Accrued Liabilities***

Accrued liabilities consisted of the following:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Performance bonus | $ 1,148 | $ 2,080 |
| Payroll and related expenses | 2,702 | 1,996 |
| Bonus feature of stock option grants | 5,102 | 4,212 |
| Commissions | 246 | 522 |
| Professional and legal services | 494 | 500 |
| Short-term minimum lease payments under capital leases | 118 | 258 |
| Warranty reserve | 264 | 313 |
| Advisory board and board of director related expenses | 3 | 124 |
| Other | 440 | 672 |
| | $ 10,517 | $ 10,677 |

***Other Liabilities, Short Term***

Other liabilities, short-term consisted of the following:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Contingent equity consideration | $ 623 | $ 922 |
| Deferred revenue | 728 | 785 |
| Cash payable for asset acquisitions | 391 | 492 |
| | $ 1,742 | $ 2,199 |

***Other Liabilities, Long Term***

Other liabilities, long-term consisted of the following:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Deferred revenue | $ 1,290 | $ 1,344 |
| Cash payable for asset acquisitions | 388 | 781 |
| Other | 348 | 336 |
| | $ 2,026 | $ 2,461 |

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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 June 30, 2020 are the result of acquisitions of certain assets formerly owned by VeriTeQ Corporation in November 2015 and Femiline AB in November 2017, and business acquisitions of Establishment Labs Brasil Productos para Saude Ltda. in January 2016, European Distribution Center Motiva BVBA in March 2016 and Motiva Implants France in September 2016. 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 six months ended June 30, 2020:

| | Balance as of January 1, 2020 | Additions | Accumulated Impairment Losses | Balance as of June 30, 2020 |
|---|---|---|---|---|
| | | (in thousands) | | |
| Goodwill | $ 465 | $ — | $ — | $ 465 |

The carrying amounts of these intangible assets other than goodwill as of June 30, 2020 were as follows:

| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | Estimated Useful Lives |
|---|---|---|---|---|
| | | (in thousands) | | (in years) |
| Patents and license rights | $ 1,731 | $ (851) | $ 880 | 7-12 |
| Customer relationships | 1,896 | (1,086) | 810 | 4-10 |
| 510(k) authorization | 567 | (175) | 392 | 15 |
| Developed technology | 62 | (42) | 20 | 10 |
| Capitalized software development costs | 1,217 | (176) | 1,041 | 2-5 |
| Other | 75 | (29) | 46 | 2-5 |
| Capitalized patents and license rights not yet amortized | 291 | — | 291 | |
| | $ 5,839 | $ (2,359) | $ 3,480 | |

The carrying amounts of intangible assets other than goodwill as of December 31, 2019 were as follows:

| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | Estimated Useful Lives |
|---|---|---|---|---|
| | | (in thousands) | | (in years) |
| Patents and license rights | $ 1,693 | $ (766) | $ 927 | 7-12 |
| Customer relationships | 1,896 | (836) | 1,060 | 4-10 |
| 510(k) authorization | 567 | (156) | 411 | 15 |
| Developed technology | 62 | (39) | 23 | 10 |
| Capitalized software development costs | 780 | (98) | 682 | 2-5 |
| Other | 75 | (28) | 47 | 2-5 |
| Capitalized patents and license rights not yet amortized | 291 | — | 291 | |
| | $ 5,364 | $ (1,923) | $ 3,441 | |

For each of the three months ended June 30, 2020 and 2019, amortization expense related to intangible assets was $0.2 million. For each of the six months ended June 30, 2020 and 2019, amortization expense related to intangible assets was $0.4 million. Non-product related amortization is recorded in SG&A while product related amortization is recorded in cost of revenue.

As of June 30, 2020, 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) |
|---|---|
| 2020 (remaining) | $ 509 |
| 2021 | 910 |
| 2022 | 585 |
| 2023 | 340 |
| 2024 | 324 |
| Thereafter | 521 |
| Total | $ 3,189 |

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 June 30, 2020, there has been no impairment of goodwill or intangible assets based on the qualitative assessments performed by the Company.

**5. Fair Value Measurements**

The carrying value of the Company's cash, accounts receivable and accounts payable approximate fair value due to the short-term nature of these items. Contingent equity consideration, warrants and embedded derivatives that qualify for liability treatment are carried at fair value and re-measured at each reporting period.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between

market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

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

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

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy at period end:

| | Fair Value Measurements at June 30, 2020 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| | (in thousands) | | | |
| **Liabilities** | | | | |
| Madryn put option liability | $ 3,509 | $ — | $ — | $ 3,509 |
| Acquisition-related contingent consideration | 623 | — | — | 623 |
| | $ 4,132 | $ — | $ — | $ 4,132 |

| | Fair Value Measurements at December 31, 2019 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| | (in thousands) | | | |
| **Liabilities** | | | | |
| Madryn put option liability | $ 3,072 | $ — | $ — | $ 3,072 |
| Acquisition-related contingent consideration | 922 | — | — | 922 |
| | $ 3,994 | $ — | $ — | $ 3,994 |

The fair value measurement of derivatives and contingent consideration related to the business acquisition completed in fiscal 2017 is based on significant inputs not observed in the market and thus represents a Level 3 measurement.

In August 2017 the Company entered into a credit agreement, or the Madryn Credit Agreement, with Madryn Health Partners, LP, or Madryn, as administrative agent, and a syndicate of lenders (see Note 6). The Company determined that the Madryn Credit Agreement contained put options related to early redemption mandatory prepayment terms in case of change in control 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 identified embedded derivatives as a debt discount on the original commitment date. 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 on August 12, 2019 (see Note 6). The Company revalued the options as of each reporting period and recorded the change in the fair value in the consolidated statement of operations as other income or expense.

Valuation of the embedded derivatives is complex and requires interest rate simulation, estimating the resultant bond valuation and the resultant pay-off to the option holder. The Company estimated the fair value of the embedded redemption options based on a “with” and “without” approach using the Black-Derman-Toy model, a form of the Binomial Lattice Model that captures interest rate variability and the prepayment optionality. The Binomial Lattice Model allows for the possibility of exercise before the end of the option’s life and considers future interest rates, volatility and other data with regards to the Company’s credit rating and credit spread. The value of the embedded derivatives was based on the difference between the “with” and “without” analysis. The probability of a change in control occurring was determined to be 50% at June 30, 2020 and December 31, 2019.

The Company used the following assumptions to value Madryn derivatives:

***Put Option Liability (Madryn)***

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Interest rate volatility | 21.8% | 21.4% |
| Market yield rate | 11.1% | 10.1% |
| Term (in years) | 5.25 | 5.75 |
| Dividend yield | — | — |

On November 17, 2017, the Company and Femiline AB and Johan Anderson, or the Seller, entered into an agreement to purchase certain assets from the Seller. The assets purchased included all existing inventory previously sold by the Company to the Seller, all customer relationships and a covenant not to compete. The aggregate purchase price for the assets purchased was 100,000 Class A Ordinary shares of the Company, contingently issuable upon achievement of specific milestones. Based on the valuation of the Company’s shares performed by a valuation specialist, the contingently issuable shares had an aggregate value of $1.0 million calculated as a product of contingently issuable shares and estimated fair value per share on the date of the agreement. As of June 30, 2020, the Company has issued 66,666 shares to the Seller after the milestones for fiscal 2018 and 2019 were met. As of June 30, 2020, the fair value of the contingently issuable shares was determined using the closing price of the Company’s publicly traded shares.

As of June 30, 2020 and December 31, 2019, the remaining contingent consideration liability was included in “Other liabilities, short term”.

The estimates are based, in part, on subjective assumptions and could differ materially in the future.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the six months ended June 30, 2020 or during the year ended December 31, 2019.

The fair value of the debt redemption feature liability includes the estimated volatility and risk-free rate. The higher/lower the estimated volatility, the higher/lower the value of the debt redemption feature liability. The higher/lower the risk-free interest rate, the higher/lower the value of the debt conversion feature liability.

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

| | Acquisition-related Contingent Consideration | Put Option Liability (Madryn) |
|---|---|---|
| Balance at December 31, 2018 | $ 1,828 | $ 4,768 |
| Change in fair value | (362) | (2,608) |
| Balance at June 30, 2019 | $ 1,466 | $ 2,160 |
| | | |
| Balance at December 31, 2019 | $ 922 | $ 3,072 |
| Change in fair value | (299) | 437 |
| Balance at June 30, 2020 | $ 623 | $ 3,509 |

**6. Debt**

***Madryn Debt***

On August 24, 2017, the Company entered into a credit agreement, or the Madryn Credit Agreement, with Madryn Health Partners, LP, or Madryn, as administrative agent, and a syndicate of lenders. On June 17, 2019, the Madryn Credit Agreement was amended to lower the interest rate on the outstanding debt facilities, provide for $25.0 million of new term loan commitments, decrease the amount of the prepayment penalties, remove all principal payments and extend the maturity date and repayment from September 30, 2023 to September 30, 2025. The Madryn Credit Agreement, as amended, provides for a term loan in a maximum principal amount of $65.0 million, $30.0 million (Term A) of which became available upon signing and was subsequently borrowed by the Company.

Prior to amending the Madryn Credit Agreement on June 17, 2019, the Company's ability to borrow the remaining term loans under the Madryn Credit Agreement was subject to the Company achieving certain revenue milestones. The Company met milestones sufficient to borrow and borrowed an additional $5.0 million (Term B-1) on October 31, 2017 and $5.00 million (Term B-2) on December 15, 2017, increasing the total outstanding principal balance to $40.0 million as of December 31, 2017.

Pursuant to the June 2019 amendment, the Company became eligible to borrow an additional $10.0 million (Term B-3) and $15.0 million (Term B-4) on or before September 30, 2019 and December 31, 2019, respectively. The Company borrowed the available funds under both tranches equal to $25.0 million on August 12, 2019, bringing up the total outstanding principal balance to $65.0 million as of June 30, 2020.

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.

The Madryn Credit Agreement contains customary affirmative and negative covenants, including, but not limited to, restrictions on the ability of the Company and its subsidiaries to incur additional indebtedness, create liens, make certain investments, make restricted payments, enter into or undertake certain liquidations, mergers, consolidations or acquisitions and dispose of assets or subsidiaries. In addition, the Madryn Credit Agreement requires the Company to maintain minimum revenues and liquidity.

Prior to the effectiveness of the June 17, 2019 amendment, borrowings under the Madryn Credit Agreement bore interest at a rate equal to 3-month LIBOR plus 11.0% per annum. As of the amendment on June 17, 2019, borrowings under the Madryn Credit Agreement bear interest at a rate equal to 3-month LIBOR plus 8.0% per annum provided that no default has occurred. In an event of a default, the interest would increase by an additional

4.0% per annum. The effective interest rate under the amended Madryn Credit Agreement is 18.4%, and the weighted average interest rate was approximately 10.6% at June 30, 2020. The Company incurred $3.5 million and $3.0 million in interest expense in connection with Madryn Credit Agreement during the six months ended June 30, 2020 and in 2019, respectively, including $0.3 million of direct costs to amend the Madryn Credit Agreement in June 2019, which were expensed as interest expense. No principal payments are 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 are 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 revalues the embedded derivatives as of each reporting period and records the change in the fair value in the consolidated statement of operations as other income or expense (see Note 5). The Company also incurred legal expenses of $1.3 million in the third quarter of fiscal 2017 and $0.3 million in August 2019, which were recorded as a debt discount and are being amortized over the term of the Madryn Credit Agreement.

The Company recorded Madryn debt on the balance sheet as follows:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Principal | $ 65,000 | $ 65,000 |
| Net unamortized debt discount and issuance costs | (16,061) | (16,858) |
| Net carrying value of Madryn debt | $ 48,939 | $ 48,142 |

As of June 30, 2020, the Company is in compliance with all financial debt covenants.

## 7. Commitments and Contingencies

***Operating Leases***

We lease certain facilities under various operating leases. Most of the lease agreements provide us with the option of renewing our leases at the end of the initial lease term, at fair market rates. In most cases, we expect that in the normal course of business, facility leases will be renewed or replaced by other leases.

For the three months ended June 30, 2020 and 2019 rent expense was $0.2 million and $0.4 million, respectively. For the six months ended June 30, 2020 and 2019 rent expense was $0.5 million and $0.7 million, respectively.

Future minimum lease payments under the operating leases as of June 30, 2020 were as follows:

| Years Ending December 31, | Operating Leases |
|---|---|
| | (in thousands) |
| 2020 (remaining) | $ 284 |
| 2021 | 483 |
| 2022 | 413 |
| 2023 | 381 |
| 2024 | 373 |
| Thereafter | 1,179 |
| | $ 3,113 |

***Capital Leases***

The Company entered into capital lease arrangements relating to software, equipment and vehicles. The lease periods are from three to seven years. The repayments are made monthly with an interest rates ranging from 7% to 12% per year.

Future minimum lease payments under these capital leases as of June 30, 2020 were as follows:

| Years Ending December 31, | Capital Leases |
|---|---|
| | (in thousands) |
| 2020 (remaining) | $ 129 |
| 2021 | 180 |
| 2022 | 39 |
| | 348 |
| Interest included in the above payments | (22) |
| Amount payable without interest | 326 |
| Short-term minimum capital lease payments (included in accrued liabilities) | 118 |
| Long-term minimum capital lease payments | $ 208 |

***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. There have been no contingent liabilities requiring accrual or disclosure at June 30, 2020 and December 31, 2019 except for contingent equity consideration related to past asset acquisitions (see Note 3).

***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, but 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.

**8. Shareholders' Equity**

Under the Memorandum of Association and Articles of Association, or Articles, in effect as of June 30, 2020 and December 31, 2019, the Company had authorized an unlimited number of common shares with no par value.

As of June 30, 2020 and December 31, 2019, 23,762,787 and 21,057,040 common shares, respectively, were issued and 23,354,717 and 20,648,970 common shares, respectively, were outstanding.

During the six months ended June 30, 2020, the Company granted stock options to employees and contractors (see Note 10).

The Company had reserved common shares for future issuances as follows:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Warrants to purchase shares | 5,500 | 5,500 |
| Options to purchase shares | 2,044,634 | 1,837,576 |
| Remaining shares available under the 2018 Equity Incentive Plan | 1,731,133 | 1,312,648 |
| Shares issuable on vesting of restricted stock awards | 102,670 | 128,682 |
| Remaining shares available under the 2018 ESPP | 474,000 | 287,000 |
| Total | 4,357,937 | 3,571,406 |

**9. 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 six months ended June 30, 2020, no warrants were exercised. As of each of June 30, 2020 and December 31, 2019, 5,500 warrants to purchase the Company's common shares were outstanding and exercisable:

| Warrant Holder | Issue Date | In Connection With | Warrant to Purchase | Shares | Exercise Price | Expiration Date |
|---|---|---|---|---|---|---|
| Rockport | 3/3/2017 | Loan agreement | Common | 5,500 | $3.80 | 8/28/2022 |

**10. Share-Based Compensation**

In December 2015, the Board of Directors approved and adopted the 2015 Equity Incentive Plan, or 2015 Plan. Pursuant to the 2015 Plan, the Company has granted RSAs and stock options to 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 shares of the Company's common shares for issuance under the 2018 Plan. Under the 2018 Plan, the Company may grant share options, equity appreciation rights, and restricted shares and restricted share units. 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 January 1, 2020, the number of common shares authorized for issuance increased automatically by 750,000 shares in accordance with the evergreen provision of the 2018 Plan, increasing the number of common shares reserved under the 2018 Plan to 3,000,000.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (in thousands) | | | |
| Sales, general and administrative | $ 1,139 | $ 1,413 | $ 2,446 | $ 2,681 |
| Research and development | 418 | 481 | 740 | 1,049 |
| Total | $ 1,557 | $ 1,894 | $ 3,186 | $ 3,730 |

***Stock Options***

| | Number of Options Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balances at December 31, 2019 | 1,837,576 | $ 14.54 | 8.06 | $ 24,122 |
| Granted (weighted-average fair value of $10.64 per share) | 367,265 | 19.11 | | |
| Exercised | (62,457) | 5.99 | | |
| Forfeited/canceled | (97,750) | 15.70 | | |
| Balances at June 30, 2020 | 2,044,634 | $ 15.57 | 8.04 | $ 10,046 |

As of June 30, 2020, 835,046 options were vested and exercisable with weighted-average exercise price of $9.98 per share and a total aggregate intrinsic value of $8.0 million.

During the six months ended June 30, 2020, 62,457 options were exercised at a weighted-average price of $5.99 per share. The intrinsic value of the options exercised during the six months ended June 30, 2020 was $0.8 million. Upon the exercise of stock options, the Company issued new shares from its authorized shares.

At June 30, 2020, unrecognized compensation expense was $8.4 million related to stock options granted to employees and Board of Directors and $2.3 million related to stock options granted to consultants. The weighted-average period over which such compensation expense will be recognized is 2.4 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 six months ended June 30, 2020 and 2019, the Company recognized $1.4 million and $0.9 million, respectively, of stock-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.* Following the IPO, 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. Prior to the IPO, the fair value of ordinary shares was estimated on a periodic basis by the Company's Board of Directors, with the assistance of an independent third-party valuation firm. 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 will experience as a publicly traded company. The Company consequently uses the Staff Accounting Bulletin 110, or SAB 110, simplified method to calculate the expected term of employee stock options, which is the average of the contractual term and vesting period. The Company plans to continue to use the SAB 110 simplified method until it has sufficient trading history as a publicly traded company. For consultant stock options, the term used is equal to the remaining contractual term on the measurement date.
- *Volatility.* The Company determines the price volatility based on the historical volatilities of industry peers as it does not have sufficient trading history for its shares. Industry peers consist of several public companies in the medical device industry with comparable characteristics, including revenue growth, operating model and working capital requirements. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies until a sufficient amount of historical information regarding the volatility of its own shares becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common share prices are publicly available would be utilized in the calculation. The volatility is calculated based on the term on the measurement date.
- *Dividend Yield.* The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. The Company has no expectation that it will declare dividends on its common shares, and therefore has used an expected dividend yield of zero.

**ESTABLISHMENT LABS HOLDINGS, INC.**

**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Volatility | 55% - 60% | 56% |
| Risk-free interest rate | 0.4% - 1.5% | 1.9% - 2.6% |
| Term (in years) | 6.25 | 6.25 |
| Dividend yield | — | — |

***Stock Options Granted to Non-Employees***

Stock-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 six months ended June 30, 2020 and 2019, the Company recognized expense of $1.5 million and $2.1 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:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Volatility | 56% - 60% | 57% |
| Risk-free interest rate | 0.6% - 1.6% | 2.1% |
| Term (in years) | 10 | 10 |
| Dividend yield | — | — |

***Restricted Stock***

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

The following table represents RSA activity for fiscal 2020:

| | Restricted Stock Awards | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding unvested at December 31, 2019 | 128,682 | $ 11.81 |
| Granted | — | — |
| Vested | (16,864) | 12.53 |
| Forfeited/canceled | (9,148) | 9.55 |
| Outstanding unvested at June 30, 2020 | 102,670 | $ 11.90 |

The fair value of restricted stock is the grant date market value of common shares. The Company recognizes share-based compensation expense related to restricted stock using a straight-line method over the vesting term of the awards. The share-based compensation expense for RSAs that vested during the six months ended June 30, 2020 and 2019, was $0.3 million and $0.7 million, respectively, which was calculated based on the market value of the Company's common shares on the applicable date of vesting.

As of June 30, 2020, we had unrecognized share-based compensation cost of approximately $0.8 million associated with unvested restricted stock awards. This cost is expected to be recognized over a weighted-average period of approximately 1.2 years.

**11. Asset Acquisitions**

*Austria*

On January 31, 2019, European Distribution Center Motiva BVBA, or EDC, entered into an asset purchase agreement with AFS Medical GMBH, or the Austria Seller, to purchase certain assets from the Austria Seller. The assets purchased included all existing inventory previously sold by the Company to the Austria Seller and all customer relationships and contracts. The aggregate purchase price for the assets purchased was the aggregate sum of book value of the inventory at the time of the transaction plus a cash payment of €293,000, or approximately $335,000, and 12,404 of the Company's common shares.

The purchase price and allocation of purchase price were as follows:

| **Purchase Price:** | | (in thousands) |
|---|---|---|
| Cash consideration | $ | 335 |
| Fair market value of common shares issued on effective date | | 337 |
| Cash paid for inventory | | 432 |
| Total purchase price | $ | 1,104 |

| **Allocation of Purchase Price:** | | (in thousands) |
|---|---|---|
| Inventory | $ | 1,104 |

As of June 30, 2020, the Company has fully paid for the Austria asset acquisition.

**ESTABLISHMENT LABS HOLDINGS, INC.**

**Notes to Condensed Consolidated Financial Statements**
**(Unaudited)**

### 12. Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share for the periods presented:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (in thousands, except share and per share data) | | | |
| **Numerator:** | | | | |
| Net loss | $ (10,471) | $ (9,040) | $ (28,230) | $ (19,819) |
| **Denominator:** | | | | |
| Weighted average common shares used for basic and diluted earnings per share | 23,482,031 | 20,448,643 | 22,969,162 | 20,407,912 |
| **Loss per share:** | | | | |
| Basic and diluted | $ (0.45) | $ (0.44) | $ (1.23) | $ (0.97) |

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:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Options to purchase common shares | 1,896,074 | 1,840,057 |
| Shares issuable on vesting of restricted stock awards | 102,670 | 228,114 |
| Warrants to purchase common shares | 5,500 | 5,500 |
| Total | 2,004,244 | 2,073,671 |

### 13. Related Party Transactions

During the six months ended June 30, 2020 and 2019, the Company recorded revenue of $0.3 million and $0.4 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 $0.1 million and $0.2 million as of June 30, 2020 and December 31, 2019, respectively.

In May 2016, the Company entered into a scientific board advisory agreement with Dr. Manuel Enrique Chacón Quirós pursuant to which Dr. Chacón Quirós joined the Company's Scientific Advisory Board, provides general scientific advice, and serves as a clinical investigator, among other services. In exchange for these services, Dr. Chacón Quirós was granted options to purchase 20,580 shares, vesting over four years in equal annual installments, provided that he continues to provide these services at such times. In September 2016, the Company entered into a separate agreement with Dr. 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. Dr. Chacón Quirós resigned from the Company's Scientific Advisory Board in November 2019. Dr. Chacón Quirós is the brother of our Chief Executive Officer, Juan José Chacón Quirós. During the six months ended June 30, 2020 and 2019, the Company paid Dr. Chacón Quirós approximately $46,000 and $72,000, respectively, for services rendered.

**14. Subsequent Events**

On August 1, 2020, Motiva Italy S.r.l, a wholly owned subsidiary of the Company, entered into an asset purchase agreement with Orion Trading S.r.l, or the Italy Seller, to purchase certain assets from the Italy Seller. The assets purchased included all existing inventory previously sold by the Company to the Italy Seller and all customer relationships and contracts. The aggregate purchase price for the assets purchased was the aggregate sum of book value of the inventory at the time of the transaction estimated to be €0.7 million, or approximately $0.8 million, a cash payment of €0.3 million, or approximately $0.3 million, and, if applicable, a cash payment equal to the true-up value of the inventory not to exceed €0.1 million, or approximately $0.1 million.

On August 5, 2020, the Company amended the Madryn Credit Agreement to adjust the minimum product revenue milestone previously applicable to December 31, 2020 to September 31, 2021 and to add Motiva Implants UK Limited, Motiva Implants France SAS, Motiva Implants Spain, S.L. and Motiva Germany GmbH, wholly-owned subsidiaries of the Company, as guarantors to the Madryn Credit Agreement.

## ITEM 2. 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 condensed consolidated financial statements and related notes that are included elsewhere in this Quarterly Report on Form 10-Q. 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 "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. See "Special Note Regarding Forward-Looking Statements" below.*

*Forward-Looking Statements*

*The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning the impact of the COVID-19 outbreak, our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.*

*Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.*

*These risks and uncertainties arise from (among other factors):*

- *our expectations and estimates concerning future financial performance, financing plans and the impact of competition;*

- *the impact that the COVID-19 pandemic may have with respect to deferrals of procedures using our products, disruptions or restrictions on the ability of many of our employees and of third parties on which we rely to work effectively, and temporary closures of our facilities and of the facilities of our customers and suppliers;*
- *the full extent to which the COVID-19 pandemic will, 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, clinical activities, and employee-related compensation, including as a result of (1) a resurgence in COVID-19 transmission and infection after the loosening of "stay at home" restrictions or resumption of surgical procedures, (2) actions required or recommended to contain or treat COVID-19, in light of any or all of the foregoing or other as-yet unanticipated developments, and (3) the direct and indirect economic impact, both domestically and abroad, of COVID-19 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, all of which currently are highly uncertain;*
- *our ability to continue to invest in medical education and training, product development, and/or sales and commercial marketing initiatives at levels sufficient to drive future revenue growth;*
- *unexpected expenses and delay and our ability to manage timelines and costs related to manufacturing our products including as a result of litigation or developing and supporting the full commercial launch of new products;*
- *our ability to obtain additional debt and equity financing to fund capital expenditures and working capital requirements and acquisitions;*
- *our ability to complete acquisitions, integrate operations post-acquisition and maintain relationships with customers of acquired entities;*
- *our ability to support the safety and efficacy of our products with long-term clinical data;*
- *existing and future regulations affecting our business, both in the United States and internationally, and enforcement of those regulations;*
- *our ability to protect our intellectual property, including unpatented trade secrets, and to operate without infringing or misappropriating the proprietary rights of others;*
- *general economic and business conditions, in both domestic and international markets; and*
- *other risk factors described in our other SEC filings, including in the section entitled "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019 and in Part II, Item 1A of our Quarterly Reports on Form 10-Q for quarters ended after December 31, 2019.*

*These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements included in this report.*

**Overview**

We are a medical technology company focused on improving patient safety and aesthetic outcomes, initially in the breast aesthetics and reconstruction market. Our line of silicone gel-filled breast implants, branded as Motiva Implants, is the centerpiece of our MotivaImagine medical technology platform. Post-market surveillance data, which was not generated in connection with the U.S. Food and Drug Administration, or FDA, PMA approval study and was self-collected rather than collected at mandatory follow-ups, and published third-party data indicates that Motiva Implants show 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 have helped drive our revenue growth. Our MotivaImagine platform enables surgical techniques that we promote as Motiva designed surgeries. We have developed other complementary products and services on our MotivaImagine platform, 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.

Our revenue for the six months ended June 30, 2020 and 2019 was $35.0 million and $42.5 million, respectively, a decrease of $7.5 million, or 17.7%. Net losses increased to $28.2 million for the six months ended June 30, 2020 from $19.8 million for the six months ended June 30, 2019. As of June 30, 2020 we had an accumulated deficit of $155.4 million.

Our cash balance as of June 30, 2020 was $86.4 million.

We are pursuing proposals related to the expansion of our manufacturing facilities and corporate offices in the Coyol Free Zone in Costa Rica. The initial $35.3 million project estimate includes approximately 170,000 square feet of facility space and would initially increase our manufacturing capacity by approximately 400,000 units per year, and potentially increase capacity by 800,000 units with an additional incremental $4.6 million investment in manufacturing equipment. Currently we are in the design phase and anticipate to breaking ground in the fourth quarter of 2020 or the first quarter of 2021. All plans are subject to final approval by the Board of Directors and the negotiation and execution of definitive agreements.

We have made and continue to make significant investments in additional manufacturing capacity, marketing, customer service, and a direct sales force in certain territories like Brazil and several countries in Europe in order to drive and support further adoption of our Motiva Implants. We expect that we will continue to incur losses at least in the near term as we expand our organization to support planned sales growth, while also continuing to invest in research and development of our products, clinical trials to enable regulatory approval in the United States, and in other commercialization efforts. We also expect to incur significant additional expenditures as a public company.

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus, or COVID-19, as a pandemic which has spread to various jurisdictions, including locations where the Company does business. The full extent of the outbreak, related business and travel restrictions and changes to behavior intended to reduce its spread are uncertain and continues to evolve globally. Therefore, the full extent to which COVID-19 may impact the Company's results of operations, liquidity or financial position is uncertain. This outbreak has already had a material disruption on the operations of the Company and its suppliers and customers. Management continues to monitor the impact that the COVID-19 pandemic is having on the Company, the breast aesthetics and reconstruction market and the economies in which the Company operates. The Company anticipates that its future results of operations, including the results for 2020, will be materially impacted by the COVID-19 outbreak, but at this time does not currently expect that the impact from the COVID-19 outbreak will have a material effect on the Company's liquidity or financial position. However, given the speed and frequency of continuously evolving developments with respect to this pandemic, the Company cannot reasonably estimate the magnitude of the impact to its results of operations. To the extent that the Company's customers continue to be materially and adversely impacted by the coronavirus outbreak, this could materially interrupt the Company's business operations.

As a result of these and other factors, we expect to continue to incur net losses in the intermediate term and may need to raise additional capital through equity and debt financings in order to fund our operations. Our operating results may fluctuate on a quarterly or annual basis in the future, and our growth or operating results may not be consistent with predictions made by securities analysts, if any. If we are unable to achieve our revenue growth objectives, we may not be able to achieve profitability.

**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 six months ended June 30, 2020, 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. 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 marketing, sales support, travel, legal services, financial audit fees, insurance costs, and consulting services. We expect to incur additional SG&A expenses in connection with our being a public company, which may increase further when we are no longer able to rely on the “emerging growth company” exemption we are afforded under the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

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 continue to increase in absolute dollars and as a percentage of revenue 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 investigational device exemption, or IDE, from the FDA in March 2018 to initiate a clinical trial and enrolled the first patient during the first half of 2018. In August 2019, we completed all patient surgeries for the IDE aesthetic cohorts, which include primary augmentation and revision. As of June 30, 2020, we successfully completed enrollment in the revision reconstruction sub-cohort and we are continuing to enroll subjects in the remaining reconstruction cohorts. Although we continue to activate trial sites and secure Institutional Review Board approvals, the COVID-19 pandemic has delayed enrollment in the reconstruction cohorts for our IDE clinical trial, which could add at least six months to our planned regulatory

timeline. We plan to enroll 800 patients in the study across 40 sites in the United States, Germany and Sweden. The results of the study are expected to support a pre-market approval, or PMA, submission to the FDA. We estimate that total costs for this IDE clinical trial will be between $30.0 million and $40.0 million over ten years. 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 June 30, 2020, we had $65.0 million in outstanding principal and accrued interest.

***Change in Fair Value of Derivative Instruments***

Change in fair value of derivative instruments consists of changes in the fair value of the put and call option liabilities associated with outstanding debt instruments.

***Change in Fair Value of Contingent Consideration***

Change in fair value of contingent consideration consists of changes in the fair value of contingent equity consideration related to past asset acquisitions.

***Other Expense, Net***

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

***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, we maintain a full valuation allowance for deferred tax assets including net operating loss carry-forwards, R&D tax credits, capitalized R&D and other book versus tax differences.

***Business Update Regarding COVID-19***

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and has materially and adversely affected our business. We continue to closely monitor developments related to the COVID-19 pandemic and our decisions will continue to be driven by the health and well-being of our employees, our distributor and plastic surgeon customers, and their patients while maintaining operations to support our customers and their patients in the near-term.

- *Surgery Deferrals:* From late March 2020 to mid-May 2020, among other impacts on our business related to the pandemic, plastic surgeons and their patients deferred surgical procedures in which our products otherwise could have been used. This decrease in demand for our products recovered to varying degrees in the latter half of May and into June 2020, though still below pre-pandemic levels, as certain geographies reopened after an initial improvement in COVID-19 infection rates and allowed plastic surgeons to resume providing procedures. However, a resurgence of infections has been observed, which may further restrict demand similar to early phases of the pandemic. As a result, we expect to see continued volatility through at least the duration of the pandemic as geographies respond to current local conditions. The duration of further deferrals of surgical procedures, the magnitude of such deferrals, the timing and extent of the economic impact of the pandemic, and the pace at which the economy recovers therefrom, cannot be determined at this time. We continue to work closely with our plastic surgeon customers, distributors and suppliers to navigate through this unforeseen event while maintaining flexible operations and investing for future growth.
- *Operations:* Our sales, marketing and research and development efforts have continued since the outbreak of the pandemic. However, the pandemic has adversely affected our business despite the steps taken to mitigate its impact. To protect the safety, health and well-being of our employees, distributor and plastic surgeon customers, and communities, we implemented preventative measures including travel restrictions and requiring all office-based employees to work from home, except for those related to manufacturing and select others, as permitted under governmental orders.

  Our manufacturing, distribution and supply chain has largely been uninterrupted, but could be disrupted as a result of the pandemic due to staffing shortages, production slowdowns, stoppages, or disruptions in delivery systems.

- *Cost Containment:* We continue to carefully manage expenses and cash spend to preserve liquidity and we initiated actions to generate savings in areas such as travel, events and consulting. Production at our manufacturing locations has been reduced based on our current forecasts and at the end of June 2020, we reduced our manufacturing headcount by approximately 70 positions.
- *First Half 2020 Results:* Given that the onset of COVID-19 occurred toward the end of the first quarter of 2020, our total revenue for the second quarter of 2020 was significantly lower compared to the same period in 2019.
- *Outlook:* At this time, the full extent of the impact of the COVID-19 pandemic on our business, financial condition and results of operations is uncertain and cannot be predicted with reasonable accuracy and will depend on future developments that are also uncertain and cannot be predicted with reasonable accuracy.

For additional information on the various risks posed by the COVID-19 pandemic on our business, financial condition and results of operations, please see Item 1A. Risk Factors in this report.

**Consolidated Results of Operations**

The following tables set forth our results of operations for the periods presented, in dollars:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (unaudited) (in thousands) | | | |
| Revenue | $ 10,474 | $ 21,684 | $ 34,955 | $ 42,462 |
| Cost of revenue | 3,240 | 8,672 | 12,243 | 18,198 |
| Gross profit | 7,234 | 13,012 | 22,712 | 24,264 |
| Operating expenses: | | | | |
| Sales, general and administrative | 14,438 | 18,394 | 33,422 | 34,450 |
| Research and development | 2,399 | 4,001 | 6,598 | 7,585 |
| Total operating expenses | 16,837 | 22,395 | 40,020 | 42,035 |
| Loss from operations | (9,603) | (9,383) | (17,308) | (17,771) |
| Interest expense | (2,130) | (2,521) | (4,276) | (4,763) |
| Change in fair value of derivative instruments | 1,492 | 2,640 | (437) | 2,608 |
| Change in fair value of contingent consideration | (141) | 137 | 299 | 362 |
| Other expense, net | 105 | 122 | (6,083) | (176) |
| Loss before income taxes | (10,277) | (9,005) | (27,805) | (19,740) |
| Provision for income taxes | (194) | (35) | (425) | (79) |
| Net loss | $ (10,471) | $ (9,040) | $ (28,230) | $ (19,819) |

**Comparison of Three Months Ended June 30, 2020 and 2019**

| | Three Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (unaudited) (in thousands) | |
| Revenue | $ 10,474 | $ 21,684 |
| Cost of revenue | 3,240 | 8,672 |
| Gross profit | $ 7,234 | $ 13,012 |
| Gross margin | 69.1 % | 60.0 % |

***Revenue***

Revenue decreased $11.2 million, or 51.7%, to $10.5 million for the three months ended June 30, 2020 as compared to $21.7 million for the three months ended June 30, 2019. The decrease was primarily due to the global COVID-19 pandemic as multiple geographies experienced a restriction of elective surgical procedures and a shut-down or slow-down in business activity deemed to be non-essential.

***Cost of Revenue and Gross Margin***

Cost of revenue decreased $5.4 million, or 62.6%, to $3.2 million for the three months ended June 30, 2020 compared to $8.7 million for the three months ended June 30, 2019. The decrease in cost of revenue is in line with the decrease in revenue due to COVID-19 pandemic.

Gross margin increased to 69.1% for the three months ended June 30, 2020 as compared to 60.0% for the three months ended June 30, 2019 due to the benefit of geographic mix, greater operating efficiencies, and enhanced manufacturing planning capabilities.

***Operating Expenses***

| | Three Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (unaudited) (in thousands) | |
| Operating expenses: | | |
| Sales, general and administrative | $ 14,438 | $ 18,394 |
| Research and development | 2,399 | 4,001 |
| Total operating expenses | $ 16,837 | $ 22,395 |

***Sales, General and Administrative Expense***

SG&A expense decreased $4.0 million, or 21.5%, to $14.4 million for the three months ended June 30, 2020, compared to $18.4 million for the three months ended June 30, 2019. The decrease in SG&A was primarily due to a $1.8 million decrease in consulting fees, a $1.0 million decrease in marketing expense, a $0.8 million decrease in sales commissions and a $0.6 million decrease in personnel and related costs. This decrease was partially offset by a $0.6 million increase in insurance and a $0.4 million increase in software costs. The decrease in SG&A expenses was primarily driven by the Company's efforts to cut costs given the projected loss of revenue due to the global COVID-19 pandemic.

***Research and Development Expense***

R&D expense decreased $1.6 million, or 40.0%, to $2.4 million for the three months ended June 30, 2020, compared to $4.0 million for the three months ended June 30, 2019 primarily due to a $1.2 million decrease in personnel costs and a $0.4 million decrease in expenditures related to our IDE clinical study in the United States. The decrease in R&D expenses was primarily driven by COVID-19 related delayed clinical trial enrollment and the Company's efforts to cut costs given the projected loss of revenue due to the global COVID-19 pandemic.

***Interest Expense***

Interest expense for the three months ended June 30, 2020 was $2.1 million as compared to $2.5 million for the three months ended June 30, 2019. The decrease was primarily due to a decrease in the contractual interest rate in the Madryn Credit Agreement, which was amended in June 2019.

***Change in Fair Value of Derivative Instruments***

Change in fair value of derivative instruments for the three months ended June 30, 2020 resulted in a gain of $1.5 million as compared to a gain of $2.6 million for the three months ended June 30, 2019. The change in fair value of derivative instruments was primarily due to changes in the fair value of Madryn derivatives embedded in the Madryn Credit Agreement we entered into in August 2017.

***Provision for Income Taxes***

Provision for income taxes increased $159,000, or 454.3%, to $194,000 for the three months ended June 30, 2020, compared to a benefit of $35,000 for the three months ended June 30, 2019. The change in the provision for income taxes is primarily due to increased pre-tax income in foreign jurisdictions.

***Other Expense, Net***

Other expense, net remained stable at $0.1 million for the three months ended June 30, 2020 and 2019.

**Comparison of the Six Months Ended June 30, 2020 and 2019**

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (unaudited) (in thousands) | |
| Revenue | $ 34,955 | $ 42,462 |
| Cost of revenue | 12,243 | 18,198 |
| Gross profit | $ 22,712 | $ 24,264 |
| Gross margin | 65.0 % | 57.1 % |

***Revenue***

Revenue decreased $7.5 million, or 17.7%, to $35.0 million for the six months ended June 30, 2020 as compared to $42.5 million for the six months ended June 30, 2019. The decrease was primarily due to the global COVID-19 pandemic as multiple geographies experienced a restriction on elective surgical procedures and a shut-down or slow down in business activity deemed to be non-essential.

***Cost of Revenue and Gross Margin***

Cost of revenue decreased $6.0 million, or 32.7%, to $12.2 million for the six months ended June 30, 2020 compared to $18.2 million for the six months ended June 30, 2019. The decrease in cost of revenue is in line with the decrease in revenue due to COVID-19 pandemic.

Gross margin increased to 65.0% for the six months ended June 30, 2020 compared to 57.1% for the six months ended June 30, 2019, primarily due to the benefit of geographic mix, greater operating efficiencies, and enhanced manufacturing planning capabilities.

***Operating Expenses***

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (unaudited) (in thousands) | |
| Operating expenses: | | |
| Sales, general and administrative | $ 33,422 | $ 34,450 |
| Research and development | 6,598 | 7,585 |
| Total operating expenses | $ 40,020 | $ 42,035 |

***Sales, General and Administrative Expense***

SG&A expense decreased $1.0 million, or 3.0%, to $33.4 million for the six months ended June 30, 2020, compared to $34.5 million for the six months ended June 30, 2019. The decrease in SG&A was primarily due to a $2.4 million decrease in consulting fees, a $0.8 million decrease in commissions and a $0.7 million decrease in marketing expenses, partially offset by a $1.2 million increase in insurance, a $0.8 million increase in software, and a $0.8 million increase in personnel and related costs.

***Research and Development Expense***

R&D expense decreased $1.0 million, or 13.0%, to $6.6 million for the six months ended June 30, 2020, compared to $7.6 million for the six months ended June 30, 2019. The decrease in R&D expense was primarily due to a $1.2 million decrease in personnel cost, COVID-19 related delayed IDE clinical trial enrollment and the Company's efforts to cut costs given the projected loss of revenue due to the global COVID-19 pandemic, and was partially offset by a $0.1 million increase in expenditures related to our IDE clinical trial in the United States, primarily consisting of fees to third parties to manage the clinical trial. The decrease in R&D expenses was primarily driven by COVID-19 related delayed clinical trial enrollment and the Company's efforts to cut costs given the projected loss of revenue due to the global COVID-19 pandemic.

***Interest Expense***

Interest expense decreased to $4.3 million for the six months ended June 30, 2020 compared to $4.8 million for the six months ended June 30, 2019. The decrease was primarily due to a decrease in the contractual interest rate in the Madryn Credit Agreement, which was amended in June 2019.

***Change in Fair Value of Derivative Instruments***

Change in fair value of derivative instruments for the six months ended June 30, 2020 resulted in a loss of $0.4 million, compared to a gain of $2.6 million for the six months ended June 30, 2019. The change in fair value of derivative instruments was due to changes in the fair value of Madryn derivatives embedded in the Madryn Credit Agreement we entered into in August 2017.

***Change in Fair Value of Contingent Consideration***

Change in the fair value of contingent consideration for the six months ended June 30, 2020 resulted in a gain of $0.3 million, compared to a gain of $0.4 million for the six months ended June 30, 2019. The change in fair value of contingent consideration was due to changes in our stock price at reporting period-end and the number of remaining contingently-issuable shares.

***Provision for Income Taxes***

Provision for income taxes increased $346,000, or 438.0%, to $425,000 for the six months ended June 30, 2020, compared to $79,000 for the six months ended June 30, 2019. The change in the provision for income taxes is primarily due to increased pre-tax income in foreign jurisdictions.

***Other Expense, Net***

Other expense, net increased $5.9 million to $6.1 million for the six months ended June 30, 2020, compared to $0.2 million for the six months ended June 30, 2019. The increase was primarily due to the weakening of Brazilian real as compared to the U.S. dollar in fiscal 2020 resulting in a foreign currency transaction loss of $5.8 million as of June 30, 2020, compared to $0.3 million for the six months ended June 30, 2019.

**Liquidity and Capital Resources**

As of June 30, 2020, we had an accumulated deficit of $155.4 million. Since our inception, we have generated losses and expect to continue to generate losses in the intermediate term. We have financed our operations through a combination of private 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 and other working capital needs. As of June 30, 2020 and December 31, 2019, we had cash of $86.4 million and $37.7 million, respectively.

On February 3, 2020, the Company completed a public follow-on offering and received net proceeds of $63.9 million, after deducting underwriting discounts and expenses. During the six months ended June 30, 2020, the Company also received $0.4 million from the exercise of stock options.

The global economy continues to be impacted by the COVID-19 pandemic, the ultimate extent and duration of which is not presently known, and our liquidity may be negatively impacted. As a result, we have taken significant actions to minimize the operational and financial impacts of the COVID-19 pandemic, including adjusting our cost structure, reducing discretionary capital and operating expenditures and improving working capital management in order to preserve our financial flexibility and liquidity position. We believe that our available cash, cash from operations, and the additional borrowing will be sufficient to satisfy our liquidity requirements for at least the next twelve months from the date of the issuance of the financial statements, inclusive of the impacts of COVID-19. 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 to obtain 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. 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 following table sets forth the primary sources and uses of cash for each of the periods presented below:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (unaudited) (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (12,897) | $ (15,061) |
| Investing activities | (2,282) | (5,666) |
| Financing activities | 64,042 | (42) |
| Effect of exchange rate changes on cash | (136) | — |
| Net (decrease) increase in cash | $ 48,727 | $ (20,769) |

*Net Cash Used in Operating Activities*

Net cash used in operating activities of $12.9 million for the six months ended June 30, 2020 was comprised of a net loss of $28.2 million partially offset by $5.6 million of unrealized foreign currency loss, a $0.4 million change in fair value of financial instruments, $3.2 million of share-based compensation expense, a $0.6 million change in provision for inventory obsolescence, $1.6 million of non-cash depreciation expense, a $1.0 million change in provision for doubtful accounts, and $0.8 million of non-cash interest expense due to accretion of debt discounts, as well as changes in operating assets and liabilities of $2.3 million.

Net cash used in operating activities of $15.1 million for the six months ended June 30, 2019 was comprised of a net loss of $19.8 million and a $2.6 million change in fair value of financial instruments, partially offset by $1.4 million of non-cash depreciation expense, $3.7 million of share-based compensation expense, and $1.7 million of non-cash interest expense due to accretion of debt discounts, as well as changes in operating assets and liabilities of $0.8 million.

*Net Cash Used in Investing Activities*

Net cash used in investing activities of $2.3 million for the six months ended June 30, 2020 primarily consisted of $1.3 million in purchases of property and equipment, $0.5 million of cash paid for past asset acquisitions and $0.5 million of purchases of intangibles.

Net cash used in investing activities of $5.7 million for the six months ended June 30, 2019 primarily consisted of $4.9 million in purchases of property and equipment including $3.2 million to purchase our manufacturing facility in Costa Rica and $0.8 million of cash used in an asset acquisition.

*Net Cash Provided by (Used in) Financing Activities*

Net cash provided by financing activities of $64.0 million for the six months ended June 30, 2020 primarily reflected $63.9 million in proceeds received from the issuance of common shares in the follow-on public offering, net of underwriters' discount and issuance costs, $0.4 million in proceeds received for stock option exercises, which were partially offset by $0.1 million in repayment of capital leases and a $48,000 tax payment related to shares withheld upon vesting of restricted stock.

Net cash used in financing activities of $42,000 for the six months ended June 30, 2019 primarily reflected $176,000 in proceeds received for stock option exercises and $58,000 for warrant exercises, which were offset by $185,000 in repayment on capital leases and a $91,000 tax payment related to shares withheld upon vesting of restricted stock.

**Indebtedness**

***Madryn Debt***

On August 24, 2017, the Company entered into a credit agreement, or the Madryn Credit Agreement, with Madryn Health Partners, LP, or Madryn, as administrative agent, and a syndicate of lenders. On June 17, 2019, the Madryn Credit Agreement was amended to lower the interest rate on the outstanding debt facilities, provide for $25.0 million of new term loan commitments, decrease the amount of the prepayment penalties, remove all principal payments and extend the maturity date and repayment from September 30, 2023 to September 30, 2025. The Madryn Credit Agreement, as amended, provides for a term loan in a maximum principal amount of $65.0 million, $30.0 million (Term A) of which became available upon signing and was subsequently borrowed by the Company.

Prior to amending the Madryn Credit Agreement on June 17, 2019, the Company's ability to borrow the remaining term loans under the Madryn Credit Agreement was subject to the Company achieving certain revenue milestones. The Company met milestones sufficient to borrow and borrowed an additional $5.0 million (Term B-1) on October 31, 2017 and $5.0 million (Term B-2) on December 15, 2017, increasing the total outstanding principal balance to $40.0 million as of December 31, 2017.

Pursuant to the June 2019 amendment, the Company became eligible to borrow an additional $10.0 million (Term B-3) and $15.0 million (Term B-4) on or before September 30, 2019 and December 31, 2019, respectively. The Company had an outstanding principal balance of $65.0 million as of June 30, 2020.

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.

The Madryn Credit Agreement contains customary affirmative and negative covenants, including, but not limited to, restrictions on the ability of the Company and its subsidiaries to incur additional indebtedness, create liens, make certain investments, make restricted payments, enter into or undertake certain liquidations, mergers, consolidations or acquisitions and dispose of assets or subsidiaries. In addition, the Madryn Credit Agreement requires the Company to maintain minimum revenues and liquidity.

The Company has estimated the negative impact of COVID-19 on its financial position, results of operations and cash flows, and believes it will continue to maintain compliance with these covenants. However, due to the inherent uncertainty of COVID-19 on the Company's business, the Company's estimates of compliance with these covenants could change in the future.

The Company also determined that the Madryn Credit Agreement contained put options which are 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 were 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 August 2019. The Company revalues the embedded derivatives as of each reporting period and records the change in the fair value in the consolidated statement of operations as other income or expense (see Note 5). The Company also incurred legal expenses of $1.3 million the third quarter of fiscal 2017 and $0.3 million in August 2019, which were recorded as a debt discount and are being amortized over the term of the Madryn Credit Agreement.

**Contractual Obligations and Commitments**

Our contractual obligations have not changed materially from those included in the Form 10-K filed with the SEC on March 16, 2020.

**Off-Balance Sheet Arrangements**

As of June 30, 2020 and December 31, 2019, we did not have any off-balance sheet arrangements.

**JOBS Act Accounting Election**

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We intend to take advantage of certain exemptions from various public company reporting requirements including following private company effective dates for new or revised accounting standards.

**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 accounting principles generally accepted 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.

We identified certain critical accounting policies that affect certain of our more significant estimates and assumptions used in preparing our consolidated financial statements in the Form 10-K filed with the SEC on March 16, 2020. We have not made any material changes to these policies as previously disclosed in the Form 10-K.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, operational expenses, manufacturing, research and development costs, IDE clinical trial enrollment and related costs, and employee-related compensation, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the

impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates.

**Recent Accounting Pronouncements**

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

## ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

**Interest Rate Risk**

We had cash of $86.4 million and $37.7 million as of June 30, 2020 and December 31, 2019, 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 six months ended June 30, 2020, foreign currency transaction loss amounted to $5.8 million primarily related to the remeasurement of transactions denominated in the U.S. dollar into the Brazilian real as part of the financial reporting consolidation process under GAAP. The Brazilian real has been experiencing a weakening since December 31, 2017 as compared to the U.S. dollar which recently has been exacerbated by the current economic impact of the global COVID-19 pandemic. 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, 2019, the effect of an immediate 10% adverse change in foreign exchange rates on foreign-denominated accounts as of December 31, 2019 would have had an impact of approximately 10.7% 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 4. CONTROLS AND PROCEDURES

**Evaluation of disclosure controls and procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this quarterly report. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) 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 due to a material weakness in internal control over financial reporting, our disclosure controls and procedures were not effective as of the end of the period covered by this quarterly report at the reasonable assurance level.

**Material Weakness in Internal Control over Financial Reporting**

We disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, that the following material weakness in our internal control over financial reporting existed as of December 31, 2019: a lack of adequate review over the manual consolidation process, resulting in an audit adjustment, or the Material Weakness.

**Changes in Internal Control over Financial Reporting**

Other than with respect to the remediation efforts discussed below, there was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Although we have altered some work routines due to the COVID-19 pandemic, the changes in our work environment, including remote work arrangements, have not materially impacted our internal controls over financial reporting and have not adversely affected the Company's ability to maintain operations.

**Plan for Remediation of the Material Weakness**

We have implemented and are continuing to implement a number of measures to address the Material Weakness identified as of December 31, 2019. 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 a third-party consulting firm to assist us with the implementation of SAP, which is a global information technology solution designed to address, among other items, the elements which gave rise to the Material Weakness. We will continue to implement additional measures to address the Material Weakness.

**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.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings, but from time-to-time may become involved in legal proceedings arising in the ordinary course of our business activities.

### ITEM 1A. RISK FACTORS

*Investing in our common shares involves a high degree of risk. 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 Quarterly Report on Form 10-Q, 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.*

#### Risk Related to COVID-19

***The COVID-19 pandemic has, and may for the foreseeable future, materially and adversely affected our business and our financial results.***

The COVID-19 pandemic has materially and adversely impacted our business and we expect the impact to continue through at least the duration of the pandemic as regions respond to local conditions. To date, the impact includes:

- the deferral of procedures using our products;
- 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; and
- temporary closures of our facilities and of the facilities of our customers and suppliers.

As jurisdictions throughout the world continue to respond to the pandemic, the degree of the foregoing impacts may increase in scope or magnitude or we may experience additional adverse effects in one or more regions. Any other outbreaks of contagious diseases or other adverse public health developments in countries where we operate or where our customers or suppliers are located could also have a material and adverse effect on our business, financial condition and results of operations.

Due to the COVID-19 pandemic, surgeons and their patients have been, and in certain regions continue to be, required, or are choosing, to defer elective procedures in which our products otherwise could be used, and many facilities that specialize in the procedures in which our products otherwise could be used have temporarily closed and in some cases continue to be temporarily closed or operating at reduced hours. In addition, even after the pandemic subsides or governmental orders no longer prohibit or recommend against performing such procedures, patients may continue to defer such procedures due to personal concerns. Further, facilities at which our products typically are used may not reopen or, even if they reopen, patients may elect to have procedures performed at facilities that are, or are perceived to be, lower-risk, such as private surgery centers, and our products may not be approved at such facilities, and we may be unable to have our products approved for use at such facilities on a timely basis, or at all. The effect of the pandemic on the broader economy could also negatively affect demand for elective procedures using our products, both in the near- and long-term.

Workforce limitations and travel restrictions resulting from government actions taken to contain the spread of COVID-19 have and will continue to adversely affect almost every aspect of our business. If a significant percentage of our workforce, or of the workforce of third parties on which we rely, cannot work, including because of illness or travel or government restrictions, our operations will be negatively affected. Because of government restrictions and social distancing guidelines in many countries around the world, there is an increased reliance on working from home for our workforce and on the workforce of third parties on which we rely. For example, most of our sales personnel and third party agents currently are working largely using virtual and online engagement tools and tactics, which may be less effective than our typical in-person sales and marketing programs. In addition, we reduced access to our hands-on surgeon trainings, which, in turn, adversely impacted our ability to educate and

train surgeons on the proper use of our products, which may make surgeons less comfortable using, and therefore less likely to use, our products. We expect that “stay-at-home” orders will also limit our ability to develop, and therefore launch, the products we believe will drive our future revenue growth on the timelines we anticipated previously, or at all, and could also delay the planned launch of products in 2021 and beyond. It may also cause us not to submit required filings on our previous time tables, including with the FDA, or other regulatory bodies, both in the U.S. and outside the U.S. The continued spread of COVID-19 has adversely impacted our IDE clinical trial operations in the United States, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, have heightened exposure to COVID-19. In addition, changes impacting workforce function at the FDA and other regulatory bodies, as well as changes impacting workforce function at the facilities at which we seek to have new products approved for use, could adversely impact the timing of when our new products are cleared for marketing and approved for use, either of which would adversely impact the timing of our ability to sell these new products and would have a material and adverse effect on our revenue growth.

Further, disruptions in the manufacture and distribution of our products or in our supply chain may occur as a result of the COVID-19 pandemic, including for the reasons above, or other events that result in staffing shortages, production slowdowns, stoppages, or disruptions in delivery systems, any of which could materially and adversely affect our ability to manufacture or distribute our products, or to obtain the raw materials and supplies necessary to manufacture and distribute our products, in a timely manner, or at all.

We may also experience other unknown adverse impacts from COVID-19 that cannot be predicted. For example, hospitals and other facilities at which we sell our products may renegotiate their purchase prices, including as a result of, or the perception that they may be suffering, financial difficulty as a result of the pandemic. Similarly, facilities at which we seek to sell our products in the future may require price reductions relative to the price at which we previously expected to sell our products. Reduction in the prices at which we sell products to existing customers may have a material and adverse effect on our future financial results and reductions in the prices at which we expected to sell products would have a material and adverse effect on our expectations for revenue growth.

Further, the global capital markets experienced, and we expect will continue to experience, disruption and volatility due to the COVID-19 pandemic, adversely impacting access to capital not only for us, but also for our customers and suppliers who need access to capital. Their inability to access capital in a timely manner, or at all, could adversely impact demand for our products and/or adversely impact our ability to manufacture or supply our products, any of which could have a material and adverse effect on our business.

The full extent to which the COVID-19 pandemic will, 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 currently highly uncertain and cannot be predicted with reasonable accuracy at this time and will depend on future developments that are also highly uncertain and cannot be predicted with reasonable accuracy at this time, including, without limitation:

- new information that may emerge concerning COVID-19, its contagiousness or virulence;
- resurgences in COVID-19 transmission and infection following the easing or lifting of “stay-at-home” or other restrictions or following resumption of surgical procedures, whether as a result thereof, as a result of reinfection, as a result of a delay in the emergence of symptoms following infection (or reinfection) by COVID-19, or as a result of COVID-19’s ability to lay dormant following infection (or reinfection), and the adverse impact the foregoing may have on our business and financial condition, including because of the adverse impact on patients’ willingness to undergo procedures in which our products could be used;
- actions required or recommended to contain or treat COVID-19, in light of any or all of the foregoing or other as-yet unanticipated developments, whether related to COVID-19 directly or indirectly; and
- the direct and indirect economic impact, both domestically and abroad, of the COVID-19 pandemic 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global financial crisis caused extreme volatility and disruptions in the capital and credit markets. 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 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. A weak or declining 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.

## Risks Related to the Development and Commercialization of Our Products

***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, which accounted for approximately 94% and 92% of our revenues for the years ended December 31, 2019 and 2018, respectively, and we expect our revenues to continue to be driven primarily by sales of these products.***

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 94% and 92% of our revenues for the years ended December 31, 2019 and December 31, 2018, respectively, 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, including our ongoing IDE clinical trial, 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 Anaplasic Large Cell Lymphoma, or BIA-ALCL.

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.

***There is no guarantee that the FDA or non-U.S. regulatory agencies will grant approval for our current or future products, and failure to obtain regulatory approvals in the United States and other international jurisdictions, or revocation of approvals in those jurisdictions, will prevent us from marketing our products.***

We intend to seek additional distribution and marketing partners for Motiva Implants and may market specific products only in international markets. We have obtained a CE Mark for Motiva Implants and are therefore authorized to sell in the EU; however, in order to market in regions such as the Asia Pacific region and many other jurisdictions, we must obtain separate regulatory approvals. 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 or FDA approval. 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.

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 efficacy 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. In connection with the initiation of a clinical study in the United States, we filed an IDE application in 2017, which was approved in March 2018 and our first patient was enrolled in April 2018. Our ongoing U.S. IDE trial may take longer to enroll than anticipated, 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.

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.

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, FDA has authority to impose postmarket approval conditions, which can include (i) restrictions on device's sale, distribution, or use, (ii) continuing evaluation of the device's safety and efficacy, (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 this 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 over one 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.

***Negative publicity, product defects and any resulting litigation concerning our products or our competitors' products could harm our reputation and reduce demand for silicone breast implants, either of which could negatively impact our financial results.***

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 products liability litigation against us or our competitors, could result in negative publicity and could materially reduce market acceptance of our products. These responses or any investigations and potential resulting negative publicity may have a material adverse effect on our business and reputation and negatively impact our financial condition, results of operations or the market price of our common shares. In addition, significant negative publicity could result in an increased number of product liability claims against us.

***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 and 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.

Furthermore, our sales force may operate independently with limited day-to-day oversight from management. They may engage in sales practices that increase certain risks to our business, including the risk of scrutiny from regulatory authorities and the risk that we violate health care or anti-corruption regulations in one or more countries. These and other independent actions may result in unexpected costs, publicity that might impair our reputation or revenues, litigation in various jurisdictions, and/or sanctions. Any of these could impair the trading price of our shares and adversely impact our results.

***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.

***If we are unable to train plastic surgeons on the safe, effective and appropriate use of our products and designed surgeries, we may be unable to achieve our expected growth.***

An important part of our sales process includes educating plastic surgeons about the benefits and advantages of our Motiva Implants and MotivaImagine products as well as training them on the safe and appropriate use of our products. As part of our effort to educate and train plastic surgeons through our MotivaEDGE educational platform, we completed 244 and 51 in-person medical training sessions worldwide during 2019 and 2018, respectively. If we are unable to train potential new plastic surgeon customers at these medical training sessions, we may be unable to achieve our expected growth. Although since the outbreak of the global COVID-19 pandemic we have offered virtual training sessions through our MotivaEDGE platform, the limited ability to train surgeons in-person may harm our ability to properly train surgeons on our products.
It is critical to the success of our commercialization efforts to train a sufficient number of plastic surgeons and provide them with adequate instructions in the appropriate use of our products and designed surgeries. This training process may take longer than expected and may therefore affect our ability to grow our business. Following completion of training, we rely on the trained plastic surgeons to advocate for our products and designed surgeries in the marketplace. Convincing plastic surgeons to dedicate the time and focus necessary for adequate training is challenging, and we cannot provide any assurances that we will be successful in these efforts. If plastic surgeons are not properly trained, they may misuse or ineffectively use our products or designed surgeries. This may also result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business and reputation.

In addition, we need to ensure that plastic surgeons are sufficiently educated regarding our implants. For example, many metal implants, such as screws or artificial joints, produce an artifact when magnetic resonance imaging, or MRI, is used to image the area in which the object resides. Our QInside 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 QInside microtransponder. If we fail to educate physicians and patients about any of these factors, they may make decisions regarding Motiva Implants without full knowledge of the risks and benefits or may view our Motiva Implants negatively.

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

Our Motiva Implants have been marketed 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, 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.

***Motiva Implants are not currently approved for commercial sale in the United States. Obtaining such approval is costly and time consuming, and we may not obtain the regulatory approval required to sell our products in the United States.***

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. In the EU and other countries, we previously obtained a CE Mark, before making Motiva Implants available for commercial sale. FDA guidance on silicone breast implants mandates approval via the PMA process. Extensive preclinical and clinical testing will be required to support the PMA. At least one well-controlled clinical trial is required for approval, such as the one we began in April 2018, which will require us to commit significant financial and personnel resources. 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, 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. The FDA approval process will take at least several years to complete, and FDA approval may never be obtained. 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.

Furthermore, FDA regulatory approval is not a guarantee, 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. 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 or our 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.

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.

Moreover, obtaining regulatory approval for marketing of our products in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

***Even if clinical trials demonstrate acceptable safety and efficacy for Motiva Implants in some patient populations, the FDA or similar regulatory authorities outside the United States may not approve the marketing of Motiva Implants or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

It is possible 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, the approval may include additional restrictions on the label that could make Motiva Implants less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of Motiva Implants.

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

***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 payors 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.

***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.

***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. 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 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.

***If changes in the economy and/or consumer spending, consumer preference and other trends reduce consumer demand for our products, our sales and profitability would suffer.***

We are subject to the risks arising from adverse changes in general economic and market conditions. Certain elective procedures, including breast augmentation, are typically not covered by insurance. Adverse changes in the economy may cause consumers to reassess their spending choices, which could have an adverse effect on consumer spending, reduce the demand for these surgeries, and therefore have an adverse effect on our revenues. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products.

***We have made multiple acquisitions in the past, and in the future we may acquire other businesses or 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 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 $25.0 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.

***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 MotivaImagine platform, including the Divina 3D simulation system, and other products and services. We expect our research and development expenses to increase significantly in 2020 and beyond, as we continue with our IDE clinical trial in the United States. We will also incur 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 MotivaImagine products outside the United States and Canada.

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 loss of key members of our executive management team could adversely affect our business.***

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Juan José Chacón Quirós, our Chief Executive Officer, Salvador Dada, our Chief Operating Officer, Roberto de Mezerville, our Chief Technology Officer, Eddie de Oliveira, our Chief Commercial Officer and Renee M. Gaeta, our Chief Financial 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. As a result of the difficulty in locating qualified new management, 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 of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. We do not have "key person" life insurance on our senior executives, and the loss of any of the key members of our team would have a negative impact to our business and financial results.

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.

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

***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 disclosure of protected health information. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to health care providers and other covered entities, collectively referred to as business associates. 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, 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 applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR can trigger steep fines 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 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.

***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 more than 80 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, 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;
- 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.

***If we are not able to satisfy data protection, security, privacy, and other government- and industry-specific requirements, our business could be harmed.***

There are a number of data protection, security, privacy and other government- and industry-specific requirements, including those that require companies to notify individuals of data security incidents involving certain types of personal data. Security compromises experienced by other companies, by our customers or by us may lead to public disclosures, which could harm our reputation, erode customer confidence in the effectiveness of our security measures, negatively impact our other products and our ability to attract new customers. As we expand into new regions, we will need to comply with new requirements. If we cannot comply or if we incur a violation in one or more of these requirements, our growth could be adversely impacted, and we could incur significant liability.

***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.

***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 new, larger manufacturing facility, in combination with our first facility, will give us adequate manufacturing capacity to meet demand for at least the next two years, we have, in the past, been unable to fill all incoming orders to meet growing demand. 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.

***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 have recently become 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.

***Legal proceedings may significantly harm our business.***

From time to time, we may become involved in litigation or other proceedings in the ordinary course of business. It is possible that such litigation or proceedings may significantly harm our future results of operations or financial condition due to expenses we may incur to defend ourselves or the ramifications of an adverse decision.

For instance, on June 18, 2020, our and Puregraft LLC's relationship terminated under the Exclusive Distribution Agreement by and between us, Puregraft LLC and its parent Bimini Technologies, LLC, dated September 7, 2016 (as amended, the "Distribution Agreement"). Pursuant to the Distribution Agreement, we were the exclusive distributor, outside the United States and Canada, of the Puregraft line of products for autologous adipose tissue harvesting and redistribution. We and Puregraft remain in discussions regarding the terms of the termination of the Distribution Agreement; however, if the discussions fail to resolve all outstanding matters, we may become subject to legal proceedings and be unable to sell our current inventory of Puregraft products. As of June 30, 2020, we had $2.2 million of Puregraft products in inventory.

## Risks Related to the Operation of Our Business

***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 Divina scanners are manufactured by contract manufacturers from components sourced globally, with final assembly in Alajuela, Costa Rica. Our QInside 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 Divina scanners and QInside 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 NuSil Technology, LLC, or NuSil, 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 below 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.

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

As of June 30, 2020, we had 487 employees. Unless it is necessary for us to continue to make reductions to our workforce as a cost management strategy due to the impact of the global COVID-19 pandemic on our business, over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of manufacturing, regulatory affairs, clinical and sales and marketing. 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:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- 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.

***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 get 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. 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.

***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 NuSil, 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.

***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.

***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, 2019, the majority of our revenues are denominated in currencies other than the U.S. dollar - primarily the British pound, the euro, and the Brazilian real. As of December 31, 2019, 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 could 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, and the Brazilian real will affect our revenues, operating income and 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. 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 may be 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.

***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.

***The results of the Referendum of the United Kingdom's Membership of the European Union may adversely affect our business and profitability.***

In June 2016, a referendum was held in the U.K. which resulted in a majority voting in favor of the U.K. withdrawing from the E.U. (commonly referred to as "Brexit"). Pursuant to legislation approved by the U.K. Parliament and the E.U. Parliament in January 2020, the U.K. withdrew from the E.U. with effect from 11 p.m. (GMT) on January 31, 2020 on the terms of a withdrawal agreement agreed between the U.K. and the E.U. in October 2019 (the "Withdrawal Agreement"). The Withdrawal Agreement provides that the U.K.'s withdrawal is followed by a "transition period", during which, in summary, the U.K. is not a member of the E.U. but most E.U. rules and regulations continue to apply to the U.K. During the transition period, the U.K. and the E.U. will seek to negotiate the terms of a long-term trading relationship between the U.K. and the E.U. based on a "Political Declaration" agreed between the U.K. and the E.U. in October 2019. The transition period provided for in the Withdrawal Agreement will expire on December 31, 2020 (unless both the U.K. and the E.U. agree to extend the period of transition by one or two years). The political negotiation surrounding the terms of the U.K.'s withdrawal from the E.U. has created significant uncertainty about the future relationship between the U.K. and the E.U., including with respect to the laws and regulations that will apply. This is because, once the "transition period" expires then, subject to the terms of any long-term trading relationship agreed between the U.K. and the E.U., the U.K. will determine which E.U.-derived laws to replace or replicate. The U.K.'s withdrawal from the E.U. has also given rise to calls for the governments of other E.U. member states to consider withdrawal, while the U.K.'s withdrawal negotiation process has increased the risk of the possibility of a further referendum concerning Scotland's independence from the rest of the U.K. If no long-term trading relationship is agreed between the U.K. and the E.U. by the end of the transition period provided for in the Withdrawal Agreement, the U.K.'s membership of the E.U. could ultimately terminate under a so-called "hard Brexit". Under this scenario, there could be increased costs from the imposition of tariffs on trade or non-tariff barriers between the U.K. and E.U., shipping delays because of the need for customs inspections and temporary shortages of certain goods.

These developments, or the perception that any of them could occur, may adversely affect European and worldwide economic and market conditions, significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets and could contribute to instability in global financial and foreign exchange markets, including increased volatility in interest rates and foreign exchange rates. The potential impacts could adversely impact other global economies, and in particular, the European economy, a region which accounted for approximately 40% of our total revenues for the year ended December 31, 2019. In the first quarter of 2019, we completed the migration of our CE Mark certificates, originally issued by BSI UK Notified Body, to BSI Group The Netherlands B.V., which is a European Notified Body designated in The Netherlands. We continue to actively monitor the ongoing potential impacts of Brexit and will seek to minimize its impact on our business through review of our existing regulatory requirements, contractual arrangements and obligations, particularly in the European region. Any of these effects of Brexit, among others, could adversely affect our business, business opportunities, results of operations, financial condition and cash flows.

***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.

## Risks Related to Our Financial Condition and Capital Requirements

***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 2020, 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 June 30, 2020, we had an accumulated deficit of $155.4 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 MotivaImagine 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.

***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, cash from operations, and the net proceeds from the follow-on public offering we completed in February 2020 will be sufficient to satisfy our liquidity requirements for at least the next 12 months. If our available cash resources, net proceeds from our follow-on public offering 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 Madryn Credit Agreement which restrict our ability to incur additional debt. Any failure to raise the funds necessary to support our operations 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.

## Risks Related to Our Business and Our Industry

***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 NuSil, 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, NuSil 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. NuSil supplies our major competitors with raw material as well, and at least two of these are larger-volume customers of NuSil than we are.

If NuSil 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.

Our current supply agreement with NuSil expires in December 2021. There can be no assurance that NuSil will agree to continue to supply us with medical-grade silicone following the expiration of our contract on terms that are acceptable to us, or at all. This would have a material adverse effect on our business, financial condition, and results of operations for the reasons set forth above.

In addition, our relationship with NuSil 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;
- NuSil may wish to discontinue supply of products to us due to its existing relationships with our competitors;
- NuSil may stop supply and claim ownership of intellectual property on materials associated with future products; and
- NuSil 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.

***Negative publicity concerning our products or our competitors' products could harm our reputation and reduce demand for silicone breast implants, either of which could 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. Any of these could reduce patient demand for our products, or could, even in the absence of a change in demand, negatively impact our share price. 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 (BIA-ALCL) 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 may lead to a reduction in the demand for silicone breast implants and could adversely affect our business.***

Breast implants have been associated with higher rates, as compared to the general population, of 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 ALCL 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 total medical device reports regarding BIA-ALCL cases since 2010. Of the 660 reports, the FDA's analysis suggested that there are 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 FDA announcement, it 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 June 2020, the FDA released draft 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.

We do not produce the types of rough textured implants that have been involved in these reports. To date, no cases of BIA-ALCL 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 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.

### Risks Related to Intellectual Property

***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 so 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.

***Our internal computer systems, or those used by third parties which we rely on, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems, or those used by third parties which we rely on, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material 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. 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our current and future products could be delayed.

***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, to market, to 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 Quarterly Report on Form 10-Q 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.

### Risks Related to Government Regulation

***The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of Motiva Implants or our planned products.***

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 more than 80 countries, but we are not permitted to market our planned products in the United States until we receive the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for Motiva Implants or any planned products in the United States. Obtaining PMA approval for sale of a medical device from the FDA can be a lengthy, expensive and uncertain process. In addition, 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.

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. 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. 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.

If Motiva Implants or any planned products fail to demonstrate safety and efficacy in preclinical and clinical studies or do not gain regulatory approval, our business and results of operations will be harmed.

***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 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 efficacy of the approved product. 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 reporting, storage, advertising, promotion and recordkeeping for our products. In addition, we are 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 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 QSR regulations. If we or a third-party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

***If we fail to comply with health care regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.***

Certain federal and state health care laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we are approved by the FDA to market our products in the United States, we could be subject to health care fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral. Unlike the federal Anti-Kickback Statute, the Stark Law is a strict liability statute, meaning that all of the requirements of a Stark Law exception must be met in order to be compliant with the law;
- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- HIPAA, which prohibits, executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- the federal transparency requirements under the PPACA which requires certain manufacturers of drugs, devices, biologics and medical supplies to annual report to the HHS information related to physician payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic health care transactions and protects the security and privacy of protected health information;
- state law equivalents of each of the above federal laws, such as anti-kickback, transparency and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as state post-marketing compliance laws; and
- state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The PPACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Similar regulations would also apply to our business in countries where we have started direct sales operations, like Brazil and several others within the European Union, where they have different regulations at European and national levels. There is a high degree of complication in complying with the different levels of regulation and the singular differences in the different countries and markets.

If 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, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and

other federal healthcare programs, individual imprisonment, additional reporting and government oversight, if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. Any such penalties or curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. 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 federal, state or international privacy, security and fraud laws may prove costly.

We have obtained the authorization to distribute our products in regions/countries such as Europe and Brazil through the certification of our Quality System by the corresponding regulatory entities. Failing to demonstrate that our Quality System is in place, that consistently and systematically ensures compliance with regulations from such regions/countries might imply losing the certifications and as such, the rights to freely distribute the products which would adversely impact the Company's revenue and reputation.

***Health care reform measures could hinder or prevent our planned products' commercial success.***

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, as amended by the Health Care and Education Reconciliation 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.

Some provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, we expect there will be additional challenges and amendments to the PPACA in the future as new administrations and politicians are elected. Since January 2017, two executive orders have been signed and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal and replace all or part of the PPACA. While Congress has previously been successful at passing comprehensive repeal legislation through both Chambers of Congress, it had then been vetoed by former President Obama; however full repeal legislation is unlikely in the current political climate. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision that would repeal one of the primary pillars of the law, the PPACA's individual mandate penalty that essentially assessed a monetary penalty or fine 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. Furthermore, legislators continue efforts to repeal and replace other elements of the PPACA. While the result of these efforts is not yet known, any changes that result in price controls reduce access to and reimbursement for care or add additional regulations may have an adverse effect on our financial condition and results of operations.

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, which, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. We cannot predict whether any additional legislative changes will affect our business.

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 payors 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.

## Risks Related to Ownership of Our Securities

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

Our common shares have only recently become publicly traded, and we expect that the price of our common shares will likely 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 the Nasdaq Capital Market, if we fail to satisfy the continued listing standards, we could be de-listed, 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;
- 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.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our common share price and trading volume could decline.***

The trading market for our common shares will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common shares would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause our share price and trading volume to decline.

***We have identified a material weakness in our internal control over financial reporting as of December 31, 2019 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 remedy our material weakness, or 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.

In connection with the preparation and audit of our 2019 financial statements, we had one material weakness. It was determined that we did not perform an adequate review over the manual consolidation process, resulting in audit adjustments. We have implemented and are continuing to implement a number of measures to address the material weakness; however, there is no guarantee that we will be able to remediate the material weakness on a timely basis, or at all.

If our remedial measures are insufficient to address the material weakness, or 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. While we have implemented a plan to remediate this material weakness, we cannot assure you that we will be able to remediate it, which could impair our ability to accurately and timely report our consolidated financial position, results of operations, or cash flows. Our failure to remediate the material weakness identified above or 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. Moreover, our failure to remediate the material weakness identified above or the identification of additional material weaknesses, could 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.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in the price of our ordinary shares, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources from our business.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of Nasdaq. The expenses that will be required in order to adequately prepare for being a public company will be material, and compliance with the various reporting and other requirements applicable to public companies will require considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our Board of Directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our second annual report on Form 10-K. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company or a smaller reporting company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our shares could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We 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. This, in turn, could have an adverse impact on trading prices for our common shares, and could adversely affect our ability to access the capital markets.

***Our directors and principal shareholders continue to maintain the ability to control or significantly influence all matters submitted to shareholders for approval.***

As of June 30, 2020, our executive officers, directors and shareholders who own more than 5% of our outstanding common shares, in the aggregate, assuming the exercise of all options held by such persons, beneficially owned shares representing approximately 36.1% of our common shares. As a result, if these shareholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our

shareholders for approval, as well as our management and affairs. For example, these shareholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other shareholders may desire.

***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. However, there can be no assurance that we will continue to qualify for or receive such favorable tax treatment. If we fail to maintain such favorable tax treatment we may be subject to tax in Costa Rica at a significantly higher rate.

***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 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 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 our operating results and financial condition.

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.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012 and a "smaller reporting company" under the Securities Exchange Act of 1934, or the Exchange Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We will remain a smaller reporting company until we have a public float, or value attributable to stock held by nonaffiliates, of at least $250 million, as measured on or prior to June 30th. After we are no longer an emerging growth company and for as long as we remain a smaller reporting company, we will remain eligible for certain exemptions, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation, but we will be required to hold a nonbinding advisory vote on executive compensation and obtain stockholder approval of golden parachute payments. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may suffer or be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act.

***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.

***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:

- our Board of Directors is divided into three classes with staggered three-year terms 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 be able to act by written consent, as a result, a holder, or holders, controlling a majority of our shares are not be 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;
- amendments of our amended and restated memorandum and articles of association will require the approval of shareholders holding 66 2/3% of our outstanding voting shares (unless amended by the Board of Directors);
- 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."

***Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.***

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $2.2 million for severance and other benefits and acceleration of vesting of share options in the event of a termination of employment in connection with a change in control of our company. The accelerated vesting of options could result in dilution to our existing shareholders and harm the market price of our common shares. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with our company.

***Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.***

We currently intend to retain all our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. For example, our credit agreement and guaranty with Madryn restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common shares will be our shareholders' sole source of gain for the foreseeable future.

***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 2019, and we do not expect to be a PFIC for our current taxable year or 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. See "Material British Virgin Island and U.S. Federal Income Tax Considerations."

***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.

## 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.

**ITEM 2. RECENT SALES OF UNREGISTERED SECURITIES AND USE OF PROCEEDS**

None

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. MINE SAFETY DISCLOSURES**

None

**ITEM 5. OTHER INFORMATION**

On June 10, 2020, June 12, 2020 and June 16, 2020, Juan José Chacón Quirós, Salvador Dada and Roberto de Mezerville, respectively, (the “Executives”) adopted Rule 10b5-1 trading plans to, over time, automatically sell Company’s common shares in accordance with each plan’s specifications. 100,000 common shares (in the case of Juan José Chacón Quirós), 50,000 common shares (in the case of Salvador Dada) and 30,000 common shares (in the case of Roberto de Mezerville) are subject to the trading plans. The trading plans were established as part of the Executives’ investment strategies for asset diversification and liquidity over time. The trading plans were adopted during an “open window” in accordance with guidelines specified by Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, and as permitted by the Company’s insider trading policy. Sales under the trading plans may commence on August 10, 2020, are based upon pre-established stock price thresholds and will expire once all of the shares have been sold or on April 9, 2022, whichever is earlier. Actual sale transactions will be disclosed publicly through Form 144 and Form 4 filings with the Securities and Exchange Commission, as required.

Rule 10b5-1 allows persons who may be considered insiders to adopt pre-arranged written plans for trading specified amounts of stock. A plan establishes predetermined trading parameters that, among other things, do not permit the person adopting the plan to exercise subsequent influence over how, when or whether to effect trades. Once a plan has been properly adopted, trades may be executed pursuant to the terms of the plan at times when the person would otherwise be restricted from trading. Trading plans are designed to allow persons to sell shares in an orderly fashion for asset diversification, liquidity, tax planning and other purposes when they might otherwise be restricted from doing so due to material, non-public information that they might possess at the time of the sale.

**ITEM 6. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

**(a) Exhibits.**

| Exhibits | Description | Incorporation by Reference |
|---|---|---|
| 10.1 | Fourth Amendment to Credit Agreement, by and among Establishment Labs Holdings Inc., the subsidiary guarantors party thereto, the lenders party thereto and Madryn Health Partners LP, as administrative agent. | |
| 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 | |
| 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 | |
| 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. | |
| 101.INS | Inline XBRL Instance Document | |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | |

* The certifications filed as Exhibits 32.1 are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

**SIGNATURES**

Pursuant to the requirements 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.**

By: */s/ Juan José Chacón Quirós*

Date: August 7, 2020

By: Juan José Chacón Quirós
Title: Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 7, 2020

By: */s/ Renee M. Gaeta*

Name: Renee M. Gaeta
Title: Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)

EXECUTION VERSION

# FOURTH AMENDMENT TO CREDIT AGREEMENT

THIS FOURTH AMENDMENT TO CREDIT AGREEMENT (this "Agreement") dated as of August 5, 2020 (the "Fourth Amendment Effective Date") is entered into among ESTABLISHMENT LABS HOLDINGS INC., a BVI business company, limited by shares and incorporated under the laws of the British Virgin Islands (the "Borrower"), the Guarantors party hereto, the Lenders party hereto and MADRYN HEALTH PARTNERS, LP, a Delaware limited partnership, as Administrative Agent. All capitalized terms used herein and not otherwise defined herein shall have the meanings given to such terms in the Existing Credit Agreement (as defined below) or the Amended Credit Agreement (as defined below).

## RECITALS

WHEREAS, the Borrower, the Guarantors party thereto, the Lenders party thereto and the Administrative Agent have entered into that certain Credit Agreement dated as of August 24, 2017 (as amended by that certain First Amendment to Credit Agreement dated as of October 31, 2017, that certain Second Amendment to Credit Agreement and Waiver dated as of June 15, 2018, that certain Third Amendment to Credit Agreement and Waiver dated as of June 17, 2019 and as further amended, restated, supplemented or modified from time to time prior to the date hereof, the "Existing Credit Agreement");

WHEREAS, the Borrower has requested that the Existing Credit Agreement be amended to provide for certain modifications of the terms of the Existing Credit Agreement, and that, as so amended, the Existing Credit Agreement for ease of reference be restated (after giving effect to this Agreement) in the form of Schedule 1 hereto; and

WHEREAS, the Lenders are willing to amend the Existing Credit Agreement subject to the terms and conditions hereof;

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendments. Effective as of the Fourth Amendment Effective Date:

(a) The Existing Credit Agreement is hereby amended by this Agreement and for ease of reference restated (after giving effect to this Agreement) in the form of Schedule 1 hereto (the Existing Credit Agreement, as so amended by this Agreement, being referred to as the "Amended Credit Agreement").

(b) Exhibit E to the Existing Credit Agreement is hereby amended and restated to read, in its entirety, as set forth on Schedule 2 hereto.

Except as expressly set forth above, all Exhibits and Schedules to the Existing Credit Agreement will continue in their present forms as Exhibits or Schedules, as applicable, to the Amended Credit Agreement.

2. Conditions Precedent. This Agreement shall be effective upon satisfaction of the following conditions precedent:

(a) Executed Agreement. Receipt by the Administrative Agent of counterparts of this Agreement duly executed by the Loan Parties (including the Additional Loan Parties (as defined below)), the Lenders and the Administrative Agent;

(b) Joinder Documentation. Receipt by the Administrative Agent of counterparts of all documentation required under Section 7.12 of the Amended Credit Agreement, in each case in form and substance satisfactory to the Administrative Agent, for (i) Motiva Implants UK Limited, (ii) Motiva Implants France SAS, (iii) Motiva Germany GmbH and (iv) Motiva Implants Spain, S.L. (collectively, the "Additional Loan Parties");

(c) Additional Collateral Documentation. Receipt by the Administrative Agent of all documentation required under Section 7.14 of the Amended Credit Agreement with respect to the Additional Loan Parties (other than Motiva Implants Spain, S.L.), in each case in form and substance satisfactory to the Administrative Agent;

(d) Organization Documents, Resolutions, Etc. Receipt by the Administrative Agent of documents of the types described in Sections 5.02(f) and (g) of the Amended Credit Agreement as applicable to each Additional Loan Party, each of which shall be originals or facsimiles (followed promptly by originals) in form and substance reasonably satisfactory to the Administrative Agent and including but not limited to:

(i) where required pursuant to the Organization Documents or the applicable Law of the jurisdiction of incorporation of the relevant Additional Loan Party, a copy of a resolution signed by all the holders of the issued shares of each Additional Loan Party, approving the terms of, and the transactions contemplated in connection with this Agreement and the other Loan Documents to which such Additional Loan Party is a party on and from the date of this Agreement;

(ii) in relation to a German Loan Party, (A) an up-to-date electronic excerpt from the commercial register (elektronischer Abruf aus dem Handelsregister), (B) a copy of the articles of association (Satzung) or partnership agreement (Gesellschaftsvertrag) and (C) (if applicable) an up-to-date shareholder's list;

(iii) in relation to each French Loan Party, a copy of the statuts and an original extrait K-bis, certificat de non-faillite and état des inscriptions, dated not more than fifteen (15) days prior to the date of this Agreement;

(iv) in relation to each Spanish Guarantor, (A) a certificate from the Commercial Registry (certificación literal parcial del Registro Mercantil) regarding due incorporation and existence (existencia y vigencia), solvency and no winding up or dissolution (solvencia y ausencia de disolución o liquidación), management body (órgano de administración), no insolvency (no insolvencia) and including up to date and consolidated by-laws (estatutos actualizados y consolidados) of the Spanish Loan Party, and (B) copies of any documents which are pending registration with the relevant Commercial Registry (if any); and

(v) [reserved]

(e) Attorney Costs. The Borrower shall have paid all reasonable and documented fees, charges and disbursements of counsel to the Administrative Agent incurred to the Fourth Amendment Effective Date.

3. Conditions Subsequent.

(a) Motiva Implants Spain, S.L. As soon as reasonably practicable from the date of this Agreement, and in any event within 30 Business Days (or such later date as the Administrative Agent may agree in its sole discretion), Motiva Implants Spain, S.L. and the Borrower shall:

(i) enter into all documentation required under Section 7.14 of the Amended Credit Agreement with respect to Motiva Implants Spain, S.L. before a Spanish notary, in each case in form and substance satisfactory to the Administrative Agent; and

(ii) raise the status of this Agreement and the Joinder Agreement entered into on or about the date of this Agreement by Motiva Implants Spain, S.L. to the status of Spanish Public Document in the form of "escritura pública".

It is understood and agreed that the requirements in Section 7.14 of the Amended Credit Agreement with respect to Motiva Implants Spain, S.L. shall be subject to this Section 3(a).

(b) Motiva Italy S.r.l. As soon as reasonably practicable from the date of this Agreement, and in any event within 10 Business Days (or such later date as the Administrative Agent may agree in its sole discretion), the Borrower shall ensure that Motiva Italy S.r.l. becomes a Guarantor by executing and delivering to the Administrative Agent a Joinder Agreement and such other documents as the Administrative Agent shall reasonably request for such purpose, including, without limitation:

(i) a good standing certificate (certificato di vigenza), indicating that as at a date not earlier than five (5) Business Days before the execution date of the Joinder Agreement and Collateral Documents delivered pursuant to clause (ii) below executed by Motiva Italy S.r.l., it is not subject to any procedura concorsuale; and

(ii) all documentation required under Section 7.14 of the Amended Credit Agreement with respect to Motiva Italy S.r.l., in each case in form and substance satisfactory to the Administrative Agent.

4. Reaffirmation. Each of the Loan Parties acknowledges and reaffirms (a) that it is bound by all of the terms of the Investment Documents to which it is a party and (b) that it is responsible for the observance and full performance of all Obligations, including without limitation, the repayment of the Loans. Furthermore, the Loan Parties acknowledge and confirm (i) that the Administrative Agent and the Lenders have performed fully all of their obligations under the Existing Credit Agreement and the other Investment Documents and (ii) that by entering into this Agreement, the Administrative Agent and the Lenders do not, except as expressly set forth herein, waive or release any term or condition of the Amended Credit Agreement or any of the other Investment Documents or any of their rights or remedies under such Investment Documents or any applicable Law or any of the obligations of the Loan Parties thereunder.

The Loan Parties confirm for the benefit of the Administrative Agent and the Lenders that it is not the intention of the parties hereto that the amendments to the Existing Credit Agreement set forth herein result in a Belgian law novation (novatie) (within the meaning of Articles 1271 et seq. of the Belgian Civil Code) (a "Novation") of the Existing Credit Agreement, it being specified that in the event this Agreement would be deemed to constitute a Novation, the Administrative Agent and the Lenders expressly preserve the benefit of the Liens created under any Loan Documents in accordance with Article 1278 of the Belgian Civil Code and each Loan Party acknowledges and agrees to such preservation.

5. Miscellaneous.

(a) The Existing Credit Agreement and the obligations of the Loan Parties thereunder and under the other Investment Documents, except as expressly modified by this Agreement, are hereby ratified and confirmed and shall remain in full force and effect according to their terms. This Agreement is a Loan Document.

(b) Each Guarantor (i) acknowledges and consents to all of the terms and conditions of this Agreement, (ii) affirms all of its obligations under the Loan Documents and (iii) agrees that this Agreement and all documents executed in connection herewith do not operate to reduce or discharge its obligations under the Existing Credit Agreement or the Loan Documents.

(c) The Loan Parties hereby represent and warrant as follows:

(i) each Loan Party has taken all necessary corporate or other organizational action to authorize the execution, delivery and performance of this Agreement.

(ii) this Agreement has been duly executed and delivered by each Loan Party party hereto and constitutes a legal, valid and binding obligation of each such Loan Party, enforceable against each such Loan Party in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium and similar laws affecting enforceability of creditors' rights generally and to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(iii) no approval, consent, exemption, authorization or other action by, or notice to, or filing with, any Governmental Authority or any other Person is necessary or required in connection with the execution, delivery or performance by, or enforcement against, any Loan Party of this Agreement.

(iv) (A) the representations and warranties of the Borrower and each other Loan Party contained in Article VI of the Amended Credit Agreement or any other Investment Document, or which are contained in any document furnished at any time under or in connection therewith, are true and correct in all material respects (and in all respects if any such representation and warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the date hereof, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they are true and correct in all material respects (and in all respects if any such representation and warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date and (B) no event has occurred and is continuing which constitutes a Default or an Event of Default.

(d) Each of the Loan Parties hereby affirms the Liens created and granted in the Loan Documents in favor of the Administrative Agent, for the benefit of the Secured Parties, and agrees that this Agreement does not adversely affect or impair such liens and security interests in any manner.

(e) This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

(f) If any provision of this Agreement is held to be illegal, invalid or unenforceable, (i) the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby and (ii) the parties shall endeavor in good faith negotiations to replace the illegal, invalid or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the illegal, invalid or unenforceable provisions. The invalidity of a provision in a particular jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

(g) THIS AGREEMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY, SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly 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

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Director

GUARANTORS:

ESTABLISHMENT LABS SOCIEDAD ANONIMA,
a Costa Rica corporation

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Secretary

EUROPEAN DISTRIBUTION CENTER MOTIVA BVBA,
a Belgium besloten vennootschap met beperkte aansprakelijkheid

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Manager

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

By: */s/ Eddie de Oliveira*
Name: Eddie de Oliveira
Title: Manager

JAMM TECHNOLOGIES, INC.,
a Delaware corporation

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: President

MOTIVA USA LLC,
a Delaware limited liability company

By: ESTABLISHMENT LABS HOLDINGS INC.
its Sole Member

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Director

MOTIVA IMPLANTS UK LIMITED,
a UK Private Limited Company

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Director

MOTIVA IMPLANTS FRANCE SAS,
a French Société par Actions Simplifiée

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: President

MOTIVA GERMANY GMBH,
a German Gesellschaft mit beschränkter Haftung

By: */s/ Juan José Chacón Quiros*
Name: Juan José Chacón Quiros
Title: Director

MOTIVA IMPLANTS SPAIN, S.L.,
a Spanish Sociedad Limitada

By: */s/ Paloma Moreno de la Santa*
Name: Paloma Moreno de la Santa
Title: Attorney in fact

ADMINISTRATIVE AGENT:

MADRYN HEALTH PARTNERS, LP

By: MADRYN HEALTH ADVISORS, LP,
its General Partner

By: MADRYN HEALTH ADVISORS GP, LLC,
its General Partner

By: */s/ Avinash N. Amin*
Name: Avinash N. Amin
Title: Member

LENDERS:

MADRYN HEALTH PARTNERS, LP

By: MADRYN HEALTH ADVISORS, LP,
its General Partner

By: MADRYN HEALTH ADVISORS GP, LLC,
its General Partner

By: */s/ Avinash N. Amin*
Name: Avinash N. Amin
Title: Member

MADRYN HEALTH PARTNERS (CAYMAN MASTER), LP

By: MADRYN HEALTH ADVISORS, LP,
its General Partner

By: MADRYN HEALTH ADVISORS GP, LLC,
its General Partner

By: */s/ Avinash N. Amin*
Name: Avinash N. Amin
Title: Member

SCHEDULE 1

AMENDED CREDIT AGREEMENT

See Attached.

SCHEDULE 1

CREDIT AGREEMENT

Dated as of August 24, 2017

among

ESTABLISHMENT LABS HOLDINGS INC.,
as the Borrower,

CERTAIN SUBSIDIARIES OF THE BORROWER,
as the Guarantors,

MADRYN HEALTH PARTNERS, LP,
as the Administrative Agent

and

THE LENDERS FROM TIME TO TIME PARTY HERETO

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C Form of Joinder Agreement
D Form of Assignment and Assumption
E Form of Compliance Certificate

CREDIT AGREEMENT

This CREDIT AGREEMENT is entered into as of August 24, 2017 among ESTABLISHMENT LABS HOLDINGS INC., a BVI business company, limited by shares and incorporated under the laws of the British Virgin Islands (the "Borrower"), the Guarantors (defined herein), the Lenders (defined herein) and MADRYN HEALTH PARTNERS, LP, a Delaware limited partnership, as the Administrative Agent.

The Borrower has requested that the Lenders make term loan facilities available to the Borrower and certain equity investments in the Borrower, and the Lenders are willing to do so on the terms and conditions set forth herein.

In consideration of the mutual covenants and agreements herein contained, the parties hereto covenant and agree as follows:

ARTICLE I.

DEFINITIONS AND ACCOUNTING TERMS

1.01 Defined Terms.

As used in this Agreement, the following terms shall have the meanings set forth below:

"510(k)" means (a) any premarket notification and corresponding FDA clearance for a Device pursuant to FDA regulations and all substantially equivalent or similar notifications, applications and clearances with respect to any other non-U.S. Regulatory Authority, including the EMA, and (b) all amendments, supplements and other additions and modifications thereto, and all documents, data and information which are necessary for, filed with, incorporated by reference in or otherwise support any of the foregoing.

"Acquisition" means the acquisition, whether through a single transaction or a series of related transactions, of (a) a majority of the Voting Stock or other controlling ownership interest in another Person (including the purchase of an option, warrant or convertible or similar type security to acquire such a controlling interest at the time it becomes exercisable by the holder thereof), whether by purchase of such equity or other ownership interest or upon the exercise of an option or warrant for, or conversion of securities into, such equity or other ownership interest, (b) assets of another Person which constitute all or substantially all of the assets of such Person or of a division, line of business or other business unit of such Person or (c) any Product.

"Act" has the meaning set forth in Section 11.17.

"Administrative Agent" means Madryn Health Partners, LP, in its capacity as administrative agent under any of the Loan Documents, or any successor administrative agent.

"Administrative Agent's Office" means the Administrative Agent's address and, as appropriate, account as set forth on Schedule 11.02 or such other address or account as the Administrative Agent may from time to time notify the Loan Parties and the Lenders.

"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.

"Agreement" means this Credit Agreement.

"All-In-Yield" means, with respect to any Indebtedness, the all-in-yield thereof, and taking into account the interest rate (but without duplication of any applicable interest rate floor), interest rate margin, interest rate floors, original issue discount and upfront fees paid generally to all Persons providing such Indebtedness (with original issue discount and upfront fees being equated to interest (as reasonably determined by the Administrative Agent in a manner consistent with customary financial practice) based on a four year life to maturity), but exclusive of any arrangement, structuring, underwriting or similar fee paid to any Person in connection therewith that is not shared generally with all Persons providing such Indebtedness.

"Anti-Money Laundering Laws" has the meaning set forth in Section 6.21(d).

"Applicable Foreign Loan Party Documents" has the meaning set forth in Section 6.26(a).

"Applicable Margin" means eight percent (8.00%) per annum.

"Applicable Percentage" means, with respect to any Lender at any time, (a) in respect of the Term A Facility, with respect to any Term A Lender at any time, the percentage (carried out to the ninth decimal place) of the Term A Facility represented by (i) on or prior to the Funding Date, such Term A Lender's Term A Commitment at such time and (ii) thereafter, the outstanding principal amount of such Term A Lender's Term A Loans at such time, (b) in respect of the Term B-1 Facility, with respect to any Term B-1 Lender at any time, the percentage (carried out to the ninth decimal place) of the Term B-1 Facility represented by (i) at any time during the Term B-1 Availability Period, such Term B-1 Lender's Term B-1 Commitments at such time and (ii) thereafter, the outstanding principal amount of such Term B-1 Lender's Term B-1 Loans at such time, (c) in respect of the Term B-2 Facility, with respect to any Term B-2 Lender at any time, the percentage (carried out to the ninth decimal place) of the Term B-2 Facility represented by (i) at any time during the Term B-2 Availability Period, such Term B-2 Lender's Term B-2 Commitments at such time and (ii) thereafter, the outstanding principal amount of such Term B-2 Lender's Term B-2 Loans at such time, (d) in respect of the Term B-3 Facility, with respect to any Term B-3 Lender at any time, the percentage (carried out to the ninth decimal place) of the Term B-3 Facility represented by (i) at any time during the Term B-3 Availability Period, such Term B-3 Lender's Term B-3 Commitments at such time and (ii) thereafter, the outstanding principal amount of such Term B-3 Lender's Term B-3 Loans at such time, (e) in respect of the Term B-4 Facility, with respect to any Term B-4 Lender at any time, the percentage (carried out to the ninth decimal place) of the Term B-4 Facility represented by (i) at any time during the Term B-4 Availability Period, such Term B-4 Lender's Term B-4 Commitments at such time and (ii) thereafter, the outstanding principal amount of such Term B-4 Lender's Term B-4 Loans at such time and (f) in respect of the Term C Facility, with respect to any Term C Lender at any time, the percentage (carried out to the ninth decimal place) of the Term C Facility represented by (i) at any time after the Term C Commitments have been established pursuant to Section 2.14, such Term C Lender's unfunded Term C Commitment at such time plus the outstanding principal amount of such Term C Lender's Term C Loans at such time and (ii) thereafter, the outstanding principal amount of such Term C Lender's Term C Loans at such time. If the Commitments of all of the Lenders to make Loans have been terminated pursuant to Section 9.02, or if the Commitments have expired, then the Applicable Percentage of each Lender in respect of the applicable Facility shall be determined based on the Applicable Percentage of such Lender in respect of such Facility most recently in effect, giving effect to any subsequent assignments. The Applicable Percentage of each Lender in respect of each Facility is set forth opposite the name of such Lender on Schedule 2.01 or in the Assignment and Assumption pursuant to which such Lender becomes a party hereto, as applicable.

"Applicable Quarter" has the meaning set forth in Section 8.16(b)(i)(A).

"Appropriate Lender" means, at any time, with respect to any Facility, a Lender that has a Commitment with respect to such Facility or holds a Loan under such Facility at such time.

"Approved Fund" means any Fund that is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) an entity or an Affiliate of an entity that administers or manages a Lender.

"Approved Strategic Investment" means an Acquisition or Investment designated by the Borrower as an "Approved Strategic Investment," which designation must be approved by the Administrative Agent in its sole and absolute discretion; provided, that, if the Borrower would like to designate an Acquisition or Investment as an "Approved Strategic Investment," the Borrower shall provide written notice to the Administrative Agent to that effect (including such other documents and certificates as the Administrative Agent shall require in connection therewith) and within ten (10) Business Days after receipt thereof, the Administrative Agent shall inform the Borrower by written notice whether it approves such Acquisition or Investment as an "Approved Strategic Investment."

"Assignment and Assumption" means an assignment and assumption entered into by a Lender and an Eligible Assignee (with the consent of any party whose consent is required by Section 11.06(b)), and accepted by the Administrative Agent, in substantially the form of Exhibit D or any other form (including electronic documentation generated by MarkitClear or other electronic platform) approved by the Administrative Agent.

"Attributable Indebtedness" means, on any date, (a) in respect of any Capital Lease of any Person, the capitalized amount thereof that would appear on a balance sheet of such Person prepared as of such date in accordance with GAAP, (b) in respect of any Synthetic Lease of any Person, the capitalized amount of the remaining lease payments under the relevant lease that would appear on a balance sheet of such Person prepared as of such date in accordance with GAAP if such lease were accounted for as a Capital Lease and (c) in respect of any Securitization Transaction of any Person, the outstanding principal amount of such financing, after taking into account reserve accounts and making appropriate adjustments, determined by the Administrative Agent in its reasonable judgment.

"Audited Financial Statements" means the audited consolidated balance sheet of the Borrower and its Subsidiaries for the fiscal year ended December 31, 2016, and the related consolidated statements of income or operations, shareholders' equity and cash flows for such fiscal year of the Borrower and its Subsidiaries, including the notes thereto, audited by independent public accountants of recognized national standing and prepared in conformity with GAAP.

"Auditor's Determination" has the meaning set forth in Section 4.12(f).

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

"Bail-In Legislation" means, 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 for such EEA Member Country from time to time which is described in the EU Bail-In Legislation Schedule.

"Banco Davivienda" means Banco Davivienda (Costa Rica) S.A.

"Banco Davivienda Documents" means, collectively, (a) that certain letter agreement dated as of May 26, 2017 between Establishment Labs Sociedad Anonima and Banco Davivienda, (b) that certain Mobile Guarantee on Inventories dated as of May 26, 2017 between Establishment Labs Sociedad

Anonima and Banco Davivienda, (c) that certain Bill of Exchange dated as of May 26, 2017 executed by Establishment Labs Sociedad Anonima in favor of Banco Davivienda and (d) all other certificates, agreements, documents and instruments related to the foregoing.

"Belgian Companies Code" means the Belgian Wetboek van Vennootschappen/Code des Sociétés, as amended from time to time.

"Belgian Loan Party" means any Loan Party that is organized under the laws of the Kingdom of Belgium.

"Belgian Share Pledge Agreement" means that certain share pledge agreement dated as of the Funding Date executed by the Administrative Agent, for the benefit of the Secured Parties, Establishment Labs Sociedad Anonima and the Borrower.

"Belgian Receivables Pledge Agreement" means that certain receivables pledge agreement dated as of the Funding Date executed by the Administrative Agent, for the benefit of the Secured Parties, and each of the Belgian Loan Parties.

"Blocking Law" means:

(a) any provision of Council Regulation (EC) No 2271/1996 of 22 November 1996 (or any law or regulation implementing such regulation in any member state of the European Union or the United Kingdom);

(b) section 7 of the German Foreign Trade Regulation (Außenwirtschaftsverordnung);

(c) any similar blocking or anti-boycott law in the United Kingdom; or

(d) any similar blocking or anti-boycott law in France (whether existing now or enacted from time to time).

"Board of Directors" means (a) with respect to a corporation, the board of directors of the corporation or any committee thereof duly authorized to act on behalf of such board, (b) with respect to a partnership, the Board of Directors of the general partner of the partnership, (c) with respect to a limited liability company, the managing member or members or any controlling committee of managing members thereof or if not member-managed, the managers thereof or any committee of managing members or managers thereof duly authorized to act on behalf of such Persons, and (d) with respect to any other Person, the board or committee of such Person serving a similar function.

"Borrower" has the meaning set forth in the introductory paragraph hereto.

"Borrowing" means a Term A Borrowing, a Term B-1 Borrowing, a Term B-2 Borrowing, a Term B-3 Borrowing, a Term B-4 Borrowing or a Term C Borrowing, as the context may require, in each case, pursuant to Section 2.01.

"Brazilian Guarantor" means any Guarantor that is organized under the laws of the Federative Republic of Brazil.

"Brazilian Loan Party" means any Loan Party that is organized under the laws of the Federative Republic of Brazil.

"Brazilian Share Pledge Agreement" means that certain quota pledge agreement dated as of the Funding Date, as amended as of the Third Amendment Effective Date, executed by the Administrative Agent, for the benefit of the Secured Parties, each of the Brazilian Loan Parties and each Loan Party that owns Equity Interests in any Brazilian Loan Party.

"Brazilian Receivables Pledge Agreement" means that certain receivables pledge agreement dated as of the Funding Date, as amended as of the Third Amendment Effective Date, executed by the Administrative Agent, for the benefit of the Secured Parties, and each of the Brazilian Loan Parties.

"Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks are authorized to close under the Laws of, or are in fact closed in, the state where the Administrative Agent's Office is located and, if such day relates to any Loan, means any such day that is also a day on which dealings in Dollar deposits are conducted by and between banks in the London interbank eurodollar market.

"Business IP Rights" means, at any time of determination, IP Rights owned by, licensed to, or otherwise authorized for use by any of the Loan Parties or any of their Subsidiaries at such time including, without limitation, the IP Rights listed on Schedule 6.17(b) to the Disclosure Letter.

"Businesses" means, at any time, a collective reference to the businesses operated by the Borrower and its Subsidiaries at such time.

"Business Facilities" means, at any time, a collective reference to the facilities and real properties owned, leased or operated by any Loan Party or any Subsidiary.

"BVI Loan Party" means any Loan Party that is organized under the laws of the British Virgin Islands.

"Capital Impairment" has the meaning set forth in Section 4.12(b).

"Capital Lease" means, as applied to any Person, any lease of any property by that Person as lessee which, in accordance with GAAP, is required to be accounted for as a capital lease on the balance sheet of that Person.

"Cash Equivalents" means any of the following types of Investments, to the extent owned by the Borrower or any of its Subsidiaries free and clear of all Liens (other than Permitted Liens):

(a) readily marketable obligations issued or directly and fully guaranteed or insured by the United States or any agency or instrumentality thereof having maturities of not more than three hundred sixty days (360) days from the date of acquisition thereof; provided, that, the full faith and credit of the United States is pledged in support thereof;

(b) time deposits with, or insured certificates of deposit or bankers' acceptances of, any commercial bank that (i) is organized under the laws of the United States, any state thereof or the District of Columbia or is the principal banking subsidiary of a bank holding company organized under the laws of the United States, any state thereof or the District of Columbia, and is a member of the Federal Reserve System, (ii) issues (or the parent of which issues) commercial paper rated as described in clause (c) of this definition and (iii) has combined capital and surplus of at least $1,000,000,000, in each case with maturities of not more than one hundred eighty (180) days from the date of acquisition thereof;

(c) commercial paper issued by any Person organized under the laws of any state of the United States and rated at least "Prime-1" (or the then equivalent grade) by Moody's or at least "A-1" (or the then equivalent grade) by S&P, in each case with maturities of not more than one hundred eighty (180) days from the date of acquisition thereof;

(d) Investments, classified in accordance with GAAP as current assets of the Borrower or any of its Subsidiaries, in money market investment programs registered under the Investment Company Act of 1940, which are administered by financial institutions that have the highest rating obtainable from either Moody's or S&P, and the portfolios of which are limited solely to Investments of the character, quality and maturity described in clauses (a), (b) and (c) of this definition;

(e) other short-term investments utilized by Foreign Subsidiaries in accordance with normal investment practices for cash management in investments of a type analogous to the foregoing; and

(f) solely with respect to any Foreign Subsidiary, non-Dollar denominated (i) certificates of deposit of, bankers acceptances of, or time deposits with, any commercial bank which is organized and existing under the laws of the country in which such Foreign Subsidiary maintains its chief executive office and principal place of business, provided such country is (x) a member of the Organization for Economic Cooperation and Development or (y) the British Virgin Islands, the Republic of Costa Rica, or the Federative Republic of Brazil, and, in each case, whose short-term commercial paper rating is at least "Prime-1" (or the then equivalent grade) by Moody's or at least "A-1" (or the then equivalent grade) by S&P (any such bank being an "Approved Foreign Bank") and maturing within one hundred eighty (180) days of the date of acquisition and (ii) equivalents of demand deposit accounts which are maintained with an Approved Foreign Bank.

"Change in Law" means the occurrence, after the Effective Date, of any of the following: (a) the adoption or taking effect of any law, rule, regulation or treaty, (b) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided, that, 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 be a "Change in Law", regardless of the date enacted, adopted or issued.

"Change of Control" means the occurrence of any of the following events:

(a) any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934), other than the Holders, is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Securities Exchange Act of 1934, except that a person or group shall be deemed to have "beneficial ownership" of all securities 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 35% or more of the aggregate ordinary voting power in the election of the Board of Directors of the Borrower represented by the issued and outstanding Equity Interests of the

Borrower on a fully diluted basis (and taking into account all such securities that such person or group has the right to acquire pursuant to any option right); or

(b) during any period of twelve (12) consecutive months, a majority of the members of the Board of Directors of the Borrower cease to be composed of individuals (i) who were members of that Board of Directors on the first day of such period, (ii) whose election, appointment or nomination to that Board of Directors was approved by individuals referred to in clause (i) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors or (iii) whose election, appointment or nomination to that Board of Directors was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors; or

(c) any "Change of Control" (or any comparable term) shall occur under any Permitted Senior Revolving Credit Document or any document or other agreement evidencing any Indebtedness with an aggregate principal amount in excess of the Threshold Amount; or

(d) except as otherwise permitted under this Agreement, the Borrower shall cease to own and control, directly or indirectly, beneficially and of record, one hundred percent (100%) of the issued and outstanding Equity Interests (other than directors' qualifying shares or Equity Interests that are required to be held by another person in order to satisfy a foreign requirement of Law prescribing an equity owner resident in the local jurisdiction) of each of its Subsidiaries, free and clear of all Liens except Liens created by the Collateral Documents.

"Collateral" means a collective reference to all real and personal property (other than, for the avoidance of doubt, Excluded Property) with respect to which Liens in favor of the Administrative Agent (including as parallel debt creditor), for the benefit of the Secured Parties, are purported to be granted pursuant to and in accordance with the terms of the Collateral Documents.

"Collateral Access Agreement" means an agreement in form and substance reasonably satisfactory to the Administrative Agent pursuant to which a lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor or other bailee of inventory or other property owned by any Loan Party, acknowledges the Liens of the Administrative Agent and waives (or, if approved by the Administrative Agent, subordinates) any Liens held by such Person on such property, and permits the Administrative Agent access to any Collateral stored or otherwise located thereon.

"Collateral Documents" means a collective reference to the Security Agreements, the Pledge Agreements, the Qualifying Control Agreements, the Collateral Access Agreements, the Mortgages, the Real Property Security Documents and other security documents as may be executed and delivered by the Loan Parties pursuant to the terms of Section 7.14.

"Commitment" means a Term A Commitment, a Term B-1 Commitment, a Term B-2 Commitment, a Term B-3 Commitment, a Term B-4 Commitment or a Term C Commitment, as the context may require.

"Compliance Certificate" means a certificate substantially in the form of Exhibit E.

"Contract" 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 the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise. "Controlling" and "Controlled" have meanings correlative thereto. Without limiting the generality of the foregoing, a Person shall be deemed to be Controlled by another Person if such other Person possesses, directly or indirectly, power to vote ten percent (10%) or more of the securities having ordinary voting power for the election of directors, managing general partners or the equivalent.

"Controlled Account" has the meaning set forth in Section 7.18(a).

"Controlled Investment Affiliate" means, as to any Person, any other Person which directly or indirectly is in control of, is controlled by, or is under common control with such Person and is organized by such first Person (or any other Person controlling such first Person) primarily for making equity investments in the Borrower or any other portfolio companies in the ordinary course of business.

"Convertible Indebtedness" means Indebtedness having a feature which entitles the holder thereof to convert or exchange all or a portion of such Indebtedness into or by reference to Equity Interests of the Borrower.

"Copyrights" means, collectively, all copyrights (whether statutory or common law, whether established or registered in the United States or any other country or any political subdivision thereof, whether registered or unregistered and whether published or unpublished), all tangible embodiments of the foregoing and all copyright registrations and applications, together with any and all (a) rights and privileges arising under applicable Law and international treaties and conventions with respect to the use of such copyrights, (b) reissues, renewals, continuations and extensions thereof and amendments thereto, (c) income, fees, royalties, damages, claims and payments now or hereafter due and/or payable with respect thereto, including damages and payments for past, present or future infringements thereof, (d) rights corresponding thereto throughout the world and (e) rights to sue for past, present or future infringements thereof.

"Corresponding Debt" has the meaning set forth in Section 11.21.

"Costa Rican Loan Party" means any Loan Party that is organized under the laws of the Republic of Costa Rica.

"Costa Rican IP Security Agreement" means the Costa Rican intellectual property pledge agreement/mobile guaranty dated as of the Funding Date, as amended as of the Third Amendment Effective Date, executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by Establishment Labs Sociedad Anonima, a Costa Rica corporation, with respect to its Costa Rican intellectual property.

"Costa Rican Security Trust Agreement" means that certain security trust agreement (which, for the avoidance of doubt, shall include a pledge of the Equity Interests of each Subsidiary that is organized under the laws of the Republic of Costa Rica) dated as of the Funding Date, as amended as of the Third Amendment Effective Date, by and among the Borrower, the Administrative Agent, each of the Costa Rican Loan Parties and the Trustee, for the benefit of the Secured Parties.

"Crown Predator" means CPH TU, LP, a Delaware limited partnership.

"Crown Predator Convertible Indebtedness" means the Indebtedness owing by the Borrower to Crown Predator pursuant to that certain Note and Warrant Purchase Agreement dated as of August 28, 2015 between the Borrower and Crown Predator, as amended, modified, extended, restated, replaced or supplemented from time to time, and as evidenced by (a) that certain Amended and Restated Convertible Secured Promissory Note dated as of September 14, 2016 executed by the Borrower in favor of Crown Predator in the original principal amount of $10,000,000, (b) that certain Amended and Restated Convertible Secured Promissory Note dated as of September 14, 2016 executed by the Borrower in favor of Crown Predator in the original principal amount of $3,000,000, (c) that certain Amended and Restated Convertible Secured Promissory Note dated as of September 14, 2016 executed by the Borrower in favor of Crown Predator in the original principal amount of $5,000,000, (d) that certain Amended and Restated Convertible Secured Promissory Note dated as of September 14, 2016 executed by the Borrower in favor of Crown Predator in the original principal amount of $1,840,000 and (e) that certain Convertible Secured Promissory Note dated as of September 14, 2016 executed by the Borrower in favor of Crown Predator in the original principal amount of $4,408,076.71.

"Cure Period" has the meaning set forth in Section 8.16(b)(i).

"Cure Right" has the meaning set forth in Section 8.16(b)(i).

"Debt Issuance" means the issuance by any Loan Party or any Subsidiary of any Indebtedness other than Indebtedness permitted under Section 8.03.

"Debt Issuance Notice" has the meaning set forth in Section 2.13(a).

"Debtor Relief Laws" means (a) the Bankruptcy Code of the United States, (b) the Insolvency Act, 2003 of the British Virgin Islands, (c) the Commercial Code, Civil Code and Civil Procedure Code, in each case, of the Republic of Costa Rica and (d) all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief Laws of the United States, the British Virgin Islands, the Republic of Costa Rica, the Kingdom of Belgium, the Federative Republic of Brazil, England and Wales, the French Republic, the Federal Republic of Germany or other applicable jurisdictions from time to time in effect.

"Default" means any event or condition that constitutes an Event of Default or that, with the giving of any notice, the passage of time, or both, would be an Event of Default.

"Default Rate" has the meaning set forth in Section 2.06(b).

"Defaulting Lender" means, subject to Section 2.12(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 Term B-1 Commitment, Term B-2 Commitment, Term B-3 Commitment, Term B-4 Commitment or Term C Commitment, 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 a proceeding under any Debtor Relief Law, (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 or (iii) taken any action in furtherance of, or indicated its consent to, approval of or acquiescence in any such proceeding or appointment; 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.

"Designated Jurisdiction" means any country or territory to the extent that such country or territory is the subject of any Sanction.

"Device" means any medical instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related item, including any component, part or accessory, that (a) is intended for use in the diagnosis of disease, malady or other conditions or in the cure, mitigation, treatment or prevention of disease or malady, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, (b) does not achieve its primary intended purpose or purposes through chemical action within or on the body of man or other animals and (c) is not dependent upon being metabolized for the achievement of its primary intended purpose or purposes.

"Device Clearance Application" means any premarket approval application submitted under Section 515 of the FDCA (21 U.S.C. § 360e) (a "PMA"), any de novo request submitted under Section 513(f) of the FDCA (21 U.S.C. § 360c(f)), or any 510(k) submitted under Section 510(k) of the FDCA (21 U.S.C. § 360(k)) seeking clearance from the FDA for a Device that is substantially equivalent to a legally marketed predicate Device, as defined in the FDCA, or any corresponding non-U.S. application in any other non-U.S. jurisdiction, including, with respect to the European Union, any equivalent submission to a Standard Body pursuant to an applicable directive of the European Council with respect to CE marking (or, if applicable, a self-certification of conformity with respect to any such directive through a "declaration of conformity").

"Disclosure Letter" means that certain disclosure letter dated as of the Effective Date containing certain schedules delivered by the Loan Parties to the Administrative Agent (for the benefit of the Lenders) (as such schedules are supplemented from time to time in accordance with Section 7.02(a)).

"Disposition" or "Dispose" means the sale, transfer, license, lease, issuance or other disposition (including (x) any Sale and Leaseback Transaction and (y) any issuance by any Subsidiary of its Equity Interests, but excluding any issuance by the Borrower of its Equity Interests) of any property by any Loan Party or any Subsidiary, including any sale, assignment, transfer or other disposal, with or without recourse, of any notes or accounts receivable or any rights and claims associated therewith, but excluding the following: (a) the sale, lease, license, transfer or other disposition of inventory in the ordinary course of business, including pursuant to exclusive distribution arrangements consistent with past practice, (b) the sale, lease, license, transfer or other disposition in the ordinary course of business of surplus, obsolete or worn out property no longer used or useful in the conduct of business of any Loan Party and its Subsidiaries, (c) any sale, lease, license, transfer or other disposition of property to any Loan Party or any Subsidiary; provided, that, (i) if the transferor of such property is a Qualified Loan Party, (A) the transferee thereof must be a Qualified Loan Party or (B) to the extent such transaction constitutes an Investment, such transaction is permitted under Section 8.02, and (ii) if the transferor of such property is a Loan Party that is not a Qualified Loan Party, (A) the transferee thereof must be a Loan Party or (B) to the extent such transaction constitutes an Investment, such transaction is permitted under Section 8.02, (d) granting licenses of intellectual property permitted by Section 8.19(b), (e) any Involuntary Disposition, (f) the sale, transfer, issuance or other disposition of a de minimis number of shares of the Equity Interests of a Foreign Subsidiary in order to qualify members of the governing body of such Subsidiary if required by applicable Law, (g) the abandonment or other disposition of IP Rights that are not material and are no longer used or useful in any material respect in the business of the Borrower and its Subsidiaries, (h) licenses, sublicenses, leases or subleases (in each case, other than with respect to IP Rights or intellectual property) granted to third parties in the ordinary course of business and not interfering with the business of the Borrower and its Subsidiaries, (i) dispositions of cash and Cash Equivalents, (j) to the extent constituting Dispositions, transactions permitted by Sections 8.02, 8.04 and 8.06 and Liens permitted by Section 8.01, (k) discounts of or forgiveness of accounts receivable or in connection with the collection or

compromise thereof, in each case, in the ordinary course of business and (l) Permitted Sale and Leaseback Transactions.

"Disqualified Capital Stock" means any Equity Interest which, by its terms (or by the terms of any security into which it is convertible or for which it is exchangeable), or upon the happening of any event, (a) matures (excluding any maturity as the result of an optional redemption by the issuer thereof) or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, or is redeemable at the option of the holder thereof, in whole or in part, prior to the one hundred eighty-first (181st) day after the Maturity Date, (b) requires the payment of any cash dividends at any time prior to the one hundred eighty-first (181st) day after the Maturity Date, (c) contains any repurchase obligation which may come into effect prior to the Facility Termination Date, or (d) is convertible into or exchangeable (unless at the sole option of the issuer thereof) for (i) debt securities or (ii) any Equity Interests referred to in clause (a), (b) or (c) above, at any time prior to the one hundred eighty-first (181st) day after the Maturity Date; provided, that, (x) any Equity Interests that would not constitute Disqualified Capital Stock 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 or an asset sale occurring prior to the one hundred eighty-first (181st) day after the Maturity Date shall not constitute Disqualified Capital Stock to the extent that such Equity Interests provide that the issuer thereof will not redeem or repurchase any such Equity Interests pursuant to such provisions prior to the Facility Termination Date and (y) only the portion of Equity Interests which so matures or is mandatorily redeemable, is so redeemable at the option of the holder thereof, has such cash dividend, has such repurchase obligation or is so convertible or exchangeable, in each case, prior to the one hundred eighty-first (181st) day after the Maturity Date will be deemed to be Disqualified Capital Stock; provided, further, however, that if such Equity Interest is issued to any current or former employee, director or consultant or to any plan for the benefit of current or former employees, directors or consultants of the Borrower or any Subsidiary or by any such plan to such current or former employees, directors or consultants such Equity Interest will not constitute Disqualified Capital Stock solely because it may be required to be repurchased by the Borrower or any Subsidiary in order to satisfy applicable statutory or regulatory obligations, including tax withholding, or as a result of such current or former employee's, director's or consultant's termination, death or disability.

"Dollar" and "$" mean lawful money of the United States.

"Domestic Subsidiary" means any Subsidiary that is organized under the laws of any state of the United States or the District of Columbia.

"DPTA" has the meaning set forth in Section 4.12(g)(ii).

"Earn Out Obligations" means, with respect to an Acquisition, all obligations of the applicable Loan Party or any Subsidiary to make earn out or other contingency payments (including purchase price adjustments, non-competition and consulting agreements, or other indemnity obligations) pursuant to the documentation relating to such Acquisition. For purposes of determining the aggregate consideration paid for an Acquisition at the time of such Acquisition, the amount of any Earn Out Obligations shall be deemed to be the maximum amount of the earn-out payments in respect thereof as specified in the documents relating to such Acquisition. For purposes of determining the amount of any Earn Out Obligations to be included in the definition of Funded Indebtedness, the amount of Earn Out Obligations shall be deemed to be the aggregate liability in respect thereof, as determined in accordance with GAAP.

"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.

"Effective Date" means August 24, 2017.

"Eligible Assets" means fixed or capital assets that are used or useful in the same or a similar line of business as the Borrower and its Subsidiaries were engaged in on the Effective Date (or any reasonable extension or expansions thereof).

"Eligible Assignee" means any Person that meets the requirements to be an assignee under Section 11.06(b)(iii) and (v) (subject to such consents, if any, as may be required under Section 11.06(b)(iii)).

"EMA" means the European Medicines Agency or any successor entity.

"Employee Benefit Non-U.S. Plan" means any plan, fund (including, without limitation, any superannuation fund) or other similar program established, contributed to (regardless of whether through direct contributions or through employee withholdings) or maintained outside the United States by the Borrower or any of its Subsidiaries primarily for the benefit of employees of the Borrower or any of its Subsidiaries residing outside the United States, which plan, fund or other similar program provides, or results in, retirement income, a deferral of income in contemplation of retirement, or payments to be made upon termination of employment, and which plan is not subject to ERISA.

"Employee Benefit Non-US Plan Event" means (a) a failure to meet any minimum funding standards, pay any required installment or make any required contribution under any Employee Benefit Non-U.S. Plan, (b) the withdrawal or termination of any Employee Benefit Non-U.S. Plan resulting in material liability to the Borrower or any of its Subsidiaries, (c) the institution by any Governmental Authority of proceedings to terminate any Employee Benefit Non-U.S. Plan, (d) the imposition of material liability on the Borrower or any of its Subsidiaries due to the failure to comply with any applicable Law relating to any Employee Benefit Non-U.S. Plan, (e) the withdrawal by the Borrower or any of its Subsidiaries from any Employee Benefit Non-U.S. Plan resulting in material liability to the Borrower or any of its Subsidiaries, (f) any imposition by any Governmental Authority of any material tax, fine or penalty against the Borrower or any of its Subsidiaries due to the failure to comply with laws and regulations applicable to any Employee Benefit Non-U.S. Plan, (g) the assertion of any material claim against the Borrower or any of its Subsidiaries with respect to any Employee Benefit Non-U.S. Plan or (h) the imposition of any Lien on the assets of the Borrower or any of its Subsidiaries to secure obligations under any Employee Benefit Non-U.S. Plan.

"Enforcement Notice" has the meaning set forth in Section 4.12(d).

"Environmental Laws" means any and all federal, state, provincial, territorial, local, foreign and other applicable statutes, laws, regulations, ordinances, rules, judgments, orders, decrees, permits,

concessions, grants, franchises, licenses, agreements or governmental restrictions relating to pollution and the protection of the environment or the release of any materials into the environment, including those related to hazardous substances or wastes, air emissions and discharges to waste or public systems.

"Environmental Liability" means any liability, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of the Borrower, any other Loan Party or any of their respective 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, all of the shares of capital stock of (or other ownership or profit interests in) such Person, all of the warrants, options or other rights for the purchase or acquisition from such Person of shares of capital stock of (or other ownership or profit interests in) such Person, all of the securities convertible into or exchangeable for shares of capital stock of (or other ownership or profit interests in) such Person or warrants, rights or options for the purchase or acquisition from such Person of such shares (or such other interests), and all of the other ownership or profit interests in such Person (including partnership, member, membership or trust interests therein), whether voting or nonvoting, and whether or not such shares, warrants, options, rights or other interests are outstanding on any date of determination; provided, however, that Equity Interests shall not include Convertible Indebtedness.

"ERISA" means the United States Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder from time to time.

"ERISA Affiliate" means any trade or business (whether or not incorporated) under common control with the Borrower within the meaning of Section 414(b) or (c) of the Internal Revenue Code (and Sections 414(m) and (o) of the Internal Revenue Code for purposes of provisions relating to Section 412 of the Internal Revenue Code).

"ERISA Event" means (a) a Reportable Event with respect to any Pension Plan, (b) the withdrawal of the Borrower or any ERISA Affiliate from any Pension Plan subject to Section 4063 of ERISA during a plan year in which such entity was a "substantial employer" as defined in Section 4001(a)(2) of ERISA or a cessation of operations that is treated as such a withdrawal under Section 4062(e) of ERISA, (c) a complete or partial withdrawal by the Borrower or any ERISA Affiliate from a Multiemployer Plan (within the meaning of Sections 4203 and 4205 of ERISA, respectively) or notification that a Multiemployer Plan is insolvent (within the meaning of Section 4245 of ERISA), (d) the filing of a notice of intent to terminate or the treatment of a Pension Plan amendment as a termination under Sections 4041 or 4041A of ERISA, (e) the institution by the PBGC of proceedings to terminate a Pension Plan, (f) any event or condition which constitutes grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Pension Plan, (g) the determination that any Pension Plan is considered an at-risk plan or a plan in endangered or critical status within the meaning of Sections 430, 431 and 432 of the Internal Revenue Code or Sections 303, 304 and 305 of ERISA, or (h) the imposition of any liability under Title IV of ERISA, other than for any PBGC premiums due but not delinquent under Section 4007 of ERISA, upon the Borrower or any ERISA Affiliate with respect to any Pension Plan.

"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.

"Event of Default" has the meaning set forth in Section 9.01.

"Exchange Act" means the Securities Exchange Act of 1934.

"Excluded Property" means, with respect to any Loan Party, including any Person that becomes a Loan Party after the Effective Date as contemplated by Section 7.12, (a) any real property which is located outside of the United States unless requested by the Administrative Agent or the Required Lenders, (b) (i) any leasehold interest of any Loan Party in real property and (ii) any fee owned real property which is subject to a Lien of the type described in Section 8.01(n), (c) solely with respect to any U.S. Loan Party, any personal property (including, without limitation, motor vehicles) of such U.S. Loan Party in respect of which perfection of a Lien is not either (i) governed by the Uniform Commercial Code or (ii) effected by appropriate evidence of the Lien being filed in either the United States Copyright Office or the United States Patent and Trademark Office, unless requested by the Administrative Agent or the Required Lenders, (d) any property which, subject to the terms of Section 8.09, is subject to a Lien of the type described in Section 8.01(i) pursuant to documents which prohibit such Loan Party from granting any other Liens in such property, (e) any United States intent-to-use trademark or service mark application to the extent that, and solely during the period in which, the grant of a security interest therein would impair the validity or enforceability of such intent-to-use trademark or service mark application under federal law, (f) any Equity Interests in any Person that is not a Wholly Owned Subsidiary of a Loan Party, to the extent that the granting of a Lien thereon, or a security interest therein, is prohibited or requires the consent of another Person (that is not the Borrower or any Affiliate thereof), in each case, pursuant to the Organization Documents of such Person that is not a Wholly Owned Subsidiary; provided, that, in the event of the termination or elimination of any such prohibition or requirement for consent, to the extent sufficient to permit any such Equity Interests to become Collateral, or upon the granting of any such consent, or waiving or terminating any requirement for such consent, a security interest in such Equity Interests shall be automatically and simultaneously granted under the applicable Collateral Document and such Equity Interests shall be included as Collateral, (g) solely with respect to any U.S. Loan Party, any General Intangible (as defined in the Uniform Commercial Code), permit, lease, license, contract or other Instrument (as defined in the Uniform Commercial Code) of such U.S. Loan Party to the extent the grant of a security interest in such General Intangible (as defined in the Uniform Commercial Code), permit, lease, license, contract or other Instrument (as defined in the Uniform Commercial Code) in the manner contemplated by the Collateral Documents, under the terms thereof or under applicable Law, is prohibited and would result in the termination thereof or give the other parties thereto the right to terminate, accelerate or otherwise alter such U.S. Loan Party's rights, titles and interests thereunder (including upon the giving of notice or the lapse of time or both); provided, that, (i) any such limitation described in this clause (g) on the security interests granted under the Collateral Documents shall only apply to the extent that any such prohibition or right to terminate or accelerate or alter a U.S. Loan Party's rights could not be rendered ineffective pursuant to the Uniform Commercial Code or any other applicable Law or principles of equity and (ii) in the event of the termination or elimination of any such prohibition or right or the requirement for any consent contained in any applicable Law, General Intangible (as defined in the Uniform Commercial Code), permit, lease, license, contract or other Instrument (as defined in the Uniform Commercial Code), to the extent sufficient to permit any such item to become Collateral, or upon the granting of any such consent, or waiving or terminating any requirement for such consent, a security interest in such General Intangible (as defined in the Uniform Commercial Code), permit, lease, license, contract or other Instrument (as defined in the Uniform Commercial Code) shall be automatically and simultaneously granted under the applicable Collateral Documents and such items shall be included as Collateral, (h) assets to the extent that pledges thereof, and security interests therein, are prohibited by applicable Law; provided, that, (i) any such limitation described in this clause (h) on the security interests granted under the Collateral Documents shall only apply to the extent that any such prohibition could not be rendered ineffective pursuant to the Uniform Commercial Code or any other applicable Law or principles of equity and (ii) in the event of the termination or elimination of any such prohibition contained in any applicable Law, a security interest in

such assets shall be automatically and simultaneously granted under the applicable Collateral Documents and such assets shall be included as Collateral and (i) any real or personal property as to which (i) the Administrative Agent and the Borrower agree in writing that the costs or other consequences of obtaining a security interest or perfection thereof are excessive in view of the benefits to be obtained by the Secured Parties therefrom or (ii) the Administrative Agent and the Borrower agree in writing that obtaining a security interest or perfection thereof would result in material adverse tax consequences to the Borrower or its Subsidiaries.

"Excluded Subsidiary" means (a) any Foreign Subsidiary, the perfected grant of a security interest in the assets of such Subsidiary in support of, and the guaranteeing of, the Obligations (i) would be prohibited by applicable Law in the jurisdiction of formation or incorporation of such Subsidiary (as reasonably determined by the Borrower with the consent of the Administrative Agent) or (ii) would result in material adverse tax consequences to the Borrower or its Subsidiaries (as reasonably determined by the Borrower with the consent of the Administrative Agent), (b) any other Foreign Subsidiary with respect to which (in the reasonable judgment of the Administrative Agent), the cost or other consequences of such Foreign Subsidiary guaranteeing the Obligations are excessive in view of the benefits to be obtained by the Secured Parties therefrom or (c) any Immaterial Subsidiary.

"Exclusivity Period" has the meaning set forth in Section 2.13(b).

"Existing Credit Agreement" means that certain Credit Agreement and Guaranty dated as of September 19, 2016 by and among the Borrower, certain of the Borrower's subsidiaries from time to time party thereto and the lenders from time to time party thereto, as amended or modified from time to time.

"Extraordinary Receipts" means any cash received by or paid to or for the account of any Person not in the ordinary course of business, including tax refunds, pension plan reversions, proceeds of insurance (other than proceeds of business interruption insurance to the extent such proceeds constitute compensation for lost earnings), condemnation awards (and payments in lieu thereof), indemnity payments and any purchase price adjustments; provided, that, "Extraordinary Receipts" shall not include (x) cash payments received by or paid to or for the account of any Loan Party pursuant to a judgment, claim (including an insurance claim), settlement, cause of action or indemnification claim, to the extent such payments are in respect of any obligations owed by such Loan Party to a third party that is not an Affiliate of a Loan Party with respect to the underlying claim for which such judgment, claim, settlement, cause of action or indemnification claim arose and are applied to pay (or reimburse such Loan Party for payment on account of) such obligations and (y) any purchase price adjustment (other than working capital purchase price adjustments) pursuant to any acquisition agreement entered into after the Effective Date in connection with a Permitted Acquisition to the extent that the purchase price of such Permitted Acquisition was paid solely with Qualified Capital Stock or with the proceeds from the issuance of Qualified Capital Stock by the Borrower or a capital contribution to the Borrower.

"Facility" means the Term A Facility, the Term B-1 Facility, the Term B-2 Facility, the Term B-3 Facility, the Term B-4 Facility or the Term C Facility, as the context may require.

"Facility Termination Date" means the date as of which all of the following shall have occurred: (a) all of the Commitments have terminated and (b) all Obligations have been paid in full in cash (other than contingent indemnification obligations for which no claim has been asserted).

"FATCA" means Sections 1471 through 1474 of the Internal Revenue Code as of the Effective Date (or any amended or successor version that is substantively comparable and not materially more onerous to comply with) and any current or future regulations thereunder, official interpretations thereof,

any agreement entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code and any intergovernmental agreements entered into thereunder.

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

"FDCA" means the U.S. Food, Drug and Cosmetic Act of 1938 (or any successor thereto), as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Federal Funds Rate" means, for any day, the rate per annum equal to the weighted average of the rates on overnight federal funds transactions with members of the Federal Reserve System arranged by federal funds brokers on such day, as published by the Federal Reserve Bank of New York on the Business Day next succeeding such day; provided, that, if such day is not a Business Day, the Federal Funds 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. Notwithstanding the foregoing, if the Federal Funds Rate shall be less than zero, such rate shall be deemed zero for purposes of this Agreement.

"Fee Letter" means that certain Amended and Restated Fee Letter dated as of the Third Amendment Effective Date, by and among the Borrower and the Administrative Agent.

"Flood Hazard Property" has the meaning set forth in the definition of "Real Property Security Documents".

"Foreign Lender" has the meaning set forth in Section 3.01(c)(ii).

"Foreign Loan Party" means each Loan Party that is not a U.S. Loan Party.

"Foreign Subsidiary" means any Subsidiary that is not a Domestic Subsidiary.

"FRB" means the Board of Governors of the Federal Reserve System of the United States.

"French Guarantor" means any Guarantor that is organized under the laws of France.

"French Loan Party" means any Loan Party that is organized under the laws of France.

"French Transaction Security Documents" has the meaning set forth in Section 10.01(e)(i).

"Fund" means any Person (other than a natural Person) that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its activities.

"Funded Indebtedness" means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with GAAP:

(a) all obligations, whether current or long-term, for borrowed money (including the Obligations) and all obligations of such Person evidenced by bonds, debentures, notes, loan agreements or other similar instruments;

(b) all purchase money Indebtedness;

(c) the principal portion of all obligations under conditional sale or other title retention agreements relating to property purchased by such Person or any Subsidiary thereof

(other than customary reservations or retentions of title under agreements with suppliers entered into in the ordinary course of business);

(d) all obligations arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments;

(e) all obligations in respect of the deferred purchase price of property or services (other than (x) trade accounts payable in the ordinary course of business and (y) obligations under deferred compensation plans), including, without limitation, any Earn Out Obligations;

(f) the Attributable Indebtedness of Capital Leases, Securitization Transactions and Synthetic Leases;

(g) all obligations of such Person to purchase, redeem, retire, defease or otherwise make any payment in respect of any Disqualified Capital Stock in such Person or any other Person, valued, in the case of a redeemable preferred interest, at the greater of its voluntary or involuntary liquidation preference plus accrued and unpaid dividends;

(h) all Funded Indebtedness of others secured by (or for which the holder of such Funded Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on, or payable out of the proceeds of production from, property owned or acquired by such Person, whether or not the obligations secured thereby have been assumed;

(i) all Guarantees with respect to Funded Indebtedness of the types specified in clauses (a) through (h) above of another Person; and

(j) all Funded Indebtedness of the types referred to in clauses (a) through (i) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person is a general partner or joint venturer, except to the extent that Funded Indebtedness is expressly made non-recourse to such Person.

For purposes hereof, the amount of any direct obligation arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments shall be the maximum amount available to be drawn thereunder.

"Funding Date" means the date on which the conditions set forth in Section 5.02 have been satisfied.

"GAAP" means generally accepted accounting principles in the United States set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board, consistently applied and as in effect from time to time.

"German Guarantor" means a Guarantor incorporated in Germany.

"German Loan Party" means any Loan Party which is organized under the laws of Germany.

"German Person" means any Person with its centre of main interest (as that term is used in article 3(1) of the Regulation) in the Federal Republic of Germany.

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

"Governmental Authority" means the government of the United States, the British Virgin Islands, the Kingdom of Belgium, the Republic of Costa Rica, the Federative Republic of Brazil, the United Kingdom, the Federal Republic of Germany, the Republic of France, the Italian Republic, the Kingdom of Spain or any other nation, or of any political subdivision thereof, whether state, provincial, territorial or local, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including any supra-national bodies such as the European Union or the European Central Bank).

"Guarantee" means, as to any Person, (a) any obligation, contingent or otherwise, of such Person guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation payable or performable by another Person (the "primary obligor") in any manner, whether directly or indirectly, and including any obligation of such Person, direct or indirect, (i) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation, (ii) to purchase or lease property, securities or services for the purpose of assuring the obligee in respect of such Indebtedness or other obligation of the payment or performance of such Indebtedness or other obligation, (iii) to maintain working capital, equity capital or any other financial statement condition or liquidity or level of income or cash flow of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation, or (iv) entered into for the purpose of assuring in any other manner the obligee in respect of such Indebtedness or other obligation of the payment or performance thereof or to protect such obligee against loss in respect thereof (in whole or in part), or (b) any Lien on any assets of such Person securing any Indebtedness or other obligation of any other Person, whether or not such Indebtedness or other obligation is assumed by such Person (or any right, contingent or otherwise, of any holder of such Indebtedness to obtain any such Lien). The amount of any Guarantee shall be deemed to be an amount equal to the stated or determinable amount of the related primary obligation, or portion thereof, in respect of which such Guarantee is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by the guaranteeing Person in good faith. The term "Guarantee" as a verb has a corresponding meaning.

"Guarantors" means (a) each Subsidiary identified as a "Guarantor" on the signature pages hereto and (b) each other Person that joins as a Guarantor pursuant to Section 7.12, together with their successors and permitted assigns; provided, that, in no event shall any Excluded Subsidiary be a Guarantor.

"Guaranty" means the Guaranty made by the Guarantors in favor of the Secured Parties pursuant to Article IV.

"Hazardous Materials" means all explosive or radioactive substances or wastes and all hazardous or toxic substances, wastes or other pollutants, including petroleum or petroleum distillates, asbestos or asbestos-containing materials, polychlorinated biphenyls, radon gas, infectious or medical wastes and all other substances or wastes of any nature regulated pursuant to any Environmental Law.

"Healthcare Laws" means, collectively, all Laws applicable to the business of any Loan Party regulating the manufacturing, labeling, promotion and provision of and payment for healthcare products, items and services, including the Health Insurance Portability and Accountability Act of 1996, Section 1128B(b) of the Social Security Act, as amended; 42 U.S.C. § 1320a-7b (Criminal Penalties Involving

Medicare or State Health Care Programs), commonly referred to as the "Federal Anti-Kickback Statute;" Section 1877 of the Social Security Act, as amended and similar state laws; 42 U.S.C. § 1395nn (Limitation on Certain Physician Referrals), commonly referred to as "Stark Statute;" U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time (21 U.S.C. § 301 et seq.); all applicable Good Manufacturing Practice requirements addressed in the FDA's Quality System Regulation (21 C.F.R. Part 820); the Medical Devices Regulations, 21 C.F.R. Part 812, and Parts 50, 54, and 56; all applicable labeling requirements addressed in the FDA's Device Labeling Regulation (21 C.F.R. Part 801); all regulations with respect to the provision of Medicare and Medicaid programs and services (42 C.F.R. Chapter IV et seq.); and all regulations promulgated under or pursuant to any of the foregoing.

"HMT" has the meaning set forth in the definition of "Sanctions".

"Holders" means, collectively, (a) the Persons set forth on Schedule 1.01(b) to the Disclosure Letter, (b) each natural relative who is a rightful heir of any of the foregoing holders described in clause (a) of this definition, (c) any trust maintained by or for the benefit of any of the foregoing holders and rightful heirs described in clauses (a) or (b) of this definition and (d) each Controlled Investment Affiliate of any holder specified in clause (a) of this definition.

"IDE" means an application, including an application filed with any Regulatory Authority, for authorization to commence human clinical studies with respect to any Device, including (a) an Investigational Device Exemption as defined in the FDCA or any successor application or procedure filed with the FDA, (b) an abbreviated Investigational Device Exemption as specified in FDA regulations in 21 C.F.R. § 812.2(b), (c) any equivalent of any of the foregoing pursuant to or under any non-U.S. country or regulatory jurisdiction, (d) all amendments, variations, extensions and renewals of any of the foregoing that may be filed with respect thereto and (e) all documents and correspondence with Institutional Review Boards, whether U.S. or non-U.S., or equivalent.

"Immaterial Subsidiary" means any Subsidiary that, as of any date of determination (a) for the four consecutive fiscal quarter period most recently ended prior to such date for which financial statements have been delivered to the Administrative Agent pursuant to Sections 7.01(a) or (b)(i), did not (together with its Subsidiaries) (i) generate Product Revenues in excess of five percent (5%) of Product Revenues (for the avoidance of doubt, for the Borrower and its Subsidiaries on a consolidated basis) for such four consecutive fiscal quarter period or (ii) together with all other Immaterial Subsidiaries at such time, generate Product Revenues in excess of ten percent (10%) of Product Revenues (for the avoidance of doubt, for the Borrower and its Subsidiaries on a consolidated basis) for such four consecutive fiscal quarter period and (b) did not have (together with its Subsidiaries) (i) total assets in excess of five percent (5%) of the consolidated total assets of the Borrower and its Subsidiaries at such date or (ii) together with all other Immaterial Subsidiaries at such time, total assets in excess of ten percent (10%) of consolidated total assets of the Borrower and its Subsidiaries at such date; provided, that, notwithstanding anything herein to the contrary, (x) in no event shall any Subsidiary that owns material Business IP Rights be deemed to be an Immaterial Subsidiary and (y) in no event shall any Subsidiary that has become a Guarantor in accordance with the terms of this Agreement be deemed to be an Immaterial Subsidiary.

"Indebtedness" means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with GAAP:

(a) all Funded Indebtedness;

(b) the Swap Termination Value of any Swap Contract;

(c) all Guarantees with respect to outstanding Indebtedness of the types specified in clauses (a) and (b) above of any other Person; and

(d) all Indebtedness of the types referred to in clauses (a) through (c) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person or a Subsidiary thereof is a general partner or joint venturer, unless such Indebtedness is expressly made non-recourse to such Person or such Subsidiary.

"Indemnitee" has the meaning set forth in Section 11.04(b).

"Information" has the meaning set forth in Section 11.07.

"InsO" has the meaning set forth in Section 9.01(g).

"Interest Payment Date" means, (a) the last day of each March, June, September and December; provided, that, if any such last day is not a Business Day, the applicable "Interest Payment Date" shall be the first Business Day immediately preceding such last day of such month; and (b) the Maturity Date.

"Interest Period" means, with respect to any Loan, (a) the period commencing on (and including) the applicable borrowing date of such Loan and ending on (and including) the last day of the calendar quarter in which such borrowing date occurs; provided, that, if any such last day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately preceding such last day of such quarter, and (b) thereafter, the period beginning on (and including) the first day following the end of the preceding Interest Period and ending on the earlier of (and including) (x) the last day of the calendar quarter following the calendar quarter in which the preceding Interest Period ended; provided, that, if any such last day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately preceding such last day of such quarter, and (y) the Maturity Date. Notwithstanding the foregoing, each Interest Period in effect as of the Second Amendment Effective Date shall end on (and include) the last day of the calendar quarter in which the Second Amendment Effective Date occurs; provided, that, if such last day is not a Business Day, each applicable Interest Period shall end on the first Business Day immediately preceding such last day of such quarter.

"Interest Rate" means, for any Interest Period, the sum of (a) the Applicable Margin plus (b) Three-Month LIBOR for such Interest Period; provided, that, at all times when a LIBOR Unavailability Period shall exist and be continuing, the "Interest Rate" shall equal the sum of (i) the total of (x) the Applicable Margin minus (y) one percent (1.00%) plus (ii) the Prime Rate.

"Interim Financial Statements" means the unaudited consolidated financial statements of the Borrower and its Subsidiaries for the fiscal quarter ended March 31, 2017, including balance sheets and statements of income or operations, shareholders' equity and cash flows.

"Internal Revenue Code" means the United States Internal Revenue Code of 1986.

"Internal Revenue Service" means the United States Internal Revenue Service.

"Invention" means any novel, inventive or 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, as to any Person, any direct or indirect acquisition or investment by such Person, whether by means of (a) the purchase or other acquisition of Equity Interests of another Person, (b) a loan, advance or capital contribution to, Guarantee or assumption of debt of, or purchase or other acquisition of any other debt or equity participation or interest in, another Person, including any partnership or joint venture interest in such other Person and any arrangement pursuant to which the investor Guarantees Indebtedness of such other Person or (c) an Acquisition. For purposes of covenant compliance, the amount of any Investment shall be the amount actually invested, without adjustment for subsequent increases or decreases in the value of such Investment.

"Investment Documents" means, collectively, the Loan Documents, the Share Purchase Agreement and the ROFR Side Letter.

"Involuntary Disposition" means any loss of, damage to or destruction of, or any condemnation or other taking for public use of, any property of any Loan Party or any of its Subsidiaries.

"IP Rights" means all Patents, Trademarks, Copyrights and Technical Information, whether registered or not, U.S. or non-U.S., Device Clearance Applications, Product Agreements, Product Authorizations or Regulatory Approvals, including (without limitation) all of the following:

(a) applications or registrations relating to such IP Rights;

(b) rights and privileges arising under any applicable Law with respect to such IP Rights;

(c) rights to sue for past, present or future infringements of such IP Rights; and

(d) rights of the same or similar effect or nature in any jurisdiction corresponding to such IP Rights throughout the world.

"Italian Civil Code" means the Italian civil code, enacted by Royal Decree No. 262 of 16 March 1942, as subsequently amended and supplemented.

"Italian Guarantor" means any Guarantor that is organized under the laws of Italy.

"Italian Law Security Documents" has the meaning set forth in Section 10.01(k)(i).

"Italian Usury Law" has the meaning set forth in Section 4.11(c).

"Joinder Agreement" means a joinder agreement substantially in the form of Exhibit C executed and delivered by a Subsidiary in accordance with the provisions of Section 7.12.

"JW Opportunities Warrant" means that certain Warrant Certificate dated as of September 30, 2016 issued by the Borrower in favor of JW Opportunities Master Fund, Ltd.

"JW Partners Warrant" means that certain Warrant Certificate dated as of September 30, 2016 issued by the Borrower in favor of JW Partners, LP.

"Laws" means, collectively, all international, foreign, federal, state, provincial, territorial and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof or determinations thereunder 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, in each case having the force of law.

"Lenders" means each of the Persons identified as a "Lender" on the signature pages hereto and their respective successors and assigns.

"Lending Office" means, as to any Lender, the office address of such Lender and, as appropriate, account of such Lender set forth on Schedule 11.02 or such other address or account as such Lender may from time to time notify the Borrower and the Administrative Agent.

"LIBOR Screen Rate" has the meaning set forth in the definition of "Three-Month LIBOR".

"LIBOR Successor Rate" has the meaning set forth in Section 3.05.

"LIBOR Successor Rate Conforming Changes" means, with respect to any proposed LIBOR Successor Rate, any conforming changes to the definition of Interest Period, Interest Rate or Three-Month LIBOR, the timing and frequency of determining rates and making payments of interest and other administrative matters as may be appropriate, in the discretion of the Administrative Agent, to reflect the adoption of such LIBOR Successor Rate and to permit the administration thereof by the Administrative Agent in a manner substantially consistent with market practice (or, if the Administrative Agent determines that adoption of any portion of such market practice is not administratively feasible or that no market practice for the administration of such LIBOR Successor Rate exists, in such other manner of administration as the Administrative Agent determines in consultation with the Borrower).

"LIBOR Unavailability Period" means a period, commencing on the date on which any of the events set forth in clauses (a), (b), (c) or (d) below occur and continuing through the earlier to occur of (x) the date on which no such conditions continue to exist and (y) the date on which a LIBOR Successor Rate is established:

(a) adequate and reasonable means do not exist for ascertaining the LIBOR Screen Rate, including, without limitation, because the LIBOR Screen Rate is not available or published on a current basis and such circumstances are unlikely to be temporary, or

(b) the administrator of the LIBOR Screen Rate or a Governmental Authority having jurisdiction over the Administrative Agent has made a public statement identifying a specific date after which the LIBOR Screen Rate shall no longer be made available, or used for determining the interest rate of loans, or

(c) loans currently being executed, or that include language similar to that contained in this definition and Section 3.05, are being executed or amended (as applicable) to incorporate or adopt a new benchmark interest rate to replace the LIBOR Screen Rate, or

(d) for any reason the LIBOR Screen Rate with respect to any Loan does not adequately and fairly reflect the cost to the Lenders of funding such Loan.

"Lien" means any mortgage, land charge, pledge, hypothecation, assignment, security transfer of assets, deposit arrangement, encumbrance, lien (statutory or other), charge or preference, priority or other security interest or preferential arrangement in the nature of a security interest of any kind or nature whatsoever (including any conditional sale or other title retention agreement, any easement, right of way or other encumbrance on title to real property, and any financing lease having substantially the same economic effect as any of the foregoing).

"Liquidity" means, as of any date, an amount equal to Unrestricted Cash as of such date.

"Loan" means an extension of credit by a Lender to the Borrower under Article II in the form of a Term A Loan, a Term B-1 Loan, a Term B-2 Loan, a Term B-3 Loan, a Term B-4 Loan or a Term C Loan.

"Loan Documents" means this Agreement, each Note, each Joinder Agreement (or such other documents as the Administrative Agent shall reasonably request pursuant to Section 7.12 for such purpose), each Collateral Document, the Disclosure Letter, the Fee Letter, any intercreditor agreement entered into in connection with Permitted Senior Revolving Credit Indebtedness, each agreement entered into in accordance with the terms of Section 2.14 and any other agreement, instrument or document designated by its terms as a "Loan Document"; provided, that, for the avoidance of doubt, the Share Purchase Agreement, the ROFR Side Letter and any document related to the Share Purchase Agreement or the ROFR Side Letter (for the avoidance of doubt, other than any document described in the text preceding this proviso), in each case, shall not be "Loan Documents".

"Loan Notice" means a notice of a Borrowing of Loans pursuant to Section 2.02(a), which shall be substantially in the form of Exhibit A.

"Loan Parties" means, collectively, the Borrower and each Guarantor.

"Management Determination" has the meaning set forth in Section 4.12(d)(ii).

"Master Agreement" has the meaning set forth in the definition of "Swap Contract".

"Material Adverse Effect" means (a) a material adverse change in, or a material adverse effect upon, the business, financial performance or condition, operations (including the financial results thereof), assets or properties of the Borrower and its Subsidiaries taken as a whole, (b) a material impairment of the rights and remedies of the Administrative Agent or any Lender under any Loan Document to which it is a party or a material impairment in the perfection, value or priority of the Administrative Agent's security interests in the Collateral, (c) an impairment of the ability of any Loan Party to perform its material obligations under any Loan Document to which it is a party or (d) a material adverse effect upon the legality, validity, binding effect or enforceability against any Loan Party of any Loan Document to which it is a party.

"Material Contracts" means all (a) employment agreements covering the management of any Loan Party or any Subsidiary, (b) collective bargaining agreements or other labor agreements covering any employees of any Loan Party or any Subsidiary, (c) agreements for managerial, consulting or similar services to which any Loan Party or any Subsidiary is a party or by which it is bound, (d) agreements regarding any Loan Party or any Subsidiary, its assets or operations or any investment therein to which any of its equityholders is a party or by which it is bound, (e) real estate leases, licenses of IP Rights or other lease or license agreements to which any Loan Party or any Subsidiary is a party, either as lessor or lessee, or as licensor or licensee (other than licenses arising from the purchase of "off the shelf" products), (f) customer, sales, distribution or supply agreements to which any Loan Party or any Subsidiary is a party, in each case with respect to the preceding clauses (a), (c), (d) and (e) requiring payment of more than $500,000 in any year, and with respect to the preceding clause (f), requiring payment of more than $750,000 in any year, (g) any other Contract to which any Loan Party or any Subsidiary is a party that (i) relates to any Product or any Product Commercialization and Development Activity and (ii) is reasonably expected to (A) result in payments or receipts (including royalty, licensing or similar payments) made to any Loan Party or any of its Subsidiaries in an aggregate amount in excess of $750,000 in any period of twelve (12) consecutive months or (B) require payments or expenditures

(including royalty, licensing or similar payments) made by any Loan Party or any of its Subsidiaries in an aggregate amount in excess of $750,000 in any period of twelve (12) consecutive months or (h) any other agreements or instruments to which any Loan Party or any Subsidiary is a party, and the breach, nonperformance, termination or cancellation of which, or the failure of which to renew, could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

"Material IP Rights" means all Business IP Rights, whether owned or licensed as of the Effective Date, or acquired, developed or otherwise licensed or obtained by a Loan Party or any of their respective Subsidiaries after the Effective Date (x) the loss of which could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect or (y) that has a fair market value in excess of $750,000.

"Maturity Date" means September 30, 2025; provided, that, if such date is not a Business Day, the Maturity Date shall be the first Business Day immediately preceding such date.

"Maximum French Guaranteed Amount" has the meaning set forth in Section 4.09(a)(ii).

"Maximum Rate" has the meaning set forth in Section 11.09.

"Moody's" means Moody's Investors Service, Inc. and any successor thereto.

"Mortgages" means the mortgages, deeds of trust or deeds to secure debt that purport to grant to the Administrative Agent, for the benefit of the Secured Parties, a security interest in the fee interest of any Loan Party in real property (other than Excluded Property).

"Multiemployer Plan" means any employee benefit plan of the type described in Section 4001(a)(3) of ERISA, to which the Borrower or any ERISA Affiliate makes or is obligated to make contributions, or during the preceding five plan years, has made or been obligated to make contributions.

"Multiple Employer Plan" means any Plan which has two or more contributing sponsors (including the Borrower or any ERISA Affiliate) at least two of whom are not under common control, as such a plan is described in Section 4064 of ERISA.

"Net Cash Proceeds" means the aggregate cash or Cash Equivalents proceeds received by any Loan Party or any Subsidiary in respect of any Disposition, Debt Issuance, Involuntary Disposition or Extraordinary Receipts, net of (a) reasonable direct costs incurred in connection therewith (including, without limitation, legal, accounting and investment banking fees, and sales commissions), (b) taxes paid or payable as a result thereof, (c) in the case of any Disposition, the amount necessary to retire any Indebtedness secured by a Permitted Lien (ranking senior to any Lien of the Administrative Agent) on the related property and (d) in the case of any Extraordinary Receipt consisting of insurance and condemnation proceeds, such proceeds to the extent applied to the repair or replacement of the applicable property within one (1) year after receipt thereof; it being understood that "Net Cash Proceeds" shall include, without limitation, any cash or Cash Equivalents received upon the sale or other disposition of any non-cash consideration received by any Loan Party or any Subsidiary in any Disposition, Debt Issuance, Involuntary Disposition or Extraordinary Receipt.

"Non-Consenting Lender" means any Lender that does not approve any consent, waiver or amendment that (a) requires the approval of all Lenders or all affected Lenders in accordance with the terms of Section 11.01 and (b) has been approved by the Required Lenders.

"Note" or "Notes" means the Term A Notes, the Term B-1 Notes, the Term B-2 Notes, the Term B-3 Notes, the Term B-4 Notes or the Term C Notes, individually or collectively, as appropriate.

"Obligations" means (a) all advances to, and all debts, liabilities, obligations, covenants and duties of, any Loan Party arising under any Loan Document or otherwise with respect to any Loan and (b) all costs and expenses incurred in connection with enforcement and collection of the foregoing, including the fees, charges and disbursements of counsel, in each case whether direct or indirect (including those acquired by assumption), absolute or contingent, due or to become due, now existing or hereafter arising and including interest and fees that accrue after the commencement by or against any Loan Party or any Affiliate thereof pursuant to any proceeding under any Debtor Relief Laws naming such Person as the debtor in such proceeding, regardless of whether such interest and fees are allowed claims in such proceeding.

"OFAC" means the Office of Foreign Assets Control of the United States Department of the Treasury.

"Organization Documents" means, (a) with respect to any corporation, the certificate or articles of incorporation and the bylaws (or equivalent or comparable constitutive documents with respect to any non-U.S. jurisdiction), (b) with respect to any BVI business company, the certificate of incorporation and the memorandum and articles of association of such company, (c) with respect to any limited liability company, the certificate or articles of formation or organization and operating agreement or limited liability company agreement (or equivalent or comparable documents with respect to any non-U.S. jurisdiction), and (d) with respect to any partnership, joint venture, trust or other form of business entity, the partnership, joint venture or other applicable agreement of formation or organization and any agreement, instrument, filing or notice with respect thereto filed in connection with its formation or organization with the applicable Governmental Authority in the jurisdiction of its formation or organization and, if applicable, any certificate or articles of formation or organization of such entity.

"Outstanding Amount" means with respect to any Loans on any date, the aggregate outstanding principal amount thereof after giving effect to any borrowings and prepayments or repayments of any Loans occurring on such date.

"Parallel Debt" has the meaning set forth in Section 11.21.

"Participant" has the meaning set forth in Section 11.06(d).

"Patents" means, collectively, all patents and all patent applications and registrations (whether issued, established or registered or recorded in the United States or any other country or any political subdivision thereof) and all tangible embodiments of the foregoing, together with any and all (a) rights and privileges arising under applicable Law and international treaties and conventions with respect to the use of any patents, (b) Inventions and improvements described and claimed therein, (c) reissues, divisions, continuations, renewals, extensions and continuations-in-part thereof and amendments thereto, (d) income, fees, royalties, damages, claims and payments now or hereafter due and/or payable thereunder and with respect thereto including damages and payments for past, present or future infringements thereof, (e) rights corresponding thereto throughout the world and (f) rights to sue for past, present or future infringements thereof.

"PBGC" means the Pension Benefit Guaranty Corporation or any successor thereto.

"Pension Funding Rules" means the rules of the Internal Revenue Code and ERISA regarding minimum required contributions (including any installment payment thereof) to Pension Plans and set

forth in Sections 412, 430, 431, 432 and 436 of the Internal Revenue Code and Sections 302, 303, 304 and 305 of ERISA.

"Pension Plan" means any employee pension benefit plan (including a Multiple Employer Plan or a Multiemployer Plan) that is maintained or is contributed to by the Borrower and any ERISA Affiliate and is either covered by Title IV of ERISA or is subject to minimum funding standards under Section 412 of the Internal Revenue Code.

"Perceptive Warrant" means that certain Warrant Certificate dated as of September 30, 2016 issued by the Borrower in favor of Perceptive Credit Holdings, LP.

"Permitted Acquisition" means an Investment consisting of an Acquisition by a Loan Party whether by purchase, merger or otherwise (whether in one or a series of related transactions); provided, that:

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

(b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all applicable Law and in conformity with all applicable governmental, shareholder and third party consents and approvals;

(c) in the case of an acquisition of Equity Interests of another Person, all of such Equity Interests shall be owned one hundred percent (100%) by such Loan Party or a Wholly Owned Subsidiary of such Loan Party, and such Loan Party shall take, or cause to be taken, each of the actions set forth in Section 7.12 and Section 7.14, if applicable, within the applicable time periods set forth therein;

(d) in the case of the Acquisition of assets, all assets acquired shall be owned by a Loan Party and such Loan Party shall take, or cause to be taken, within the time periods set forth in Section 7.14 and/or in the Collateral Documents, all necessary actions to comply with Section 7.14(b);

(e) such acquired Person (in the case of an Acquisition of Equity Interests) or assets (in the case of an Acquisition of assets, a Product or a line of business or division) (i) shall be engaged or used, as the case may be, in (A) a similar or reasonably related business or line of business or (B) a business or line of business that is reasonably related or similar to those in which the Loan Parties and their respective Subsidiaries are engaged as of the Effective Date or (ii) shall have a reasonably related or similar customer base as the Loan Parties and their respective Subsidiaries;

(f) on a Pro Forma Basis after giving effect to such Acquisition, the Loan Parties and their respective Subsidiaries shall be in compliance with the financial covenants set forth in Sections 8.16 and 8.17 as of the last day of the four fiscal quarter period most recently ended for which financial statements have been delivered to the Administrative Agent pursuant to Section 7.01(a) or (b)(i);

(g) in the case of an Acquisition of the Equity Interests of another Person, the Board of Directors of such other Person shall have duly approved such Acquisition;

(h) the purchase price (or equivalent consideration) for such Acquisition shall be paid only in cash or Qualified Capital Stock of the Borrower and (i) to the extent such purchase price is paid in cash, when taken together with all other Acquisitions consummated or effected for cash consideration since the Effective Date, does not exceed $5,000,000 in the aggregate, or (ii) to the extent such purchase price is paid in Qualified Capital Stock of the Borrower, when taken together with all other Acquisitions consummated or effected for Qualified Capital Stock consideration since the Effective Date, does not exceed the fair market value of $10,000,000 (with fair market value being determined in good faith by the Borrower's Board of Directors at the time of the applicable Acquisition) in the aggregate; and

(i) the Loan Parties shall have provided the Administrative Agent with at least ten (10) Business Days' 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 Loan Parties or their respective Subsidiaries, as applicable, prior to such Acquisition, and the Administrative Agent shall have received a certificate of a Responsible Officer of the Borrower (prepared in reasonable detail) disclosing the Borrower's reasonable, good faith belief as to any contingent liabilities and prospective research and development costs associated with the Person or assets being acquired.

"Permitted Liens" means, at any time, Liens in respect of property of any Loan Party or any of its Subsidiaries permitted to exist at such time pursuant to the terms of Section 8.01.

"Permitted Refinancing" means, with respect to any Indebtedness, any extensions, renewals and replacements of such Indebtedness; provided, that, such extension, renewal or replacement (a) shall not increase the outstanding principal amount of such Indebtedness (other than by the aggregate amount of any fees and expenses incurred in connection with such refinancing and any reasonable premium paid in connection with such refinancing), (b) contains terms relating to outstanding principal amount, amortization, maturity, collateral (if any) and subordination (if any), and other material terms taken as a whole no less favorable in any material respect to the Loan Parties and their respective Subsidiaries or the Secured Parties than the terms of any agreement or instrument governing such existing Indebtedness, (c) shall have an applicable interest rate or equivalent yield which does not exceed the interest rate or equivalent yield of the Indebtedness being extended, renewed or replaced, (d) shall not contain any new requirement to grant any Lien or to give any Guarantee that was not an existing requirement of the Indebtedness being extended, renewed or replaced and (e) after giving effect to such extension, renewal or replacement, no Default or Event of Default shall have occurred (or would reasonably be expected to occur) as a result thereof.

"Permitted Sale and Leaseback Transaction" means, with respect to any Loan Party or any Subsidiary, any Sale and Leaseback Transaction whereby such Loan Party or such Subsidiary shall sell fixed assets to any Person and thereafter rent or lease such fixed assets for the same or a similar purpose, in each case, entered into in connection with the incurrence by such Loan Party or Subsidiary of Indebtedness permitted by Section 8.03(e); provided, that, (a) such Sale and Leaseback Transaction shall be consummated within six (6) months of the purchase of the applicable fixed asset(s) (or, in the case of any such fixed assets owned by such Loan Party or such Subsidiary as of the Effective Date, within six (6) months of the Effective Date) and (b) the fixed assets that are the subject of such Sale and Leaseback Transaction shall be financed with Indebtedness incurred in reliance on Section 8.03(e).

"Permitted Senior Revolving Credit Documents" means each agreement, instrument and document entered into by Establishment Labs Sociedad Anonima in connection with any Permitted Senior Revolving Credit Indebtedness, in each case in form and substance satisfactory to the Administrative Agent, as the same may be amended, modified, extended, restated, replaced or

supplemented from time to time subject to the terms and provisions of the intercreditor agreement entered into by the Administrative Agent in connection therewith.

"Permitted Senior Revolving Credit Indebtedness" means senior secured Indebtedness of Establishment Labs Sociedad Anonima which satisfies the following requirements: (a) the Loan Parties shall have delivered to the Administrative Agent and the Lenders the applicable Permitted Senior Revolving Credit Documents prior to incurrence of the Permitted Senior Revolving Credit Indebtedness thereunder, in each case certified by a Responsible Officer of Establishment Labs Sociedad Anonima, (b) the Administrative Agent shall have approved the financial institution providing such Permitted Senior Revolving Credit Indebtedness (each such financial institution, a "Permitted Senior Revolving Credit Lender") and (c) no Loan Party nor any Subsidiary of a Loan Party (in each case, other than Establishment Labs Sociedad Anonima) shall Guarantee, or provide a Lien with respect to, such Indebtedness.

"Permitted Senior Revolving Credit Lender" has the meaning set forth in the definition of "Permitted Senior Revolving Credit Indebtedness."

"Permitted Senior Revolving Credit Priority Collateral" has the meaning set forth in Section 8.03(g).

"Person" means any natural person, corporation, limited liability company, trust, joint venture, association, company, partnership, Governmental Authority or other entity.

"Plan" means any employee benefit plan within the meaning of Section 3(3) of ERISA (including a Pension Plan), and public or private, statutory or in addition to statutory requirements, maintained for employees of the Borrower or any of its Subsidiaries or any of their respective Affiliates, or any ERISA Affiliate or any such Plan to which the Borrower or any of its Subsidiaries or any of their respective Affiliates or any ERISA Affiliate is required to contribute, sponsor, maintain, or contribute on behalf of any of its employees.

"Pledge Agreements" means, collectively, the U.S. Pledge Agreements, the Brazilian Share Pledge Agreement and the Belgian Share Pledge Agreement.

"PMA" has the meaning set forth in the definition of "Device Clearance Application".

"Prime Rate" means, with respect to any Interest Period, the fluctuating rate per annum equal to the highest rate published in the "Money Rates" section of The Wall Street Journal as the "prime rate" then in effect (or, if such source is not available for any reason, such alternative source as determined by the Administrative Agent) on the first Business Day of such Interest Period; provided, that, the "Prime Rate" initially shall be set on the first Business Day of the applicable LIBOR Unavailability Period for the Interest Period in which such LIBOR Unavailability Period commences.

"Pro Forma Basis", "Pro Forma Compliance" and "Pro Forma Effect" means, in respect of a Specified Transaction, that such Specified Transaction and the following transactions in connection therewith (to the extent applicable) shall be deemed to have occurred as of the first day of the applicable period for the applicable covenant or requirement: (a)(i) with respect to any Disposition, Involuntary Disposition or sale, transfer or other disposition that results in a Person ceasing to be a Subsidiary, income statement and cash flow statement items (whether positive or negative) attributable to the Person or property disposed of shall be excluded and (ii) with respect to any Acquisition or Investment, income statement and cash flow statement items (whether positive or negative) attributable to the Person or property acquired shall be included to the extent relating to any period applicable in such calculations to

the extent (A) such items are not otherwise included in such income statement items for the Borrower and is Subsidiaries in accordance with GAAP or in accordance with any defined terms set forth in Section 1.01 and (B) such items are supported by financial statements or other information reasonably satisfactory to the Administrative Agent, (b) any retirement of Indebtedness and (c) any incurrence or assumption of Indebtedness by any Loan Party or any Subsidiary (and if such Indebtedness has a floating or formula rate, such Indebtedness shall have an implied rate of interest for the applicable period for purposes of this definition determined by utilizing the rate which is or would be in effect with respect to such Indebtedness as at the relevant date of determination); provided, that, Pro Forma Basis, Pro Forma Compliance and Pro Forma Effect in respect of any Specified Transaction shall be calculated in a reasonable and factually supportable manner and certified by a Responsible Officer of the Borrower.

"Product" means (a) those Devices set forth (and described in reasonable detail) on Schedule 1.01(a) to the Disclosure Letter and (b) any current or future Device developed, manufactured, licensed, marketed, sold or otherwise commercialized by any Loan Party or any Subsidiary, including any such Device currently in development.

"Product Agreement" means, with respect to any Product, any contract, license, document, instrument, interest (equity or otherwise) or the like under which one or more Persons grants or receives (a) any right, title or interest with respect to any Product Commercialization and Development Activities in respect of such Product or (b) any right to exclude any other Person from engaging in, or otherwise restricting any right, title or interest as to, any Product Commercialization and Development Activities with respect to such Product, including any contract with suppliers, manufacturers, distributors, clinical research organizations, hospitals, group purchasing organizations, wholesalers, pharmacies or any other Person related to such entity.

"Product Assets" means, with respect to any Product, (a) any and all rights, title and interest of any Loan Party or any Subsidiary in any assets relating to such Product or any Product Commercialization and Development Activities with respect to such Product, (b) all Product Related Information with respect to such Product or any related Product Commercialization and Development Activities, (c) any Product Agreement related to such Product or any such Product Commercialization and Development Activities, (d) any IP Rights, Regulatory Approvals and similar assets with respect to such Product or any such Product Commercialization and Development Activities and (e) all rights, title and interests in any other property, tangible or intangible, manifesting or otherwise in respect of such Product or any such Product Commercialization and Development Activities, including, without limitation, inventory, accounts receivable or similar rights to receive money or payment pertaining thereto and all proceeds of the foregoing.

"Product Authorizations" means any and all Regulatory Approvals (including all applicable IDEs, PMAs, 510(k)s, Device Clearance Applications, Product Standards, supplements, amendments, pre- and post- approvals, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), clearances, licenses, notifications, registrations or authorizations of or required by any applicable Regulatory Authority in each case necessary 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, whether U.S. or non-U.S.

"Product Commercialization and Development Activities" means, with respect to any Product, any combination of research, development, manufacture, import, use, sale, licensing, importation, storage, labeling, marketing, promotion, supply, distribution, testing, 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.

"Product Related Information" means, with respect to any Product, all materials and information owned or possessed by the Loan Parties or any of their respective Subsidiaries that is necessary or required for any Product Commercialization and Development Activities relating to such Product, including (a) brand materials, packaging and other trade dress, 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, (b) clinical data, information included or supporting any Product Authorization or other Regulatory Approval, 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 relating to product development, manufacture and use, (c) litigation and dispute records, and accounting records, (d) all documents, records and files relating to IP Rights, including all correspondence from and to third parties (including IP Rights counsel and patent, trademark and other intellectual property registries, including the United States Patent and Trademark Office) and (e) all other information, techniques and know-how necessary or required in connection with the Product Commercialization and Development Activities for any Product.

"Product Revenues" means, for any period, for the Borrower and its Subsidiaries on a consolidated basis, all amounts paid to and received by the Borrower and its Subsidiaries in the ordinary course of business that, in accordance with GAAP, would be classified as net revenue, excluding upfront payments, milestones, royalties and other similar one-time payments received by the Borrower and its Subsidiaries that are not related to the sale of products or services; provided, that, "Product Revenues" shall exclude the revenues generated by any Subsidiary to the extent that the declaration or payment of dividends or similar distributions by that Subsidiary of the income resulting from such revenues is not at the time permitted by operation of the terms of its Organization Documents or any agreement, instrument, judgment, decree, order, statute, rule or governmental regulation applicable to that Subsidiary.

"Product Standards" means all safety, quality and other specifications and standards applicable to any Product, including all medical device and other standards promulgated by Standards Bodies.

"Proposed Term Sheet" has the meaning set forth in Section 2.13(b).

"Proposed Terms" has the meaning set forth in Section 2.13(b).

"Qualified Capital Stock" of any Person means any Equity Interests of such Person that are not Disqualified Capital Stock.

"Qualified Loan Party" means (a) any BVI Loan Party, (b) any Costa Rican Loan Party, (c) any U.S. Loan Party or (d) any Loan Party (other than any BVI Loan Party, Costa Rican Loan Party or U.S. Loan Party), that is organized in a jurisdiction (as designated by the Administrative Agent to the Borrower in writing): (i) that permits such Loan Party to grant to the Administrative Agent, for the benefit of the Secured Parties, Liens that are first priority and perfected in substantially all of the assets of such Loan Party (other than Excluded Property), pursuant to Section 7.14 and the Collateral Documents and (ii) the Laws of which, in the reasonable determination of the Administrative Agent, provide the Administrative Agent with the ability to enforce such Liens in a manner that is substantially equivalent to the ability to enforce Liens against a U.S. Loan Party.

"Qualifying Control Agreement" means an agreement among a Loan Party, a depository institution or securities intermediary and the Administrative Agent (or the Trustee), for the benefit of the Secured Parties, which agreement is in form and substance reasonably satisfactory to the Administrative

Agent and which provides the Administrative Agent (or the Trustee, as applicable) with "control" (as such term is used in Article 9 of the Uniform Commercial Code) or dominion over the deposit account(s) or securities account(s) described therein.

"Real Property Security Documents" means with respect to the fee interest of any Loan Party in any real property (other than Excluded Property):

(a) a fully executed and notarized Mortgage encumbering the fee interest of such Loan Party in such real property;

(b) if requested by the Administrative Agent in its sole discretion, maps or plats of an as-built survey of the sites of such real property certified to the Administrative Agent and the title insurance company issuing the policies referred to in clause (c) of this definition in a manner satisfactory to each of the Administrative Agent and such title insurance company, dated a date satisfactory to each of the Administrative Agent and such title insurance company by an independent professional licensed land surveyor, which maps or plats and the surveys on which they are based shall be sufficient to delete any standard printed survey exception contained in the applicable title policy and be made in accordance with the Minimum Standard Detail Requirements for Land Title Surveys jointly established and adopted by the American Land Title Association and the American Congress on Surveying and Mapping in 2011 with items 2, 3, 4, 6(b), 7(a), 7(b)(1), 7(c), 8, 9, 10, 11(a), 13, 14, 16,17, 18 and 19 on Table A thereof completed;

(c) ALTA mortgagee title insurance policies issued by a title insurance company acceptable to the Administrative Agent with respect to such real property, assuring the Administrative Agent that the Mortgage covering such real property creates a valid and enforceable first priority mortgage lien on such real property, free and clear of all defects and encumbrances except Permitted Liens, which title insurance policies shall otherwise be in form and substance satisfactory to the Administrative Agent and shall include such endorsements as are requested by the Administrative Agent;

(d) evidence as to (i) whether such real property is in an area designated by the Federal Emergency Management Agency as having special flood or mud slide hazards (a "Flood Hazard Property") and (ii) if such real property is a Flood Hazard Property, (A) whether the community in which such real property is located is participating in the National Flood Insurance Program, (B) the applicable Loan Party's written acknowledgment of receipt of written notification from the Administrative Agent (1) as to the fact that such real property is a Flood Hazard Property and (2) as to whether the community in which each such Flood Hazard Property is located is participating in the National Flood Insurance Program and (C) copies of insurance policies or certificates of insurance of the Borrower and its Subsidiaries evidencing flood insurance satisfactory to the Administrative Agent and naming the Administrative Agent and its successors and/or assigns as sole loss payee on behalf of the Secured Parties;

(e) if requested by the Administrative Agent in its sole discretion, an environmental assessment report, as to such real property, in form and substance and from professional firms acceptable to the Administrative Agent;

(f) if requested by the Administrative Agent in its sole discretion, evidence reasonably satisfactory to the Administrative Agent that such real property, and the uses of such real property, are in compliance in all material respects with all applicable zoning laws (the evidence submitted as to which should include the zoning designation made for such real

property, the permitted uses of such real property under such zoning designation and, if available, zoning requirements as to parking, lot size, ingress, egress and building setbacks); and

(g) if requested by the Administrative Agent in its sole discretion, an opinion of legal counsel to the Loan Party granting the Mortgage on such real property, addressed to the Administrative Agent and each Lender, in form and substance reasonably acceptable to the Administrative Agent.

"Recipient" means the Administrative Agent, any Lender, and any other recipient of any payment by or on account of any obligation of any Loan Party under any Loan Document.

"Referral Source" has the meaning set forth in Section 6.16(b).

"Register" has the meaning set forth in Section 11.06(c).

"Regulation" means Regulation (EU) 2015/848 of the European Parliament and of the Council of 20 May 2015 on insolvency proceedings.

"Regulatory Approval" means any Governmental Approval relating to any Product or any Product Commercialization and Development Activities, including any Product Authorizations with respect thereto.

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

"Related Parties" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors, sub-advisors and representatives of such Person and of such Person's Affiliates.

"Relativity Warrant" means that certain Warrant Certificate dated as of September 30, 2016 issued by the Borrower in favor of Relativity Healthcare Fund, LLC.

"Reportable Event" means any of the events set forth in Section 4043(c) of ERISA, other than events for which the thirty-day notice period has been waived.

"Required Lenders" means, at any time, Lenders having Total Credit Exposures representing more than fifty percent (50%) of the Total Credit Exposures of all Lenders. The Total Credit Exposure of any Defaulting Lender shall be disregarded in determining Required Lenders at any time.

"Responsible Officer" means a director, the chief executive officer, president, chief legal officer, chief financial officer, treasurer, assistant treasurer or controller of a Loan Party and, solely for purposes of the delivery of certificates pursuant to Sections 5.02 or 7.12, the secretary or any assistant secretary of a Loan Party. Any document delivered hereunder that is signed by a Responsible Officer of a Loan Party shall be conclusively presumed to have been authorized by all necessary corporate, partnership and/or other action on the part of such Loan Party and such Responsible Officer shall be conclusively presumed to have acted on behalf of such Loan Party.

"Restricted" means, when referring to cash or Cash Equivalents of the Loan Parties, that such cash or Cash Equivalents (a) appear (or would be required to appear) as "restricted" on a consolidated

balance sheet of the Borrower and its Subsidiaries as determined in accordance with GAAP, or (b) are subject to any Lien in favor of any Person (other than bankers' liens and rights of setoff) other than the Administrative Agent for the benefit of the Secured Parties.

"Restricted Payment" means (a) any dividend or other distribution, direct or indirect, on account of any shares (or equivalent) of any class of Equity Interests of any Loan Party or any of its Subsidiaries, now or hereafter outstanding, (b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of any shares (or equivalent) of any class of Equity Interests of any Loan Party or any of its Subsidiaries, now or hereafter outstanding, (c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Equity Interests of any Loan Party or any of its Subsidiaries, now or hereafter outstanding and (d) any payment made in cash to holders of Convertible Indebtedness in excess of the original principal (or notional) amount thereof and interest thereon (and, to the extent not permissible to be satisfied with shares of common stock, customary redemption, mandatory conversion or similar premiums, if any).

"ROFR Side Letter" means that certain letter agreement dated as of the Funding Date by and between the Borrower and the Lenders from time to time party thereto with respect to the purchase of certain Equity Interests of the Borrower in connection with a sale of the Equity Interests of the Borrower.

"S&P" means Standard & Poor's Financial Services LLC, a subsidiary of The McGraw-Hill Companies, Inc., and any successor thereto.

"Sale and Leaseback Transaction" means, with respect to any Loan Party or any Subsidiary, any arrangement, directly or indirectly, with any Person whereby such Loan Party or such Subsidiary shall sell or transfer any property used or useful in its business, whether now owned or hereafter acquired, and thereafter rent or lease such property or other property that it intends to use for substantially the same purpose or purposes as the property being sold or transferred.

"Sanction(s)" means any sanction administered or enforced by the United States government (including, without limitation, OFAC), the United Nations Security Council, the European Union, Her Majesty's Treasury ("HMT"), the Costa Rican Institute of Drugs or other relevant sanctions authority.

"SEC" means the Securities and Exchange Commission, or any Governmental Authority succeeding to any of its principal functions.

"Second Amendment Effective Date" means June 15, 2018.

"Secured Obligor" has the meaning set forth in Section 4.12(b).

"Secured Parties" means, collectively, the Administrative Agent, the Lenders and the Indemnitees.

"Securities Act" means the Securities Act of 1933.

"Securitization Transaction" means, with respect to any Person, any financing transaction or series of financing transactions (including factoring arrangements) pursuant to which such Person or any Subsidiary of such Person may sell, convey or otherwise transfer, or grant a security interest in, accounts, payments, receivables, rights to future lease payments or residuals or similar rights to payment to a special purpose subsidiary or affiliate of such Person.

"Security Agent" has the meaning set forth in Section 10.01(k)(i).

"Security Agreements" means, collectively, the U.S. Security Agreement, the U.S. IP Security Agreement, the U.S. Deposit Account Security Agreement, the Belgian Receivables Pledge Agreement, Brazilian Receivables Pledge Agreement, the Costa Rican IP Security Agreement, the Costa Rican Security Trust Agreement and the French Transaction Security Documents.

"Share Purchase Agreement" means that certain Series F Share Purchase Agreement dated as of the Funding Date by and between the Borrower and the Lenders.

"Solvent" or "Solvency" means, with respect to (a) any BVI Loan Party as of a particular date, that on such date such BVI Loan Party is "solvent" as such term is determined under Section 8 of the Insolvency Act, 2003 of the British Virgin Islands and (b) any Person (including, for the avoidance of doubt, any BVI Loan Party) as of a particular date, that on such date (i) such Person is able to pay its debts and other liabilities, contingent obligations and other commitments as they mature in the ordinary course of business, (ii) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay as such debts and liabilities mature in their ordinary course, (iii) such Person is not engaged in a business or a transaction, and is not about to engage in a business or a transaction, for which such Person's property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which such Person is engaged or is to engage, (iv) the fair value of the property of such Person is greater than the total amount of liabilities, including, without limitation, contingent liabilities, of such Person and (v) the present fair salable value of the assets 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 computing the amount of contingent liabilities at any time, it is intended that such liabilities will be computed at the amount which, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"Spanish Civil Procedural Law" means the Spanish Law 1/2000, of 7 January, on Civil Procedural Act (Ley de Enjuiciamiento Civil), as amended from time to time.

"Spanish Companies Law" means Spanish Royal Legislative Decree 1/2010, of 2 July, approving the Spanish Capital Companies Law (Ley de Sociedades de Capital), as amended from time to time.

"Spanish Guarantor" means a Guarantor incorporated in Spain.

"Spanish Insolvency Law" means the Spanish Law 22/2003, of 9 July, on Insolvency (Ley Concursal) as amended or restated from time to time.

"Spanish Public Document" means a documento público, being an escritura pública, póliza or efecto intervenido por fedatario público.

"Specified Cure Contribution" has the meaning set forth in Section 8.16(b)(i).

"Specified Deposit Account" has the meaning set forth in the U.S. Deposit Account Security Agreement.

"Specified Transaction" means (a) any Acquisition, any Disposition, any sale, transfer or other disposition that results in a Person ceasing to be a Subsidiary, any Involuntary Disposition, or any Investment that results in a Person becoming a Subsidiary, in each case, whether by merger, amalgamation, consolidation or otherwise or any incurrence or repayment of Indebtedness or (b) any

other event that by the terms of the Loan Documents requires Pro Forma Compliance with a test or covenant, calculation as to Pro Forma Effect with respect to a test or covenant or requires such test or covenant to be calculated on a Pro Forma Basis.

"Standard Bodies" means applicable organizations that create, sponsor or maintain safety, quality or other standards, including ISO, ANSI, CEN and SCC.

"Subsidiary" of a Person means a corporation, partnership, joint venture, limited liability company or other business entity of which a majority of the shares of Voting Stock is at the time beneficially owned, or the management of which is otherwise controlled, directly, or indirectly through one or more intermediaries, or both, by such Person. Unless otherwise specified, all references herein to a "Subsidiary" or to "Subsidiaries" shall refer to a Subsidiary or Subsidiaries of the Borrower.

"Swap Contract" means (a) any and all rate swap transactions, basis swaps, credit derivative transactions, forward rate transactions, commodity swaps, commodity options, forward commodity contracts, equity or equity index swaps or options, bond or bond price or bond index swaps or options or forward bond or forward bond price or forward bond index transactions, interest rate options, forward foreign exchange transactions, cap transactions, floor transactions, collar transactions, currency swap transactions, cross-currency rate swap transactions, currency options, spot contracts, or any other similar transactions or any combination of any of the foregoing (including any options to enter into any of the foregoing), whether or not any such transaction is governed by or subject to any master agreement, and (b) any and all transactions of any kind, and the related confirmations, which are subject to the terms and conditions of, or governed by, any form of master agreement published by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement (any such master agreement, together with any related schedules, a "Master Agreement"), including any such obligations or liabilities under any Master Agreement; provided, that, the term "Swap Contract" shall not include (i) phantom stock, stock option plans or similar plans providing for payments only on account of services provided by current or former directors, officers, employees or consultants of the Borrower or its Subsidiaries or (ii) any option or warrant agreement for the purchase of Equity Interests of the Borrower.

"Swap Termination Value" means, in respect of any one or more Swap Contracts, after taking into account the effect of any legally enforceable netting agreement relating to such Swap Contracts, (a) for any date on or after the date such Swap Contracts have been closed out and termination value(s) determined in accordance therewith, such termination value(s) and (b) for any date prior to the date referenced in clause (a), the amount(s) determined as the mark-to-market value(s) for such Swap Contracts, as determined based upon one or more mid-market or other readily available quotations provided by any recognized dealer in such Swap Contracts (which may include a Lender or any Affiliate of a Lender).

"Synthetic Lease" means any synthetic lease, tax retention operating lease, off-balance sheet loan or similar off-balance sheet financing arrangement whereby the arrangement is considered borrowed money indebtedness for tax purposes but is classified as an operating lease or does not otherwise appear on a balance sheet under GAAP.

"Taxes" has the meaning set forth in Section 3.01(a).

"Technical Information" means all trade secrets and other proprietary or confidential information, public information, non-proprietary know-how, any information of a scientific, technical or business nature in any form or medium, standards and specifications, conceptions, ideas, innovations, discoveries, Inventions, invention disclosures, all documented research, developmental, demonstration or engineering

work and all other information, data, plans, specifications, reports, summaries, experimental data, manuals, models, samples, know-how, technical information, systems, methodologies, computer programs, information technology and any other information.

"Term A Borrowing" means a borrowing consisting of simultaneous Term A Loans made by each of the Term A Lenders pursuant to Section 2.01(a).

"Term A Commitment" means, as to each Term A Lender, its obligation to make a Term A Loan to the Borrower pursuant to Section 2.01(a), in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Term A Commitments of all of the Term A Lenders as in effect on the Effective Date is THIRTY MILLION DOLLARS ($30,000,000).

"Term A Facility" means, at any time, (a) on or prior to the Funding Date, the aggregate amount of the Term A Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term A Loans of all Term A Lenders outstanding at such time.

"Term A Lender" means (a) at any time on or prior to the Funding Date, any Lender that has a Term A Commitment at such time and (b) at any time after the Funding Date, any Lender that holds one or more Term A Loans at such time.

"Term A Loan" means an advance made by any Term A Lender under the Term A Facility.

"Term A Note" has the meaning set forth in Section 2.09.

"Term B-1 Availability Period" means the period from and after October 31, 2017 (or such earlier date as may be agreed to by the Administrative Agent in its sole discretion) to the earliest of (a) June 30, 2019, (b) the date of termination of the Term B-1 Commitments pursuant to Section 2.04 and (c) the date of termination of the Term B-1 Commitments pursuant to Section 9.02.

"Term B-1 Borrowing" means a borrowing consisting of simultaneous Term B-1 Loans made by each of the Term B-1 Lenders pursuant to Section 2.01(b)(i).

"Term B-1 Commitment" means, as to each Term B-1 Lender, its obligation to make a Term B-1 Loan to the Borrower pursuant to Section 2.01(b)(i), in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Term B-1 Commitments of all of the Term B-1 Lenders as in effect on the Effective Date is FIVE MILLION DOLLARS ($5,000,000).

"Term B-1 Facility" means, at any time, (a) on or prior to the funding of the Term B-1 Loans, the aggregate amount of the Term B-1 Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term B-1 Loans of all Term B-1 Lenders outstanding at such time.

"Term B-1 Lender" means (a) at any time on or prior to the funding of the Term B-1 Loans, any Lender that has a Term B-1 Commitment at such time and (b) at any time after the funding of the Term B-1 Loans, any Lender that holds one or more Term B-1 Loans at such time.

"Term B-1 Loan" means an advance made by any Term B-1 Lender under the Term B-1 Facility.

"Term B-1 Note" has the meaning set forth in Section 2.09.

"Term B-2 Availability Period" means the period from and after the Funding Date to the earliest of (a) June 30, 2019, (b) the date of termination of the Term B-2 Commitments pursuant to Section 2.04 and (c) the date of termination of the Term B-2 Commitments pursuant to Section 9.02.

"Term B-2 Borrowing" means a borrowing consisting of simultaneous Term B-2 Loans made by each of the Term B-2 Lenders pursuant to Section 2.01(b)(ii).

"Term B-2 Commitment" means, as to each Term B-2 Lender, its obligation to make a Term B-2 Loan to the Borrower pursuant to Section 2.01(b)(ii), in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Term B-2 Commitments of all of the Term B-2 Lenders as in effect on the Effective Date is FIVE MILLION DOLLARS ($5,000,000).

"Term B-2 Facility" means, at any time, (a) on or prior to the funding of the Term B-2 Loans, the aggregate amount of the Term B-2 Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term B-2 Loans of all Term B-2 Lenders outstanding at such time.

"Term B-2 Lender" means (a) at any time on or prior to the funding of the Term B-2 Loans, any Lender that has a Term B-2 Commitment at such time and (b) at any time after the funding of the Term B-2 Loans, any Lender that holds one or more Term B-2 Loans at such time.

"Term B-2 Loan" means an advance made by any Term B-2 Lender under the Term B-2 Facility.

"Term B-2 Note" has the meaning set forth in Section 2.09.

"Term B-3 Availability Period" means the period from and after the Funding Date to the earliest of (a) September 30, 2019, (b) the date of termination of the Term B-3 Commitments pursuant to Section 2.04 and (c) the date of termination of the Term B-3 Commitments pursuant to Section 9.02.

"Term B-3 Borrowing" means a borrowing consisting of simultaneous Term B-3 Loans made by each of the Term B-3 Lenders pursuant to Section 2.01(b)(iii).

"Term B-3 Commitment" means, as to each Term B-3 Lender, its obligation to make a Term B-3 Loan to the Borrower pursuant to Section 2.01(b)(iii), in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Term B-3 Commitments of all of the Term B-3 Lenders as in effect on the Third Amendment Effective Date is TEN MILLION DOLLARS ($10,000,000).

"Term B-3 Facility" means, at any time, (a) on or prior to the funding of the Term B-3 Loans, the aggregate amount of the Term B-3 Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term B-3 Loans of all Term B-3 Lenders outstanding at such time.

"Term B-3 Lender" means (a) at any time on or prior to the funding of the Term B-3 Loans, any Lender that has a Term B-3 Commitment at such time and (b) at any time after the funding of the Term B-3 Loans, any Lender that holds one or more Term B-3 Loans at such time.

"Term B-3 Loan" means an advance made by any Term B-3 Lender under the Term B-3 Facility.

"Term B-3 Note" has the meaning set forth in Section 2.09.

"Term B-4 Availability Period" means the period from and after the Third Amendment Effective Date to the earliest of (a) December 31, 2019, (b) the date of termination of the Term B-4 Commitments

pursuant to Section 2.04 and (c) the date of termination of the Term B-4 Commitments pursuant to Section 9.02.

"Term B-4 Borrowing" means a borrowing consisting of simultaneous Term B-4 Loans made by each of the Term B-4 Lenders pursuant to Section 2.01(b)(iv).

"Term B-4 Commitment" means, as to each Term B-4 Lender, its obligation to make a Term B-4 Loan to the Borrower pursuant to Section 2.01(b)(iv), in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Term B-4 Commitments of all of the Term B-4 Lenders as in effect on the Third Amendment Effective Date is FIFTEEN MILLION DOLLARS ($15,000,000).

"Term B-4 Facility" means, at any time, (a) on or prior to the funding of the Term B-4 Loans, the aggregate amount of the Term B-4 Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term B-4 Loans of all Term B-4 Lenders outstanding at such time.

"Term B-4 Lender" means (a) at any time on or prior to the funding of the Term B-4 Loans, any Lender that has a Term B-4 Commitment at such time and (b) at any time after the funding of the Term B-4 Loans, any Lender that holds one or more Term B-4 Loans at such time.

"Term B-4 Loan" means an advance made by any Term B-4 Lender under the Term B-4 Facility.

"Term B-4 Note" has the meaning set forth in Section 2.09.

"Term C Availability Period" means the period from and after the institution of the Term C Commitments pursuant to Section 2.14 to the earliest of (a) December 31, 2020, (b) the date of termination of the Term C Commitments pursuant to Section 2.04 and (c) the date of termination of the Term C Commitments pursuant to Section 9.02.

"Term C Borrowing" means a borrowing consisting of simultaneous Term C Loans made by each of the Term C Lenders pursuant to Section 2.01(c).

"Term C Commitment" means, as to each Term C Lender, its obligation to make Term C Loans to the Borrower pursuant to Section 2.01(c). The aggregate principal amount of the Term C Commitments of all of the Term C Lenders shall not exceed TEN MILLION DOLLARS ($10,000,000.00).

"Term C Facility" means, at any time, (a) on or prior to the funding of the Term C Loans, the aggregate amount of the Term C Commitments at such time and (b) thereafter, the aggregate Outstanding Amount of the Term C Loans of all Term C Lenders outstanding at such time.

"Term C Lender" means (a) at any time at or prior to the funding of the Term C Loans, any Lender that has a Term C Commitment at such time and (b) at any time after the funding of the Term C Loans, any Lender that holds one or more Term C Loans at such time.

"Term C Loan" means an advance made by any Term C Lender under the Term C Facility.

"Term C Note" has the meaning set forth in Section 2.09.

"Third Amendment Effective Date" means June 17, 2019.

"Three-Month LIBOR" means, with respect to any Interest Period, a rate per annum equal to the greater of (x) two and one-half percent (2.50%) per annum and (y) the three-month London Interbank Offered Rate for deposits in Dollars at approximately 11:00 a.m. (London, England time), as determined by the Administrative Agent from the appropriate Bloomberg or Telerate page selected by the Administrative Agent (the "LIBOR Screen Rate") (or any successor thereto or similar source reasonably determined by the Administrative Agent from time to time), two (2) Business Days prior to the first Business Day of such Interest Period and rounded up to the nearest 1/16 of one percent (1.00%). The Administrative Agent's determination of interest rates shall be determinative in the absence of manifest error.

"Threshold Amount" means $750,000.

"Total Credit Exposure" means, as to any Lender at any time, the unused Commitments of such Lender at such time and the Outstanding Amount of all Loans of such Lender at such time.

"Trademarks" means, collectively, all trademarks (including service marks), slogans, logos, symbols, certification marks, collective marks, trade dress, uniform resource locators (URL's), domain names, corporate names and trade names, whether statutory or common law, whether registered or unregistered and whether established or registered in the United States or any other country or any political subdivision thereof, all registrations and applications for the foregoing and all tangible embodiments of the foregoing, together with, in each case, the goodwill symbolized thereby and any and all (a) rights and privileges arising under applicable Law and international treaties and conventions with respect to the use of any trademarks, (b) reissues, continuations, extensions and renewals thereof and amendments thereto, (c) income, fees, royalties, damages and payments now and hereafter due and/or payable thereunder and with respect thereto, including damages, claims and payments for past, present or future infringements thereof, (d) rights corresponding thereto throughout the world and (e) rights to sue for past, present and future infringements thereof.

"Trustee" means Intermanagement Costa Rica, Ltda., acting as fiduciary in the Costa Rican Security Trust Agreement.

"United States" and "U.S." mean the United States of America.

"Unrestricted Cash" means, at any time, the aggregate cash and Cash Equivalents of the Loan Parties (without duplication) that are not Restricted at such time.

"U.S. Deposit Account Security Agreement" means the U.S. deposit account security agreement dated as of the Funding Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by Establishment Labs Sociedad Anonima, a Costa Rica corporation, with respect to the Specified Deposit Account.

"U.S. IP Security Agreement" means the U.S. intellectual property security agreement dated as of the Funding Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by Establishment Labs Sociedad Anonima, a Costa Rica corporation, with respect to its U.S. intellectual property.

"U.S. Loan Party" means any Loan Party that is organized under the laws of any state of the United States or the District of Columbia.

"U.S. Pledge Agreements" means, collectively, (a) the U.S. pledge agreement dated as of the Funding Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by

each of the U.S. Loan Parties and each of the BVI Loan Parties other than the Borrower and (b) the U.S. pledge agreement dated as of the Funding Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by the Borrower.

"U.S. Security Agreement" means the U.S. security agreement dated as of the Funding Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by the U.S. Loan Parties and the BVI Loan Parties.

"VAT" mean a consumption or value-added tax, including any similar Tax which may be imposed in place thereof from time to time.

"Voting Stock" means, with respect to any Person, Equity Interests issued by such Person the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of directors (or persons performing similar functions) of such Person, even though the right so to vote has been suspended by the happening of such a contingency.

"Wholly Owned Subsidiary" means, as to any Person, (a) any corporation one hundred percent (100%) of whose Equity Interests is at the time owned by such Person and/or one or more Wholly Owned Subsidiaries of such Person and (b) any partnership, association, joint venture or other entity in which such Person and/or one or more Wholly Owned Subsidiaries of such Person owns one hundred percent (100%) of the Equity Interests at such time (other than, in the case of a Foreign Subsidiary with respect to the preceding clauses (a) or (b), director's qualifying shares and/or other nominal amounts of shares required to be held by Persons other than the Borrower and its Subsidiaries under applicable law). Unless otherwise specified, all references herein to a "Wholly Owned Subsidiary" or to "Wholly Owned Subsidiaries" shall refer to a Wholly Owned Subsidiary or Wholly Owned Subsidiaries of the Borrower.

"Withholding Agent" means any Loan Party, the Administrative Agent and any other Person required by applicable Law to withhold or deduct amounts from a payment made by or on account of any obligation of any Loan Party under any Loan Document.

"Write-Down and Conversion Powers" means, 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.

1.02 Other Interpretive Provisions.

With reference to this Agreement and each other Investment Document, unless otherwise specified herein or in such other Investment Document:

(a) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document (including the Loan Documents and any Organization Document) shall be construed as referring to such agreement, instrument or other document as from time to time amended, modified, extended, restated, replaced or supplemented from time to time (subject to any restrictions set forth herein or in any other Investment Document), (ii) any reference herein to any Person shall be construed to include such Person's successors and assigns, (iii) the words

"hereto", "herein," "hereof" and "hereunder," and words of similar import when used in any Investment Document, shall be construed to refer to such Investment Document in its entirety and not to any particular provision thereof, (iv) all references in any Investment Document to Articles, Sections, Preliminary Statements, Exhibits and Schedules shall be construed to refer to Articles and Sections of, and Preliminary Statements, Exhibits and Schedules to, the Investment Document in which such references appear, (v) any reference to any law shall include all statutory and regulatory provisions or determinations consolidating, amending, replacing or interpreting such law and any reference to any law or regulation shall, unless otherwise specified, refer to such law or regulation as amended, modified, extended, restated, replaced or supplemented from time to time, (vi) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer to any and all real and personal property and tangible and intangible assets and properties, including cash, securities, accounts and contract rights and (vii) the parties hereto have participated jointly in the negotiation and drafting of this Agreement and in the event an ambiguity or question of intent or interpretation arises, no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement.

(b) In the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including;" the words "to" and "until" each mean "to but excluding;" and the word "through" means "to and including."

(c) Section headings herein and in the other Investment Documents are included for convenience of reference only and shall not affect the interpretation of this Agreement or any other Investment Document.

1.03 Accounting Terms.

(a) Generally. Except as otherwise specifically prescribed herein, all accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data (including financial ratios and other financial calculations) required to be submitted pursuant to this Agreement shall be prepared in conformity with, GAAP applied on a consistent basis, as in effect from time to time, applied in a manner consistent with that used in preparing the Audited Financial Statements, except as otherwise specifically prescribed herein; provided, however, that, calculations of Attributable Indebtedness under any Synthetic Lease or the implied interest component of any Synthetic Lease shall be made by the Loan Parties in accordance with accepted financial practice in the United States and consistent with the terms of such Synthetic Lease. Notwithstanding the foregoing, for purposes of determining compliance with any covenant contained herein, Indebtedness of the Borrower and its Subsidiaries shall be deemed to be carried at 100% of the outstanding principal amount thereof, and the effects of FASB ASC 825 and FASB ASC 470-20 on financial liabilities shall be disregarded. The parties hereto acknowledge and agree that for purposes of all calculations hereunder, the principal amount of Convertible Indebtedness shall be the outstanding principal (or notional) amount thereof, valued at par.

(b) Changes in GAAP. The Loan Parties will provide a written summary of material changes in GAAP and in the consistent application thereof with each annual and quarterly financial statement delivered in accordance with Section 7.01. If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Loan Document, and either the Borrower or the Required Lenders shall so request, the Administrative Agent, the Lenders and the Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in GAAP (subject to the approval of

the Required Lenders); provided, that, until so amended, (i) such requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) the Loan Parties shall provide to the Administrative Agent and the Lenders financial statements and other documents required under this Agreement or as requested hereunder setting forth a reconciliation between calculations of such requirement made before and after giving effect to such change in GAAP. Notwithstanding any other provision contained herein, other than for purposes of the delivery of financial statements prepared in accordance with GAAP, all terms of an accounting or financial nature used herein shall be construed, all calculations herein shall be made, and all covenants shall be interpreted without giving effect to any change (whether occurring prior to or after the date hereof) in accounting for leases pursuant to GAAP resulting from the implementation of Financial Accounting Standards Board ASU No. 2016-02, Leases (Topic 842) (and, for the avoidance of doubt, (x) the terms "operating lease," "capital lease" and "Capital Lease" shall be interpreted without giving effect to any change in accounting for leases pursuant to GAAP resulting from the implementation of Financial Accounting Standards Board ASU No. 2016-02, Leases (Topic 842) and (y) the amount of total assets (or any similar term or calculation) at any time shall be determined without giving effect to any change in accounting for leases pursuant to GAAP resulting from the implementation of Financial Accounting Standards Board ASU No. 2016-02, Leases (Topic 842), in each case whether or not such lease obligations were in effect prior to or after such implementation); provided, that, for purposes of this sentence, in connection with the computation of any amount or ratios referred to herein, the Borrower shall provide to the Administrative Agent financial statements and other customary documentation as may reasonably be requested in writing by the Administrative Agent or any Lender to reconcile calculations of such amount or ratio with the financial statements delivered by the Loan Parties pursuant to Section 7.01(a) or Section 7.01(b)(i).

(c) Consolidation of Variable Interest Rate Entities. All references herein to consolidated financial statements of the Borrower and its Subsidiaries or to the determination of any amount for the Borrower and its Subsidiaries on a consolidated basis or any similar reference shall, in each case, be deemed to include each variable interest entity that the Borrower is required to consolidate pursuant to FASB ASC 810 as if such variable interest entity was a Subsidiary as defined herein.

(d) Pro Forma Calculations. Notwithstanding anything to the contrary contained herein, all calculations of the financial covenant set forth in Section 8.16(a) shall be made on a Pro Forma Basis with respect to all Specified Transactions occurring during the applicable period to which such calculation relates.

1.04 Times of Day.

Unless otherwise specified, all references herein to times of day shall be references to Eastern time (daylight or standard, as applicable).

1.05 Belgian Terms.

All references herein in the context of Belgian law or a Belgian Loan Party to:

(a) a receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer includes any curator/curateur, vereffenaar/liquidateur, voorlopig bewindvoerder/administrateur judiciaire, ondernemingsbemiddelaar/médiateur d'entreprise, 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 person being unable to pay its debts is that person being in a state of cessation of payments (staking van betaling/cessation de paiements);

(d) a receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition 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);

(e) a writ or warrant of attachment or execution or similar process includes any uitvoerend beslag/saisie exécutoire and bewarend beslag/saisie conservatoire;

(f) a guaranty refers, only for the purpose of the Guaranty granted by the Belgian Loan Parties pursuant to Article IV, to the Belgian legal concept of a guarantee ("garantie / vrijwaring") and not a surety ("borg / cautionnement");

(g) organized under the laws of the Kingdom of Belgium means that such Loan Party has its principal place of business (voornaamste vestiging/établissement principal) in Belgium; and

(h) Organization Documents means the oprichtingsakte/acte constitutif, statuten/statuts and uittreksel van de Kruispuntbank voor Ondernemingen/extrait de la Banque Carrefour des Entreprises.

1.06 French Terms.

All references herein in the context of French law or a French Loan Party to:

(a) a "guarantee" includes any "cautionnement", "aval", any "garantie" which is independent from the debt to which it relates and any type of "sûreté personnelle";

(b) a "security interest" includes any type of security (sûreté réelle) and transfer by way of security;

(c) a "moratorium" includes a moratorium under a mandat ad hoc or conciliation procedure in accordance with articles L. 611-3 to L. 611-16 of the French Code de commerce; and

(d) a "dissolution" or "reorganization" includes liquidation judiciaire, redressement judiciaire, sauvegarde, sauvegarde accélérée, sauvegarde financière accélérée, mandat ad hoc or conciliation proceedings under Livre Six of the French Code de commerce.

1.07 German Terms.

All references herein in the context of German law or a German Loan Party to:

(a) "director" or "manager" includes any statutory legal representative(s) (organschaftlicher Vertreter) of a person, including but not limited to, a managing director (Geschäftsführer) or member of the board of directors (Vorstand);

(b) "German Civil Code" means the Bürgerliches Gesetzbuch;

(c) "gross negligence" includes grobe Fahrlässigkeit; and

(d) "wilful misconduct" includes Vorsatz.

1.08 Spanish Terms.

All references herein in the context of Spanish law or a Spanish Guarantor to:

(a) "financial assistance" has the meaning stated under:

(i) Article 150 of the Spanish Companies Law for a Spanish public company (Sociedad Anónima) or in any other legal provision that may substitute such Article 150 or be applicable to any Spanish Guarantor in respect of such financial assistance; or

(ii) Article 143 of the Spanish Companies Law for a Spanish limited liability company (Sociedad de Responsabilidad Limitada) or in any other legal provision that may substitute such Article 143 or be applicable to any Spanish Guarantor in respect of such financial assistance;

(b) "insolvency" (concurso or any other equivalent legal proceeding) and any step or proceeding related to it has the meaning attributed to them under the Spanish Insolvency Law and "insolvency proceeding" includes, without limitation, a declaración de concurso, necessary or voluntary (necesario o voluntario) and the filing of the notice foreseen in Article 5 bis of the Spanish Insolvency Law;

(c) "winding-up, administration or dissolution" includes, without limitation, disolución, liquidación, or administración concursal or any other similar proceedings;

(d) "receiver, administrative receiver, administrator" or the like includes, without limitation, administración del concurso or any other person performing the same function;

(e) "composition, compromise, assignment or arrangement with any creditor" includes, without limitation, the celebration of a convenio;

(f) "person being unable to pay its debts" includes that person being in a state of insolvencia or concurso;

(g) "matured obligation" includes, without limitation, any crédito líquido, vencido y exigible; and

(h) "security interest" includes any mortgage (hipoteca), pledge (prenda), and, in general, any right in rem (garantia real) governed by Spanish law, created for the purpose of granting security.

1.09 Italian Terms.

In each Loan Document, where it relates to a person incorporated or having its centre of main interests in Italy (for the purposes of Regulation (EU) 2015/848 of 20 May 2015), a reference to:

(a) a winding-up, administration, liquidation or dissolution includes, without limitation, any scioglimento, liquidazione, procedura concorsuale, cessione dei beni ai creditori, or any other similar proceedings;

(b) an insolvency proceeding or a proceeding seeking a judgment of insolvency or bankruptcy or any other relief includes, without limitation, any procedura concorsuale (including fallimento, liquidazione giudiziale, concordato preventivo, concordato fallimentare, accordo di ristrutturazione dei debiti pursuant to article 182-bis of the Italian Bankruptcy Law, accordo di ristrutturazione con intermediari finanziari and convenzione di moratoria pursuant to article 182-septies of the Italian Bankruptcy Law, concordato con continuità aziendale pursuant to article 186-bis of the Italian Bankruptcy Law, piano di risanamento pursuant to article 67, paragraph 3 of the Italian Bankruptcy Law, liquidazione coatta amministrativa, amministrazione straordinaria, amministrazione straordinaria delle grandi imprese in stato di insolvenza, domanda di "pre-concordato" pursuant to article 161, paragraph 6 of the Italian Bankruptcy Law, any procedura di risanamento or procedura di liquidazione pursuant to Legislative Decree No. 170 of 21 May 2004 and cessione dei beni ai creditori pursuant to Article 1977 of the Italian Civil Code) and any other proceedings or legal concepts similar to the foregoing;

(c) a liquidator, receiver, administrative receiver, administrator or other similar officer includes, without limitation, a curatore, commissario giudiziale, commissario staordinario, commissario liquidatore or any other person performing the same function of any of the foregoing;

(d) a matured obligation includes, without limitation, any credito scaduto, liquido ed esigibile;

(e) a lease includes, without limitations, a contratto di locazione, an affitto d'azienda and an affitto di ramo d'azienda;

(f) a security includes, without limitation, any pegno, ipoteca, privilegio speciale (including the privilegio speciale created pursuant to Article 46 of the Italian Legislative Decree No. 385 of 1 September 1993, as amended from time to time), cessione del credito in garanzia, diritto reale di garanzia and any other garanzia reale or other transactions having the same effect as any of the foregoing;

(g) an attachment includes a pignoramento;

(h) guarantee includes without limitation a garanzia autonoma and contratto autonomo di garanzia;

(i) gross negligence and wilful misconduct includes, respectively, without limitation, colpa grave and dolo; and

(j) a right of occupation or right to receive rent includes uso, locazione, usufrutto e comodato.

ARTICLE II.

THE COMMITMENTS

2.01 Commitments.

(a) Term A Borrowing. Subject to the terms and conditions set forth herein, each Term A Lender severally agrees to make a single loan to the Borrower, in Dollars, on the Funding Date in an aggregate amount not to exceed such Term A Lender's Term A Commitment. The Term A Borrowing shall consist of Term A Loans made simultaneously by the Term A Lenders in accordance with their respective Term A Commitments. Term A Borrowings repaid or prepaid may not be reborrowed.

(b) Term B-1 Borrowing, Term B-2 Borrowing, Term B-3 Borrowing and Term B-4 Borrowing.

(i) Term B-1 Borrowing. Subject to the terms and conditions set forth herein, each Term B-1 Lender severally agrees to make a single loan to the Borrower, in Dollars, at the request of the Borrower on any Business Day during the Term B-1 Availability Period, in an aggregate amount not to exceed such Term B-1 Lender's Term B-1 Commitment; provided, that, the Administrative Agent shall have received (A) a Compliance Certificate pursuant to Section 7.02(a) certifying that Product Revenues were at least $25,000,000 (without giving effect to any Cure Right) for the four consecutive fiscal quarter period most recently ended prior to the date of the Term B-1 Borrowing for which financial statements have been delivered to the Administrative Agent pursuant to Sections 7.01(a) or (b)(i) or (B) on or before the earlier of (1) November 29, 2017 and (2) the date on which the Loan Parties deliver to the Administrative Agent a Compliance Certificate pursuant to Section 7.02(a) for the fiscal quarter ending September 30, 2017, a certificate of a Responsible Officer of the Borrower certifying that Product Revenues are projected to have been at least $25,000,000 (without giving effect to any Cure Right) for the four consecutive fiscal quarter period ending September 30, 2017 based on financial statements and projections reasonably satisfactory to the Administrative Agent. The Term B-1 Borrowing shall consist of Term B-1 Loans made simultaneously by the Term B-1 Lenders in accordance with their respective Term B-1 Commitments. Term B-1 Borrowings repaid or prepaid may not be reborrowed.

(ii) Term B-2 Borrowing. Subject to the terms and conditions set forth herein, each Term B-2 Lender severally agrees to make a single loan to the Borrower, in Dollars, at the request of the Borrower on any Business Day during the Term B-2 Availability Period, in an aggregate amount not to exceed such Term B-2 Lender's Term B-2 Commitment; provided, that, (A) the Administrative Agent shall have received a Compliance Certificate pursuant to Section 7.02(a) certifying that Product Revenues were at least $30,000,000 (without giving effect to any Cure Right) for the four consecutive fiscal quarter period most recently ended prior to the date of the Term B-2 Borrowing for which financial statements have been delivered to the Administrative Agent pursuant to Sections 7.01(a) or (b)(i) and (B) the Borrower shall have drawn the full amount of the Term B-1 Facility pursuant to Section 2.01(b)(i) prior to the date of the Term B-2 Borrowing. The Term B-2 Borrowing shall consist of Term B-2 Loans made simultaneously by the Term B-2 Lenders in accordance with their respective Term B-2 Commitments. Term B-2 Borrowings repaid or prepaid may not be reborrowed.

(iii) Term B-3 Borrowing. Subject to the terms and conditions set forth herein, each Term B-3 Lender severally agrees to make a single loan to the Borrower, in Dollars, at the request of the Borrower on any Business Day during the Term B-3 Availability Period, in an aggregate amount not to exceed such Term B-3 Lender's Term B-3 Commitment; provided, that, the Borrower shall have drawn the full amount of the Term B-1 Facility and Term B-2 Facility pursuant to Sections 2.01(b)(i) and (ii), respectively, prior to the date of the Term B-3 Borrowing. The Term B-3 Borrowing shall consist of Term B-3 Loans made simultaneously by the Term B-3 Lenders in accordance with their respective Term B-3 Commitments. Term B-3 Borrowings repaid or prepaid may not be reborrowed.

(iv) Term B-4 Borrowing. Subject to the terms and conditions set forth herein, each Term B-4 Lender severally agrees to make a single loan to the Borrower, in Dollars, at the request of the Borrower on any Business Day during the Term B-4 Availability Period, in an aggregate amount not to exceed such Term B-4 Lender's Term B-4 Commitment; provided, that, the Borrower shall have drawn the full amount of the Term B-1 Facility, Term B-2 Facility and Term B-3 Facility pursuant to Sections 2.01(b)(i), (ii) and (iii), respectively, prior to the date of the Term B-4 Borrowing. The Term B-4 Borrowing shall consist of Term B-4 Loans made simultaneously by the Term B-4 Lenders in accordance with their respective Term B-4 Commitments. Term B-4 Borrowings repaid or prepaid may not be reborrowed.

(c) Term C Borrowings. Subject to Section 2.14 and the other terms and conditions set forth herein, each Term C Lender severally agrees to make a single loan to the Borrower, in Dollars, during the Term C Availability Period, in an aggregate amount not to exceed such Term C Lender's Term C Commitment. The Term C Borrowing shall consist of Term C Loans made simultaneously by the Term C Lenders in accordance with their respective Term C Commitments. Term C Borrowings repaid or prepaid may not be reborrowed.

2.02 Borrowings.

(a) Each Borrowing shall be made upon the Borrower's irrevocable notice (in the form of a written Loan Notice, appropriately completed and signed by a Responsible Officer of the Borrower) to the Administrative Agent, which must be given not later than 11:00 a.m. (x) on the Effective Date in the case of the Term A Borrowing, (y) at least ten (10) Business Days (or such shorter period as may be agreed to by the Administrative Agent in its sole discretion) in advance of the requested date of such Borrowing in the case of the Term B-1 Borrowing or (z) at least fifteen (15) Business Days (or such shorter period as may be agreed to by the Administrative Agent in its sole discretion) in advance of the requested date of such Borrowing (other than the Term A Borrowing and the Term B-1 Borrowing). Each Loan Notice shall specify (i) the requested date of such Borrowing (which shall be a Business Day), (ii) the applicable Facility under which the Borrower is requesting such Borrowing and (iii) the principal amount of Loans to be borrowed. The Borrowing of Term A Loans shall be in an aggregate principal amount of $30,000,000. The Borrowing of Term B-1 Loans shall be in an aggregate principal amount of $5,000,000. The Borrowing of Term B-2 Loans shall be in an aggregate principal amount of $5,000,000. The Borrowing of Term B-3 Loans shall be in an aggregate principal amount of $10,000,000. The Borrowing of Term B-4 Loans shall be in an aggregate principal amount of $15,000,000. The Borrowing of Term C Loans shall be in an aggregate principal amount of $10,000,000.

(b) Following receipt of a Loan Notice for a Facility, the Administrative Agent shall promptly notify each Appropriate Lender of the amount of its Applicable Percentage under such Facility of the applicable Loans. Each Appropriate Lender shall make the amount of its Loan available to the Administrative Agent in immediately available funds at the Administrative Agent's Office not later than 1:00 p.m. on the Business Day specified in the applicable Loan Notice. Upon satisfaction of the applicable conditions set forth in Section 5.03 and Section 5.04 (and, if such Borrowing is the initial Borrowing, Section 5.01 and Section 5.02), the Administrative Agent shall make all funds so received available to the Borrower in like funds as received by the Administrative Agent by wire transfer of such funds in accordance with instructions provided to (and acceptable to) the Administrative Agent by the Borrower.

2.03 Prepayments.

(a) Voluntary Prepayments. Subject to the payment of any prepayment premium as required under Section 2.03(d) and any other fees or amounts payable hereunder at such time, the Borrower may, upon notice from the Borrower to the Administrative Agent, voluntarily prepay the Loans, in whole or in part; provided, that, (i) such notice must be received not later than 11:00 a.m. three (3) Business Days prior to the date of prepayment, (ii) any such prepayment shall only be made on an Interest Payment Date (it being understood that the requirement set forth in this sub-clause (ii) shall not be applicable to any voluntary prepayment in full of the aggregate Outstanding Amount of the Loans in connection with a Facility Termination Date) and (iii) any such prepayment shall be in a principal amount of $5,000,000 or a whole multiple of $1,000,000 in excess thereof (or, if less, the entire principal amount thereof then outstanding). Each such notice shall specify the date and amount of such prepayment. If such notice is given by the Borrower, the Borrower shall make such prepayment and the payment amount specified in such notice shall be due and payable on the date specified therein; provided, that, any such notice of prepayment may indicate that such prepayment is conditioned upon the consummation of a refinancing of this Agreement, capital raising or a particular Disposition or the occurrence of a Change of Control and may be revoked by the Borrower in the event such refinancing or other transaction is not consummated, and if so revoked, such prepayment shall not be due and payable. Any prepayment pursuant to this Section 2.03(a) shall be accompanied by (x) all accrued interest on the principal amount of the Loans prepaid, (y) the prepayment premium required under Section 2.03(d) and (z) all fees, costs, expenses, indemnities and other amounts due and payable hereunder at the time of prepayment. Each such prepayment shall be applied ratably to the Term A Facility, the Term B-1 Facility, the Term B-2 Facility, the Term B-3 Facility, the Term B-4 Facility and the Term C Facility. Each such prepayment shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages in respect of each of the relevant Facilities.

(b) Mandatory Prepayments.

(i) Dispositions and Involuntary Dispositions. The Borrower shall promptly (and in any event, within five (5) Business Days) prepay the Obligations in an aggregate amount equal to 100% of the Net Cash Proceeds of all Dispositions and Involuntary Dispositions received by any Loan Party or any Subsidiary; provided, that, such Net Cash Proceeds shall not be required to be so applied (A) until the aggregate amount of Net Cash Proceeds derived from all such Dispositions or Involuntary Dispositions in any fiscal year is equal to or greater than $500,000 (and then only in excess of such amount) and (B) if, at the election of the Borrower, such Loan Party or such Subsidiary reinvests all or any portion of such Net Cash Proceeds in Eligible Assets within three hundred sixty five (365) days of the date of such Disposition or Involuntary Disposition; provided,

further, that, for purposes of the foregoing clause (B), if such Net Cash Proceeds shall have not been so reinvested by the end of such period, such Net Cash Proceeds shall be immediately applied to prepay the Loans. Any prepayment pursuant to this clause (i) shall be applied as set forth in clause (iv) below.

(ii) Extraordinary Receipts. The Borrower shall promptly (and, in any event, within five (5) Business Days) upon the receipt by any Loan Party or any Subsidiary of the Net Cash Proceeds of any Extraordinary Receipt, prepay the Obligations in an aggregate amount equal to 100% of such Net Cash Proceeds; provided, that, such Net Cash Proceeds shall not be required to be so applied (A) until the aggregate amount of Net Cash Proceeds derived from all such Extraordinary Receipts in any fiscal year is equal to or greater than $500,000 (and then only in excess of such amount) and (B) if, at the election of the Borrower, such Loan Party or such Subsidiary reinvests all or any portion of such Net Cash Proceeds in Eligible Assets within three hundred sixty five (365) days of the date of receipt thereof; provided, further, that, for purposes of the foregoing clause (B), if such Net Cash Proceeds shall have not been so reinvested by the end of such period, such Net Cash Proceeds shall be immediately applied to prepay the Loans. Any prepayment pursuant to this clause (ii) shall be applied as set forth in clause (iv) below.

(iii) Debt Issuance. The Borrower shall immediately upon the receipt by any Loan Party or any Subsidiary of the Net Cash Proceeds of any Debt Issuance, prepay the Obligations in an aggregate amount equal to 100% of such Net Cash Proceeds. Any prepayment pursuant to this clause (iii) shall be applied as set forth in clause (iv) below.

(iv) Application of Mandatory Prepayments. All payments under this Section 2.03(b) shall be applied first to all fees, costs, expenses, indemnities and other amounts due and payable hereunder, then proportionately (based on the relation of such amounts to the total amount of the relevant payment under this Section 2.03(b)) to the payment or prepayment (as applicable) of the following amounts of the Obligations: default interest, if any, prepayment premium required by Section 2.03(d), accrued interest and principal. Each such prepayment shall be applied ratably to the Term A Facility, the Term B-1 Facility, the Term B-2 Facility, the Term B-3 Facility, the Term B-4 Facility and the Term C Facility. Each such prepayment shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages in respect of each of the relevant Facilities.

(c) Change of Control. Upon the occurrence of a Change of Control, the Borrower shall, at the direction of the Required Lenders, and may, at its option upon three (3) Business Days' prior written notice from the Borrower to the Administrative Agent, prepay the Outstanding Amount of the Loans together with all accrued and unpaid interest thereon plus the prepayment premium required by Section 2.03(d) plus all other Obligations. Each such direction or notice shall specify the date and amount of such prepayment. If such notice is given by the Borrower, the Borrower shall make such prepayment and the payment amount specified in such notice shall be due and payable on the date specified therein; provided, that, any such notice of prepayment may indicate that such prepayment is conditioned upon the occurrence of such Change of Control and may be revoked by Borrower in the event such transaction is not consummated, and if so revoked, such prepayment shall not be due and payable. Each prepayment under this Section 2.03(c) shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages in respect of each of the relevant Facilities.

(d) Prepayment Premiums. If all or any portion of the Loans are prepaid, or required to be prepaid, pursuant to this Section 2.03, Article IX (whether by acceleration or otherwise) or otherwise, then, in all cases, the Borrower shall pay to the Lenders, for their respective ratable accounts, on the date on which such prepayment is paid or required to be paid, in addition to the other Obligations so prepaid or required to be prepaid, a prepayment premium equal to: (i) with respect to any prepayment paid or required to be paid on or prior to December 31, 2021, fifteen percent (15.00%) of the principal amount of the Loans prepaid or required to be prepaid, (ii) with respect to any prepayment paid or required to be paid after December 31, 2021 but on or prior to December 31, 2022, ten percent (10.00%) of the principal amount of the Loans prepaid or required to be prepaid, (iii) with respect to any prepayment paid or required to be paid after December 31, 2022 but on or prior to December 31, 2023, five percent (5.00%) of the principal amount of the Loans prepaid or required to be prepaid, (iv) with respect to any prepayment paid or required to be paid after December 31, 2023 but on or prior to December 31, 2024, two and one-half percent (2.50%) of the principal amount of the Loans prepaid or required to be prepaid, and (v) with respect to any prepayment paid or required to be paid thereafter, zero percent (0.00%) of the principal amount of the Loans prepaid or required to be prepaid.

2.04 Termination or Reduction of Commitments.

(a) Voluntary. The Borrower may, upon notice to the Administrative Agent during the Term B-1 Availability Period with respect to the Term B-1 Facility, during the Term B-2 Availability Period with respect to the Term B-2 Facility, during the Term B-3 Availability Period with respect to the Term B-3 Facility, during the Term B-4 Availability Period with respect to the Term B-4 Facility and during the Term C Availability Period with respect to the Term C Facility, terminate in full the Commitments under any Facility, or from time to time permanently reduce the Commitments under any Facility; provided, that: (i) any such notice shall be received by the Administrative Agent not later than 11:00 a.m. five (5) Business Days prior to the date of termination or reduction and (ii) any such partial reduction shall be in an aggregate amount of $5,000,000 or any whole multiple of $1,000,000 in excess thereof; provided, further, that, any such notice of termination or reduction may indicate that such termination or reduction is conditioned upon the consummation of a refinancing of this Agreement, capital raising or a particular Disposition or the occurrence of a Change of Control and may be revoked by the Borrower in the event such refinancing or other transaction is not consummated, and if so revoked, such termination or reduction shall not be due and payable. Upon any termination or reduction of the Commitments under a Facility, the Commitments of each Appropriate Lender shall be reduced by such Lender's Applicable Percentage of such reduction amount.

(b) Mandatory. The Commitments under the Term A Facility shall be automatically and permanently reduced to zero on the date of the Borrowing under such Facility pursuant to Section 2.01. The Commitments under the Term B-1 Facility, the Term B-2 Facility, the Term B-3 Facility and the Term B-4 Facility shall be automatically and permanently reduced to zero on the earlier of (x) the date of the Borrowing under such Term B-1 Facility, Term B-2 Facility, Term B-3 Facility or Term B-4 Facility, as applicable, pursuant to Section 2.01 and (y) the date that the Term B-1 Availability Period, Term B-2 Availability Period, Term B-3 Availability Period or Term B-4 Availability Period, as applicable, shall end. The Term C Commitments shall be automatically and permanently reduced to zero on the earlier to occur of (x) the date of the Borrowing under the Term C Facility pursuant to Section 2.01 and (y) the date that the Term C Availability Period shall end. Upon any reduction of the Commitments under a Facility, the Commitments of each Appropriate Lender shall be reduced by such Lender's Applicable Percentage of such reduction amount.

2.05 Repayment of Loans.

The Borrower shall repay the outstanding principal amount of all Loans, together with all accrued and unpaid interest thereon and all other outstanding Obligations, on the Maturity Date. If any principal repayment to be made by the Borrower shall come due on a day other than a Business Day, such principal repayment shall be due on the first immediately preceding Business Day.

2.06 Interest.

(a) Pre-Default Rate. Subject to the provisions of subsection (b) below, each Loan shall bear interest on the outstanding principal amount thereof for each Interest Period from the applicable borrowing date at a rate per annum equal to the Interest Rate for such Interest Period.

(b) Default Rate. (i) Upon the occurrence and during the existence of any Event of Default, all outstanding Obligations shall thereafter bear interest at an interest rate per annum at all times equal to the Interest Rate for the applicable Interest Period plus four percent (4.00%) per annum (the "Default Rate"), to the fullest extent permitted by applicable Laws and (ii) accrued and unpaid interest on past due amounts (including interest on past due interest) shall be due and payable in cash on demand.

(c) Interest Generally. Interest on each Loan shall be due and payable in arrears on each Interest Payment Date and at such other times as may be specified herein. Interest hereunder shall be due and payable in accordance with the terms hereof before and after judgment, and before and after the commencement of any proceeding under any Debtor Relief Law.

2.07 Fees.

The Borrower shall pay to the Administrative Agent and the Lenders, for their own respective accounts, fees in the amounts and at the times specified in the Fee Letter. Such fees shall be fully earned when paid and shall not be refundable for any reason whatsoever.

2.08 Computation of Interest.

All computations of interest shall be made on the basis of a 360-day year and actual days elapsed. Interest shall accrue on each Loan for the day on which such Loan is made, and shall not accrue on a Loan, or any portion thereof, for the day on which such Loan or such portion is paid.

2.09 Evidence of Debt.

The Loans made by each Lender shall be evidenced by one or more accounts or records maintained by such Lender in the ordinary course of business. The accounts or records maintained by each Lender shall be conclusive absent manifest error of the amount of Loans made by the Lenders to the Borrower and the interest and payments thereon. Any failure to so record or any error in doing so shall not, however, limit or otherwise affect the obligation of the Borrower hereunder to pay any amount owing with respect to the Obligations. Upon the request of any Lender made through the Administrative Agent, the Borrower shall execute and deliver to such Lender a promissory note, which shall evidence such Lender's Loans in addition to such accounts or records. Each such promissory note shall (i) in the case of the Term A Loans, be in the form of Exhibit B-1 (a "Term A Note"), (ii) in the case of the Term B-1 Loans, be in the form of Exhibit B-2 (a "Term B-1 Note"), (iii) in the case of the Term B-2 Loans, be in the form of Exhibit B-3 (a "Term B-2 Note"), (iv) in the case of the Term B-3 Loans, be in the form of

Exhibit B-4 (a "Term B-3 Note"), (v) in the case of the Term B-4 Loans, be in the form of Exhibit B-5 (a "Term B-4 Note") and (vi) in the case of the Term C Loans, be in the form of Exhibit B-6 (a "Term C Note"). Each Lender may attach schedules to its Notes and endorse thereon the date, amount and maturity of its Loans and payments with respect thereto.

2.10 Payments Generally.

(a) General. All payments to be made by the Borrower shall be made free and clear of and without condition or (except as expressly provided in Section 3.01) deduction for any counterclaim, defense, recoupment or setoff. Subject to Section 9.03, all payments of principal, interest, prepayment premiums and fees on the Loans and all other Obligations payable by any Loan Party under the Loan Documents shall be due, without any presentment thereof, directly to the Lenders, at the respective Lending Offices of the Lenders; provided, that, if at the time of any such payment a Lender is a Defaulting Lender, such Defaulting Lender's pro rata share of such payment shall be made directly to the Administrative Agent. The Loan Parties will make such payments in Dollars, in immediately available funds not later than 2:00 p.m. on the date due, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Lenders may from time to time direct in writing. All payments received by the Lenders after 2:00 p.m. shall be deemed received on the next succeeding Business Day and any applicable interest or fee shall continue to accrue. If any payment to be made by the Borrower shall come due on a day other than a Business Day, payment shall be made on the next following Business Day, and such extension of time shall be reflected in computing interest.

(b) Obligations of Lenders Several. The obligations of the Lenders hereunder to make Loans and to make payments pursuant to Section 11.04(c) are several and not joint. The failure of any Lender to make any Loan or to make any payment under Section 11.04(c) on any date required hereunder shall not relieve any other Lender of its corresponding obligation to do so on such date, and no Lender shall be responsible for the failure of any other Lender to so make its Loan or to make its payment under Section 11.04(c).

(c) Funding Source. Nothing herein shall be deemed to obligate any Lender to obtain the funds for any Loan in any particular place or manner or to constitute a representation by any Lender that it has obtained or will obtain the funds for any Loan in any particular place or manner.

2.11 Sharing of Payments by Lenders.

If any Lender shall, by exercising any right of setoff or otherwise, obtain payment in respect of any principal of or interest on its portion of any of the Loans or prepayment premium in connection therewith resulting in such Lender's receiving payment of a proportion of the aggregate amount of the Loans and accrued interest thereon and prepayment premium in connection therewith greater than its pro rata share thereof as provided herein, then the Lender shall (a) notify the Administrative Agent of such fact and (b) purchase (for cash at face value) participations in the portions of the Loans of the other Lenders, or make such other adjustments as shall be equitable, so that the benefit of all such payments shall be shared by the Lenders ratably in accordance with the aggregate amount of principal of, accrued interest on and prepayment premium in connection with their respective portions of the Loans and other amounts owing them; provided, that:

(i) if any such participations are purchased and all or any portion of the payment giving rise thereto is recovered, such participations shall be rescinded and the purchase price restored to the extent of such recovery, without interest; and

(ii) the provisions of this Section 2.11 shall not be construed to apply to (x) any payment made by or on behalf of the Borrower pursuant to and in accordance with the express terms of this Agreement (including the application of funds arising from the existence of a Defaulting Lender) or (y) any payment obtained by a Lender as consideration for the assignment of or sale of a participation in any of its portion of the Loans to any assignee or participant, other than an assignment to any Loan Party or any Subsidiary (as to which the provisions of this Section 2.11 shall apply).

Each Loan Party consents to the foregoing and agrees, to the extent it may effectively do so under applicable Law, that any Lender acquiring a participation pursuant to the foregoing arrangements may exercise against such Loan Party rights of setoff and counterclaim with respect to such participation as fully as if such Lender were a direct creditor of such Loan Party in the amount of such participation.

2.12 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 the definition of "Required Lenders" and Section 11.01.

(ii) Reallocation of Payments. Any payment of principal, interest, fees or any other amount received by the Administrative Agent for the account of that Defaulting Lender (whether voluntary or mandatory, at maturity, pursuant to Article IX or otherwise, and including any amounts made available to the Administrative Agent by that Defaulting Lender pursuant to Section 11.08), 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 5.03 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 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 2.12(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.

2.13 Right of First Offer.

(a) If the Borrower or any Subsidiary contemplates undertaking an issuance of any Indebtedness (other than (x) Indebtedness permitted under Section 8.03(a), (c), (d), (e), (f), (j), (k) or (m) or (y) Indebtedness in an aggregate principal amount below the Threshold Amount), then, not less than thirty (30) Business Days prior to the proposed date of such issuance, the Borrower shall provide written notice (a "Debt Issuance Notice") thereof to the Lenders, and shall deliver promptly to the Lenders such information concerning such issuance as the Lenders may reasonably request.

(b) For a period of twenty (20) Business Days (the "Exclusivity Period") after receipt by the Lenders of a Debt Issuance Notice, the Lenders shall have the exclusive option, but not the obligation, to propose the material terms and conditions (the "Proposed Terms") under which they would be willing to provide such Indebtedness by delivering written notice (a "Proposed Term Sheet") thereof to the Borrower, setting forth such Proposed Terms. Failure by the Lenders to deliver a Proposed Term Sheet within the applicable Exclusivity Period shall be deemed an election by the Lenders not to provide such Indebtedness. If the Lenders deliver a Proposed Term Sheet to the Borrower that purports to provide not less than the aggregate amount of financing contemplated by the issuance contemplated in the Debt Issuance Notice, then neither the Borrower nor any Subsidiary may then undertake any such issuance with any other Person unless such issuance with such other Person (x) includes financial covenants and events of default and other terms including amortization, mandatory prepayments and maturity dates that are more favorable (taken as a whole) to the Borrower and its Subsidiaries than the Indebtedness contemplated by the Proposed Term Sheet (such determination to be made by the Borrower in good faith) and (y) has an All-In-Yield that is less than the All-In-Yield of the Indebtedness contemplated by the Proposed Term Sheet; provided, that, prior to undertaking any such issuance with any other Person, the Borrower or such Subsidiary shall provide the Lenders with at least ten (10) Business Days' notice thereof (and such information with respect thereto as the Lenders shall reasonably request) and afford the Lenders a period of five (5) Business Days thereafter to propose a Proposed Term Sheet containing economic terms at least as favorable to the Borrower or such Subsidiary as the economic terms of such Indebtedness.

2.14 Term C Facility.

At any time on or after the Funding Date but prior to December 31, 2020, upon prior written notice by the Borrower to the Administrative Agent, the Borrower may establish the Term C Facility in an aggregate amount not to exceed TEN MILLION DOLLARS ($10,000,000); provided, that,

(a) the Borrower shall have drawn the full amount of the Term B-1 Facility, the Term B-2 Facility, the Term B-3 Facility and the Term B-4 Facility pursuant to Section 2.01(b);

(b) no existing Lender shall be under any obligation to make any Term C Loan and any such decision whether to make a Term C Loan shall be in such Lender's sole and absolute discretion;

(c) (i) no Default or Event of Default shall exist and be continuing at the time of the establishment of the Term C Facility and (ii) the conditions precedent set forth in Section 5.04 shall have been satisfied prior to or contemporaneously with funding of any Term C Loans;

(d) the maturity date for the Term C Facility shall be the Maturity Date;

(e) the Borrower shall have paid all fees required to be paid in connection therewith, whether pursuant to the Fee Letter or otherwise;

(f) the Term C Lenders, the Administrative Agent and the Loan Parties shall have entered into such technical amendments to this Agreement as are necessary, in the Administrative Agent's reasonable discretion, to effect the inclusion of the Term C Facility herein;

(g) the Borrower shall have obtained commitments for the aggregate amount of the Term C Facility from existing Lenders pursuant to joinder documentation reasonably satisfactory to the Administrative Agent; and

(h) the Borrower shall have delivered to the Administrative Agent a certificate of each Loan Party dated as of the date of such institution and effectiveness (in sufficient copies for each Lender) signed by a Responsible Officer of such Loan Party (i) certifying and attaching the resolutions adopted by such Loan Party approving or consenting to the Term C Facility and (ii) certifying that, before and after giving effect to the Term C Facility, (x) the representations and warranties contained in Article VI and the other Investments Documents are true and correct in all respects on and as of the date of such increase, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they are true and correct in all respects as of such earlier date, and except that for purposes of this Section 2.14, the representations and warranties contained in subsections (a) and (b) of Section 6.05 shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b), respectively, of Section 7.01 and (y) no Default or Event of Default exists.

## ARTICLE III.

## TAXES

3.01 Taxes.

(a) Except as required by applicable Law, all payments of principal and interest on the Loans and all other amounts payable hereunder shall be made free and clear of and without deduction for any present or future income, excise, stamp, documentary, property or franchise taxes, VAT and other taxes, fees, duties, levies, assessments, withholdings or other charges of any nature whatsoever (including interest and penalties thereon) imposed by any taxing authority, excluding (x) taxes imposed on or measured by net income imposed by the jurisdiction (or any political subdivision thereof) under which a Recipient is organized or in which such Recipient has its principal office, applicable Lending Office or with which such Recipient otherwise has a

present or former connection (other than solely as the result of entering into any of the Loan Documents or taking any action thereunder), (y) U.S. federal withholding taxes imposed on amounts payable to or for the account of a Recipient with respect to an applicable interest in a Loan or Commitment pursuant to a law in effect on the date on which (i) such Recipient acquires such interest in the Loan or Commitment (other than pursuant to an assignment request by the Borrower pursuant to Section 11.13) or (ii) such Recipient changes its Lending Office, except in each case to the extent that, pursuant to this Section 3.01, amounts with respect to such taxes were payable either to such Recipient's assignor immediately before such Recipient became a party hereto or to such Recipient immediately before it changed its Lending Office and (z) U.S. federal withholding tax imposed under FATCA (all non-excluded items being called "Taxes"). If any withholding or deduction of any Taxes from any payment by or on account of any obligation of any Loan Party hereunder is required in respect of any Taxes pursuant to any applicable Law, then (i) the applicable Withholding Agent shall be entitled to make such withholding or deduction and shall pay directly to the relevant Governmental Authority the full amount required to be so withheld or deducted, (ii) the applicable Withholding Agent shall promptly forward to the Administrative Agent an official receipt or other documentation reasonably satisfactory to the Administrative Agent evidencing such payment to such Governmental Authority and (iii) the sum payable by the applicable Loan Party shall be increased by such additional amount or amounts as is necessary to ensure that the net amount actually received by the applicable Recipient will equal the full amount such Recipient would have received had no such withholding or deduction for Taxes been required.

(b) The Borrower or the Guarantors, as applicable, shall indemnify each Recipient, within ten (10) days after demand therefor, for the full amount of any Taxes (including Taxes imposed on or attributable to amounts payable under this Section 3.01) payable or paid by such Recipient or required to be withheld or deducted from a payment by such Recipient 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.

(c) (i) Any Lender that is entitled to an exemption from or reduction of withholding tax, including under FATCA, 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 prescribed by applicable Law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) or 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 applicable Law or 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 sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 3.01(c)(ii) below) shall not be required if in the 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) Each Lender that is not a "United States person" as defined in Section 7701(a)(30) of the Internal Revenue Code that purports to become an assignee of an interest pursuant to Section 11.06 after the Effective Date (each such Lender a "Foreign Lender") shall, to the extent it is legally entitled to do so, execute and deliver to each of the Borrower and the

Administrative Agent on or prior to the date that such Lender becomes a party hereto (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), one or more (as the Borrower or the Administrative Agent may reasonably request) duly completed and executed copies of United States Internal Revenue Service Forms W-8ECI, W-8BEN, W-8BEN-E, W-8IMY and other certification documents from each beneficial owner (as applicable). Each Lender that is a "United States person" as defined in Section 7701(a)(30) of the Internal Revenue Code shall execute and deliver to the Borrower and the Administrative Agent on or prior to the date such Lender becomes a party hereto (and from time to time thereafter upon the reasonable request of the Borrower or the Administrative Agent), one or more (as the Borrower or the Administrative Agent may reasonably request) duly completed and executed copies of United States Internal Revenue Service Form W-9 certifying that such Lender is not subject to United States backup withholding.

(iii) The Borrower shall not be required to pay additional amounts to any Lender pursuant to this Section 3.01 with respect to taxes attributable to the failure of such Foreign Lender to comply with this Section 3.01(c), and such taxes shall be excluded from the definition of Taxes.

(d) Each Lender agrees that if any form or certification it previously delivered pursuant to this Section 3.01 expires or becomes obsolete or inaccurate in any respect, it shall promptly update such form or certification or promptly notify the Administrative Agent and the Borrower of its inability to do so.

(e) If any party 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 3.01 (including by the payment of additional amounts pursuant to this Section 3.01), 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 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party 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 clause (e) (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 clause (e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (e) 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 paragraph 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.

3.02 Increased Costs.

(a) Increased Costs Generally. If any Change in Law shall:

(i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or for the account of, or credit extended or participated in by, any Lender (except any reserve requirement contemplated by Section 3.02(d);

(ii) subject any Recipient to any taxes (other than (A) Taxes that are covered by Section 3.01(b) and (B) taxes that are excluded from the definition of Taxes in Section 3.01(a)) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto; or

(iii) impose on any Lender or the London interbank market any other condition, cost or expense (other than taxes) affecting this Agreement;

and the result of any of the foregoing shall be to increase the cost to such Lender of making or maintaining any Loan (or of maintaining its obligation to make any such Loan), then, upon request of such Lender, the Borrower will pay to such Lender, as the case may be, such additional amount or amounts as will compensate such Lender, as the case may be, for such additional costs incurred or reduction suffered.

(b) Capital Requirements. If any Lender determines that any Change in Law affecting such Lender or any Lending Office of such Lender or such Lender's holding company, if any, regarding capital or liquidity requirements has or would have the effect of reducing the rate of return on such Lender's capital or on the capital of such Lender's holding company, if any, as a consequence of this Agreement, the Commitments of such Lender or the Loans made by such Lender to a level below that which such Lender or such Lender's holding company could have achieved but for such Change in Law (taking into consideration such Lender's policies and the policies of such Lender's holding company with respect to capital adequacy), then from time to time the Borrower will pay to such Lender, as the case may be, such additional amount or amounts as will compensate such Lender or such Lender's holding company for any such reduction suffered.

(c) Certificates for Reimbursement. A certificate of a Lender setting forth the amount or amounts necessary to compensate such Lender or its holding company, as the case may be, as specified in subsection (a) or (b) of this Section and delivered to the Borrower shall be conclusive absent manifest error. The Borrower shall pay such Lender the amount shown as due on any such certificate within ten (10) days after receipt thereof.

(d) Reserves on Loans. The Borrower shall pay to each Lender, (i) as long as such Lender shall be required to maintain reserves with respect to liabilities or assets consisting of or including eurocurrency funds or deposits (currently known as "Eurocurrency liabilities"), additional interest on the unpaid principal amount of each Loan equal to the actual costs of such reserves allocated to such Loan by such Lender (as determined by such Lender in good faith, which determination shall be conclusive), and (ii) as long as such Lender shall be required to comply with any reserve ratio requirement or analogous requirement of any central banking or financial regulatory authority imposed in respect of the maintenance of the Commitments or the funding of the Loans, such additional costs (expressed as a percentage per annum and rounded upwards, if necessary, to the nearest five decimal places) equal to the actual costs allocated to such Commitment or Loan by such Lender (as determined by such Lender in good faith, which determination shall be conclusive), which in each case shall be due and payable on each date on which interest is payable on such Loan; provided, that, the Borrower shall have received at least ten (10) days' prior notice (with a copy to the Administrative Agent) of such additional interest or costs from such Lender. If a Lender fails to give notice ten (10) days prior to the relevant Interest Payment Date, such additional interest shall be due and payable ten (10) days from receipt of such notice.

(e) Delay in Requests. Failure or delay on the part of any Lender to demand compensation pursuant to the foregoing provisions of this Section shall not constitute a waiver of such Lender's right to demand such compensation, provided, that, the Borrower shall not be required to compensate a Lender pursuant to the foregoing provisions of this Section for any increased costs incurred or reductions suffered more than nine (9) 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 nine-month period referred to above shall be extended to include the period of retroactive effect thereof).

3.03 Mitigation Obligations; Replacement of Lenders.

(a) Designation of a Different Lending Office. If any Lender requests compensation under Section 3.02 or requires the Borrower to pay any Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to Section 3.01, or if any Lender gives a notice pursuant to Section 3.02, then at the request of the Borrower such Lender shall, as applicable, use reasonable efforts to designate a different Lending Office for funding or booking its Loans hereunder or to assign its rights and obligations hereunder to another of its offices, branches or affiliates, if, in the judgment of such Lender, such designation or assignment (i) would eliminate or reduce amounts payable pursuant to Section 3.01 or 3.02, as the case may be, in the future, or eliminate the need for the notice pursuant to Section 3.02, as applicable, and (ii) in each case, would not subject such Lender, as the case may be, to any unreimbursed cost or expense and would 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.

(b) Replacement of Lenders. If any Lender requests compensation under Section 3.02, or if the Borrower is required to pay any Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to Section 3.01 and, in each case, such Lender has declined or is unable to designate a different Lending Office in accordance with Section 3.03(a), the Borrower may replace such Lender in accordance with Section 11.13.

3.04 Illegality.

If any Lender determines that any Law has made it unlawful, or that any Governmental Authority has asserted that it is unlawful, for any Lender or its Lending Office to perform any of its obligations hereunder or to make, maintain or fund or charge interest with respect to any Borrowing, or any Governmental Authority has imposed material restrictions on the authority of such Lender to purchase or sell, or to take deposits of, Dollars in the London interbank market, then, on notice thereof by such Lender to the Borrower through the Administrative Agent, any obligation of such Lender to issue, make, maintain, fund or charge interest with respect to any such Borrowing or to make Loans shall be suspended until such Lender notifies the Administrative Agent and the Borrower that the circumstances giving rise to such determination no longer exist. Upon receipt of such notice, the Borrower shall, upon demand from such Lender (with a copy to the Administrative Agent), prepay the Loans immediately. Upon any such prepayment, the Borrower shall also pay accrued interest on the amount so prepaid.

3.05 Three-Month LIBOR Unavailability Period.

Notwithstanding anything to the contrary in this Agreement or any other Loan Document, if the Administrative Agent determines (which determination shall be conclusive absent manifest error) that a

LIBOR Unavailability Period has commenced and is continuing, then, reasonably promptly after such determination, the Administrative Agent shall give the Borrower notice thereof and the Administrative Agent and the Borrower may amend this Agreement to replace Three-Month LIBOR with an alternate benchmark rate (including any mathematical or other adjustments to the benchmark (if any) incorporated therein), giving due consideration to any evolving or then existing convention for similar U.S. dollar denominated credit facilities for such alternative benchmarks (any such proposed rate, a "LIBOR Successor Rate"), together with any proposed LIBOR Successor Rate Conforming Changes and any such amendment shall become effective at 5:00 p.m. (New York time) on the fifth (5th) Business Day after the Administrative Agent shall have posted such proposed amendment to all Lenders and the Borrower unless, prior to such time, Lenders comprising the Required Lenders have delivered to the Administrative Agent written notice that such Required Lenders do not accept such amendment. It is understood and agreed that, for all purposes of this Agreement, once commenced, a "LIBOR Unavailability Period" shall be deemed to exist and be continuing unless and until such amendment has become effective in accordance with the terms hereof.

During the continuance of any LIBOR Unavailability Period, the obligation of the Lenders to make or maintain Loans with an Interest Rate calculated based on Three-Month LIBOR shall be suspended and the Borrower may revoke any pending request for a Borrowing of Loans with an Interest Rate calculated based on Three-Month LIBOR or, failing that, will be deemed to have converted such request into a request for a Borrowing of Loans with an Interest Rate calculated based on the Prime Rate.

Notwithstanding anything else herein, any definition of LIBOR Successor Rate shall provide that in no event shall such LIBOR Successor Rate be less than zero for purposes of this Agreement.

3.06 Survival.

All of the Borrower's obligations under this Article III shall survive termination of the Commitments, repayment of all Obligations and resignation of the Administrative Agent.

## ARTICLE IV.

## GUARANTY

4.01 The Guaranty.

Each of the Guarantors hereby jointly and severally guarantees to each Secured Party as hereinafter provided, as primary obligor and not as surety, the prompt payment of the Obligations in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise) strictly in accordance with the terms thereof. The Guarantors hereby further agree that if any of the Obligations are not paid in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise), the Guarantors will, jointly and severally, promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Obligations, the same will be promptly paid in full when due (whether at extended maturity, as a mandatory prepayment, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

Notwithstanding any provision to the contrary contained herein or in any other of the Loan Documents, the obligations of each Guarantor under this Agreement and the other Loan Documents shall be limited to an aggregate amount equal to the largest amount that would not render such obligations subject to avoidance under Debtor Relief Laws or any comparable provisions of any applicable state law.

4.02 Obligations Unconditional.

The obligations of the Guarantors under Section 4.01 are joint and several, absolute and unconditional, irrespective of the value, genuineness, validity, regularity or enforceability of any of the Loan Documents, or any other agreement or instrument referred to therein, or any substitution, release, impairment or exchange of any other guarantee of or security for any of the Obligations, and, to the fullest extent permitted by applicable law, irrespective of any law or regulation or other circumstance whatsoever which might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, it being the intent of this Section 4.02 that the obligations of the Guarantors hereunder shall be absolute and unconditional under any and all circumstances. Each Guarantor agrees that such Guarantor shall have no right of subrogation, indemnity, reimbursement or contribution against the Borrower or any other Guarantor for amounts paid under this Article IV until such time as the Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Commitments have expired or terminated. Without limiting the generality of the foregoing, it is agreed that, to the fullest extent permitted by law, the occurrence of any one or more of the following shall not alter or impair the liability of any Guarantor hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to any Guarantor, the time for any performance of or compliance with any of the Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents shall be done or omitted;

(c) the maturity of any of the Obligations shall be accelerated, or any of the Obligations shall be modified, supplemented or amended in any respect, or any right under any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents shall be waived or any other guarantee of any of the Obligations or any security therefor shall be released, impaired or exchanged in whole or in part or otherwise dealt with;

(d) any Lien granted to, or in favor of, any Secured Party as security for any of the Obligations shall fail to attach or be perfected; or

(e) any of the Obligations shall be determined to be void or voidable (including, without limitation, for the benefit of any creditor of any Guarantor) or shall be subordinated to the claims of any Person (including, without limitation, any creditor of any Guarantor).

With respect to its obligations hereunder, each Guarantor hereby expressly waives, to the extent permitted by applicable Law, diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that the Secured Parties exhaust any right, power or remedy or proceed against any Person under any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents, or against any other Person under any other guarantee of, or security for, any of the Obligations.

4.03 Reinstatement.

The obligations of the Guarantors under this Article IV shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of any Person in respect of the Obligations is rescinded or must be otherwise restored by any Secured Party, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and each Guarantor agrees that it will indemnify the Secured

Parties on demand for all reasonable costs and expenses (including, without limitation, the fees, charges and disbursements of counsel) incurred by the Secured Parties in connection with such rescission 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 bankruptcy, insolvency or similar law.

4.04 Certain Additional Waivers.

Each Guarantor agrees that such Guarantor shall have no right of recourse to security for the Obligations, except through the exercise of rights of subrogation pursuant to Section 4.02 and through the exercise of rights of contribution pursuant to Section 4.06. For the avoidance of doubt and notwithstanding the fact that the obligations of each Brazilian Guarantor under this Article IV are governed by the law 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.

4.05 Remedies.

The Guarantors agree that, to the fullest extent permitted by law, as between the Guarantors, on the one hand, and the Secured Parties, on the other hand, the Obligations may be declared to be forthwith due and payable as provided in Section 9.02 (and shall be deemed to have become automatically due and payable in the circumstances provided in said Section 9.02) for purposes of Section 4.01 notwithstanding any stay, injunction or other prohibition preventing such declaration (or preventing the Obligations from becoming automatically due and payable) as against any other Person and that, in the event of such declaration (or the Obligations being deemed to have become automatically due and payable), the Obligations (whether or not due and payable by any other Person) shall forthwith become due and payable by the Guarantors for purposes of Section 4.01. The Guarantors acknowledge and agree that their obligations hereunder are secured in accordance with the terms of the Collateral Documents and that the Secured Parties may exercise their remedies thereunder in accordance with the terms thereof.

4.06 Rights of Contribution.

The Guarantors agree among themselves that, in connection with payments made hereunder, each Guarantor shall have contribution rights against the other Guarantors as permitted under applicable law. Such contribution rights shall be subordinate and subject in right of payment to the obligations of such Guarantors under the Loan Documents and no Guarantor shall exercise such rights of contribution until all Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Commitments have terminated.

4.07 Guarantee of Payment; Continuing Guarantee.

The guarantee in this Article IV is a guaranty of payment and not of collection, is a continuing guarantee, and shall apply to all Obligations whenever arising.

4.08 Limitations Applicable to Belgian Loan Parties.

(a) The total liability of a Belgian Loan Party for the Obligations of any other Loan Party 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 Loan Parties (through intra-group loans or otherwise and whether retained for its own purposes or on-lent) made available to such Belgian Loan Party (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 Loan Party's own net assets (netto actief/actif net) (as determined in accordance with the second paragraph of article 320, 429 or 617 of the Belgian Companies Code (as applicable) and accounting principles generally accepted in Belgium and ignoring the Guaranty of such Belgian Loan Party) 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 Loan Party shall be liable for the Obligations of any other Loan Party under the Loan Documents to the extent that such liability would result in such guarantee constituting unlawful financial assistance within the meaning of Article 329, 430 or 629 of the Belgian Companies Code (as applicable).

4.09 Limitations Applicable to French Guarantors.

(a) In the case of each French Guarantor, its obligations under this Article IV shall apply only insofar as required to:

(i) guarantee the payment obligations under the Loan Documents of its direct or indirect Subsidiaries which are or become Loan Parties from time to time under this Agreement and incurred by those Subsidiaries as a Borrower (if such Subsidiary is not a French Loan Party) or as a Borrower and/or Guarantor (if such Subsidiary is a French Loan Party); and

(ii) guarantee the payment obligations of the other Loan Parties which are not direct or indirect Subsidiaries of such French Guarantor; provided, that, in each such case such guarantee shall (A) be limited to the payment obligations of such other Loan Parties under the Loan Documents and (B) not exceed an amount equal to the aggregate amount borrowed by such other Loan Parties under this Agreement (either directly in their capacity as a Borrower or indirectly by way of one or more intra-group loans made to such other Loan Parties directly or indirectly by the Borrower), and (without double counting) on-lent to such French Guarantor by way of one or more intra-group loans directly or indirectly from such other Loan Parties and outstanding from time to time (such amount being the "Maximum French Guaranteed Amount").

(b) Any payment made by a French Guarantor in accordance with clause (a)(ii) above in respect of the obligations of any other Loan Party shall reduce pro tanto the outstanding amount of the intra-group loans due by such French Guarantor to such other Loan Party under the intra-group loans referred to therein.

(c) For the avoidance of doubt, any payment made by a French Guarantor in respect of the payment obligations of another Loan Party referred to in clause (a)(ii) above shall reduce the relevant Maximum French Guaranteed Amount.

(d) Notwithstanding any other provision of this Article IV, no French Guarantor shall secure liabilities under this Agreement 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 Code de commerce and/or would constitute a misuse of corporate assets within the meaning of article L. 241-3 or L. 242-6 of the French Code de commerce or any other laws or regulations having the same effect, as interpreted by French courts.

(e) Notwithstanding anything in this Agreement to the contrary (including Section 4.02), it is acknowledged that each French Guarantor is not acting jointly and severally with the other Guarantors and shall not be considered as "co-débiteur solidaire" as to their obligations pursuant to the guarantee given in accordance with this Article IV.

4.10 Limitations Applicable to Spanish Guarantors.

Notwithstanding anything in this Agreement to the contrary, the obligations and liabilities of each Spanish Guarantor shall be deemed not to be assumed by such Spanish Guarantor to the extent that they constitute or may constitute unlawful financial assistance within the meaning of article 150 of the Spanish Companies Law (where the company is a Spanish public company (Sociedad Anónima)) or article 143 of the Spanish Companies Law (where the company is a Spanish limited liability company (Sociedad de Responsabilidad Limitada)). Accordingly, the obligations and liabilities of each Spanish Guarantor under this Agreement (including, without limitation, this Article IV) and the other Loan Documents shall not include and shall not be extended to any repayment obligations in respect of financing used in or towards the payment or refinance of the purchase price or subscription for the shares or quotas in such Spanish Guarantor and/or the acquisition of or subscription for the shares or quotas in such Spanish Guarantor's controlling corporation (or, where such Spanish Guarantor is a Spanish limited liability company (Sociedad de Responsabilidad Limitada), of any company of its group), either directly or indirectly. The guarantee, indemnity and other obligations of each Spanish Guarantor incorporated as a Spanish limited liability company (Sociedad de Responsabilidad Limitada) expressed to be assumed by it hereunder shall not include and shall not extend to any obligations which could reasonably be expected to result in a breach of article 401 of the Spanish Companies Law.

4.11 Limitations Applicable to Italian Guarantors.

Notwithstanding the foregoing and any provisions to the contrary in any Loan Document:

(a) the guarantee and indemnification obligations expressed to be assumed by each Italian Guarantor hereunder shall, at any time, not exceed the aggregate at that time of:

(i) the outstanding principal amount from time to time of any sums made available to such Italian Guarantor or any of its direct or indirect subsidiaries pursuant to Section 2359 of the Italian Civil Code as a borrower under this Agreement; and

(ii) the outstanding principal amount of any loan in any form (including, without limitation, any intercompany loan), documentary credit (including any intercompany documentary credit) or other form of financial support, directly or indirectly made available from time to time after the Effective Date to that Italian Guarantor or any of its direct or indirect subsidiaries pursuant to Section 2359 of the Italian Civil Code by any Loan Party or any direct or indirect subsidiary of any Loan Party;

(b) in any case, for the sole purposes of compliance with Article 1938 of the Italian Civil Code, the maximum amount that each Italian Guarantor may be required to pay in respect of its obligations as a Guarantor under this Agreement shall not exceed an overall amount equal to $112,500,000.00 (or the equivalent in any other currency); and

(c) in order to comply with (i) the mandatory provisions of Italian Law in relation to maximum interest rates (including Italian Law No. 108 of 7 March 1996, as subsequently amended and/or supplemented (the "Italian Usury Law") and article 1815 of the Italian Civil Code) and (ii) the Italian Law provisions relating to financial assistance (including Sections 2358 and 2474 of the Italian Civil Code), the obligations of each Italian Guarantor hereunder shall not include and shall not extend to (A) any interest qualifying as usurious pursuant the Italian Usury Law and (B) any amount made available to any Loan Party under any Loan Document the proceeds of which have been applied towards, either directly or indirectly, the financing or re-financing of the acquisition of, or the subscription for, shares in that Italian Guarantor and/or any entity of which that Italian Guarantor is a direct or indirect subsidiary pursuant to Section 2359 of the Italian Civil Code, including any related costs and expenses.

4.12 Limitations Applicable to German Guarantors.

(a) In this Section 4.12, "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 security granted under this Agreement), C, D and E German Commercial Code (Handelsgesetzbuch)), 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 (Handelsgesetzbuch) (if any) and the amount of its stated share capital (Stammkapital).

(b) The Administrative Agent agrees not to enforce the security granted under this Agreement if and to the extent that the security granted under this Agreement secures any liability of a Loan Party which is an Affiliate of any German Guarantor (other than such German Guarantor's Wholly Owned Subsidiaries) (each, a "Secured Obligor") and if and to the extent that a payment under the security granted under this Agreement would cause such German Guarantor's (or, where such German Guarantor is a GmbH & Co. KG, its general partner's) Net Assets (determined pursuant to clause (c) below) to be reduced below zero, or further reduced if already below zero ("Capital Impairment").

(c) For the purposes of the calculation of the Net Assets, the following balance sheet items shall be adjusted as follows:

(i) if the registered share capital of any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, of its general partner) is not fully paid up (nicht voll eingezahlt), the relevant amount which is not paid up shall be deducted from the registered share capital in accordance with section 272 para. 1 sentence 2 of the German Commercial Code (Handelsgesetzbuch) to the extent such amount is not demanded or, if demanded, to the extent not accounted as an asset of such German Guarantor pursuant to section 272 para. 1 of the German Commercial Code;

(ii) the amount of any increase of the stated share capital (Erhöhungen des Stammkapitals) of any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, of its general partner) 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;

(iii) loans provided to any German Guarantor by any of its direct or indirect holding companies (other than any direct or indirect Subsidiaries of such German Guarantor) which by contractual provision or Law are subordinated to the Obligations or are considered subordinated in insolvency proceedings, unless the waiver or contribution of such loan claim would give rise to a personal liability of the relevant managing director due to a breach of section 30 of the German Limited Liability Companies Act (GmbHG) and provided that such German Guarantor (A) has, as consequence of enforcement of the security granted under this Agreement, a reimbursement claim against the relevant lender of such loan which can be set-off and (B) is entitled to set-off this reimbursement claim with the repayment claim under such loan without triggering or increasing the risk of any personal and/or criminal liability of any managing director or member of the board of such German Guarantor; and

(iv) liabilities incurred by any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, its general partner) in negligent or willful violation of the Loan Documents shall be disregarded.

(d) The enforcement of the security granted under this Agreement shall initially be excluded pursuant to clause (b) above if, no later than twenty (20) Business Days following the Administrative Agent's notification of its intention to enforce the security interest created under this Agreement (the "Enforcement Notice"), the managing directors on behalf of each German Guarantor have confirmed in writing to the Administrative Agent:

(i) to what extent the security granted under this Agreement is an up-stream or cross-stream security described in clause (b) above; and

(ii) which amount of such cross-stream and/or up-stream guarantee cannot be enforced as it would cause the Net Assets of the German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, of its general partner) to be less than its respective registered share capital (taking into account the adjustments set out in clause (c) above and the realisation duties set out in clause (f) below) (the "Management Determination") and such confirmation is supported by a reasonably satisfactory calculation; provided, that, the Administrative Agent shall in any event be entitled to enforce the security granted under this Agreement for any amounts where such enforcement would, in accordance with the Management Determination, not cause the German Guarantor's, or, as the case may be, its general partner's, Net Assets to be less than (or to fall further below) the amount of its respective registered share capital (in each case as calculated and adjusted in accordance with clause (c) above).

(e) Following the Administrative Agent's receipt of a Management Determination, any further enforcement of the security granted under this Agreement (i.e., any enforcement to which the Administrative Agent is not already entitled to pursuant to clause (f) below) shall be excluded pursuant to clause (b) above. However, the further enforcement of the security granted under this Agreement shall be limited only if the Administrative Agent receives within thirty (30) Business Days upon its request following the Administrative Agent's receipt of the Management Determination (i) an up-to date balance sheet together and (ii) a determination, in each case prepared by auditors of international standard and reputation appointed by each applicable German Guarantor either confirming the Management Determination or setting out deviations

from the Management Determination (the "Auditor's Determination"), if and to the extent such enforcement would, in accordance with the Auditor's Determination cause any German Guarantor's (or, where such German Guarantor is a GmbH & Co. KG, its general partner's) Net Assets to be less than (or to fall further below) the amount of its respective registered share capital in each case as calculated and adjusted in accordance with clause (c) above. If any German Guarantor fails to deliver an Auditor's Determination within such thirty (30) Business Day period after the Administrative Agent's request, the Administrative Agent shall be entitled to enforce the security granted under this Agreement without any limitation or restriction.

(f) In addition, each German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, its general partner) shall upon request of the Administrative Agent realise, to the extent legally permitted and commercially justifiable and to the extent necessary to satisfy the Obligations, any and all of its assets which are not required for the German Guarantor's business (nicht betriebsnotwendig) that are shown in the balance sheet with a book value (Buchwert) that is substantially lower than the market value of the relevant assets if, as a result of the enforcement of the security granted under this Agreement, its Net Assets would be reduced below zero or further reduced if already below zero.

(g) The restrictions under clause (b) above shall not apply:

(i) to the extent that the security granted under this Agreement secures (A) any Loans that are on-lent, actually disbursed or otherwise passed on to any German Guarantor or, as the case may be, its general partner, or any of its Subsidiaries and not repaid or (B) any guarantees issued under this Agreement for the benefit of any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, its general partner) or any of its Subsidiaries which are not returned, in each case if and to the extent that the German Guarantor or, as the case may be, its general partner is able to (1) set-off its recourse claims (if any) against the loan obligation in respect of the amounts on-lent to it or (2) otherwise use its recourse claims (if any) to settle or discharge the relevant loan obligation under the Loan Documents;

(ii) if any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, its general partner) (as dominated entity) is subject to a domination and/or profit transfer agreement (Beherrschungs- und/oder Gewinnabführungsvertrag) (a "DPTA") with the Borrower or a Secured Obligor, whether directly or indirectly through a chain of DPTAs between each company and its shareholder (or, as the case may be, between its general partner and its shareholder), and has a fully recoverable compensation claim (Verlustausgleichsanspruch) pursuant to section 302 German Stock Corporation Act (Aktiengesetz) against its dominating entity;

(iii) if and to extent any German Guarantor has on the date of enforcement of the security granted under this Agreement a fully recoverable indemnity or claim for refund ("vollwertiger Gegenleistungs- oder Rückgewähranspruch") against its shareholder or a Secured Obligor;

(iv) if any German Guarantor has not complied with any of its obligations pursuant to clauses (d) or (e) above; or

(v) if and to the extent for any other reason (including, without limitation, as a result of a change in the relevant rules of law or as a result of relevant jurisprudence of the German supreme court (höchstrichterliche Rechtsprechung)) such limitation is not

necessary in order to protect the managing directors of any German Guarantor (or, where such German Guarantor is a GmbH & Co. KG, of its general partner) from personal liability pursuant to sections 30, 43 paragraph 3 or 43 paragraph 2 of the German Act on Limited Liability Companies (GmbH-Gesetz) (each as amended, supplemented and/or replaced from time to time).

## ARTICLE V.

## CONDITIONS PRECEDENT TO BORROWINGS

5.01 Condition to Effectiveness.

This Agreement shall become effective upon receipt by the Administrative Agent of executed counterparts of this Agreement, properly executed by a Responsible Officer of each Loan Party and by each Lender, together with all exhibits and schedules hereto.

5.02 Conditions to Initial Extensions of Credit.

The obligation of each Lender to make its initial Loans hereunder is subject to satisfaction of the following conditions precedent:

(a) Investment Documents. Receipt by the Administrative Agent of executed counterparts of the Investment Documents, each properly executed by a Responsible Officer of the signing Loan Party and each other party to such documents, including, without limitation, the Share Purchase Agreement and the ROFR Side Letter, in each case in form and substance reasonably satisfactory to the Administrative Agent and the Lenders.

(b) Opinions of Counsel. Receipt by the Administrative Agent of favorable opinions of legal counsel to the Loan Parties, addressed to the Administrative Agent and each Lender, dated as of the Funding Date, and in form and substance reasonably satisfactory to the Administrative Agent.

(c) Financial Statements; Due Diligence. The Administrative Agent shall have received the Audited Financial Statements, the Interim Financial Statements and such other reports, statements and due diligence items as the Administrative Agent or any Lender shall request.

(d) No Material Adverse Change. There shall not have occurred a material adverse change since December 31, 2016 in the business, financial performance or condition, operations (including the financial results thereof), assets or properties of the Borrower and its Subsidiaries, taken as a whole.

(e) Litigation. There shall not exist any action, suit, investigation or proceeding pending or threatened (in writing) in any court or before an arbitrator or Governmental Authority that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

(f) Organization Documents, Resolutions, Etc. Receipt by the Administrative Agent of the following, each of which shall be originals or facsimiles (followed promptly by originals), in form and substance reasonably satisfactory to the Administrative Agent and its legal counsel:

(i) copies of the Organization Documents of each Loan Party certified to be true and complete as of a recent date by (A) the appropriate Governmental Authority of the state or other jurisdiction of its incorporation or organization, where applicable, or (B) in the case of each Costa Rican Loan Party, a notarial certification, and in each case certified by a director, secretary or assistant secretary of such Loan Party to be true and correct as of the Funding Date;

(ii) such certificates of resolutions or other action, incumbency certificates and/or other certificates of Responsible Officers of each Loan Party as the Administrative Agent may require evidencing the identity, authority and capacity of each Responsible Officer thereof authorized to act as a Responsible Officer in connection with this Agreement and the other Investment Documents to which such Loan Party is a party;

(iii) such documents and certifications as the Administrative Agent may require to evidence that each Loan Party is duly organized or formed, and is validly existing, in good standing and qualified to engage in business in its state or other jurisdiction of organization or formation (such certifications to include, without limitation, a good standing certificate of the Borrower issued by the Registrar of Corporate Affairs in the British Virgin Islands);

(iv) a registered agent's certificate issued by the Borrower's registered agent in the British Virgin Islands and dated within one month of the Effective Date;

(v) a copy of a resolution of the Board of Directors of each Belgian Loan Party setting out the reasons it is considered that the entry into this Agreement, and in particular the assumption of its guaranty obligations in accordance with Article IV, is of benefit to such Belgian Loan Party;

(vi) in relation to each Belgian Loan Party, a solvency certificate (attest niet-faillissement/certificat de non-faillite) and an uittreksel van de Kruispuntbank voor Ondernemingen/extrait de la Banque Carrefour des Entreprises, each dated not more than three (3) Business Days prior to the Effective Date; and

(vii) a certificate of the Articles of Incorporation and organizational documents, and a recent certificación de personería jurídica, of each Costa Rican Loan Party.

(g) Perfection and Priority of Liens. Receipt by the Administrative Agent of the following:

(i) searches of Uniform Commercial Code filings (or the equivalent) in the jurisdiction of formation of each Loan Party or where a filing would need to be made in order to perfect the Administrative Agent's security interest in the Collateral, copies of the financing statements (or the equivalent) on file in such jurisdictions and evidence that no Liens exist other than Permitted Liens;

(ii) Uniform Commercial Code (or the equivalent) financing statements for each appropriate jurisdiction as is necessary, in the Administrative Agent's sole discretion, to perfect the Administrative Agent's security interest in the Collateral and filings of the particulars of the relevant charges with the Registrar of Corporate Affairs in

the British Virgin Islands in accordance with Section 163 of the BVI Business Companies Act, 2004;

(iii) (A) all certificates evidencing any certificated Equity Interests pledged to the Administrative Agent pursuant to any Pledge Agreement or any Security Agreement other than the Costa Rican Security Trust Agreement, together with duly executed in blank and undated stock powers attached thereto and (B) all certificates evidencing the delivery of any share certificates of any Costa Rican Loan Party to the Trustee pursuant to the Costa Rican Security Trust Agreement, together with the entries in each such Costa Rican Loan Party's Shareholders Registry Book and Shareholders Meeting Minutes Book regarding the transfer of said secured shares to the Trustee;

(iv) searches of ownership of, and Liens on, the Business IP Rights of the Loan Parties in the appropriate governmental offices;

(v) duly executed notices of grant of security interest in the form required by the applicable Security Agreement as are necessary, in the Administrative Agent's sole discretion, to perfect the Administrative Agent's security interest in the Business IP Rights of the Loan Parties;

(vi) such Qualifying Control Agreements as shall be necessary to cause the Loan Parties to be in compliance with Section 7.18;

(vii) to the extent required to be delivered pursuant to the terms of the Collateral Documents, all instruments, documents and chattel paper in the possession of any of the Loan Parties, together with allonges or assignments as may be necessary or appropriate to perfect the Administrative Agent's security interest in the Collateral; and

(viii) in the case of any personal property Collateral located at a premises leased by a Loan Party, such Collateral Access Agreements as may be required by the Administrative Agent.

(h) Real Property Collateral. Receipt by the Administrative Agent of Mortgages and other Real Property Security Documents with respect to the fee interest of any Loan Party in each real property identified on Schedule 6.20(a) to the Disclosure Letter (other than any Excluded Property).

(i) Evidence of Insurance. Receipt by the Administrative Agent of copies of insurance policies or certificates of insurance of the Loan Parties evidencing liability and casualty insurance meeting the requirements set forth in the Loan Documents, including, but not limited to, naming the Administrative Agent as additional insured (in the case of liability insurance) or Lender's loss payee (in the case of hazard insurance) on behalf of the Secured Parties.

(j) Funding Certificate. Receipt by the Administrative Agent of a certificate signed by a Responsible Officer of the Borrower certifying (i) that the conditions specified in Sections 5.02(d), (e) and (l) and Sections 5.03(a) and (b) have been satisfied, (ii) that the Borrower and its Subsidiaries (after giving effect to the transactions contemplated hereby and the incurrence of Indebtedness related thereto) are Solvent on a consolidated basis and (iii) that neither the Borrower nor any Subsidiary as of the Funding Date has outstanding any Disqualified Capital Stock.

(k) Existing Indebtedness.

(i) All of the existing Indebtedness for borrowed money of the Loan Parties and their respective Subsidiaries (including all Indebtedness under the Existing Credit Agreement but, for the avoidance of doubt, excluding (A) Indebtedness permitted to exist pursuant to Section 8.03 and (B) the Crown Predator Convertible Indebtedness), shall be repaid in full and all security interests related thereto shall be terminated on or prior to the Funding Date.

(ii) All of the Crown Predator Convertible Indebtedness shall be either (A) repaid in full or (B) converted into Qualified Capital Stock of the Borrower, and in each case all security interests related thereto shall be terminated on or prior to the Funding Date.

(l) Governmental and Third Party Approvals. The Loan Parties and their respective Subsidiaries shall have received all governmental, shareholder and third party consents and approvals necessary in connection with the transactions contemplated by this Agreement and the other Investment Documents and the other transactions contemplated hereby and all applicable waiting periods shall have expired without any action being taken by any Person that could reasonably be expected to restrain, prevent or impose any material adverse conditions on the Loan Parties or any of their respective Subsidiaries or such other transactions or that could seek to threaten any of the foregoing, and no law or regulation shall be applicable which could reasonably be expected to have such effect.

(m) Corporate Structure and Capitalization. The capital and ownership structure and the equity holder arrangements of the Borrower and its Subsidiaries on the Funding Date, on a pro forma basis after giving effect to the transactions contemplated by the Investment Documents shall be reasonably satisfactory to the Lenders.

(n) Letter of Direction. Receipt by the Administrative Agent of a satisfactory letter of direction containing funds flow information with respect to the proceeds of the Loans to be made on the Funding Date.

(o) Fees. Receipt by the Administrative Agent and the Lenders of any fees required to be paid on or before the Funding Date.

(p) Attorney Costs; Due Diligence Expenses. The Borrower shall have paid all fees, charges and disbursements of counsel to the Administrative Agent incurred to the Funding Date, plus such additional amounts of such fees, charges and disbursements as shall constitute its reasonable estimate of such fees, charges and disbursements incurred or to be incurred by it through the closing proceedings (provided, that, such estimate shall not thereafter preclude a final settling of accounts between the Borrower and the Administrative Agent).

(q) Condition to Effectiveness. The condition to effectiveness specified in Section 5.01 shall have been satisfied.

(r) Equity Documents. Receipt by the Administrative Agent of a certificate signed by a Responsible Officer of the Borrower attaching executed copies of each document necessary to effectuate the Share Purchase Agreement and authorize the Borrower's entry into the ROFR Side Letter, including, without limitation, (i) the Restated Articles, (ii) the Rights Agreement, (iii)

the Voting Agreement and (iv) ROFR Agreement, in each case as such terms are defined in the Share Purchase Agreement and in form and substance satisfactory to the Lenders.

(s) Termination of the Banco Davivienda Documents. The Banco Davivienda Documents shall be terminated, all existing Indebtedness under the Banco Davivienda Documents shall be repaid in full and all security interests related thereto shall be terminated on or prior to the Funding Date.

(t) Cancellation of Certain Warrants. The Borrower shall have cancelled the Relativity Warrant, JW Opportunities Warrant and JW Partners Warrant on or prior to the Funding Date, on terms and conditions satisfactory to the Administrative Agent.

(u) Perceptive Warrant. The Borrower shall have committed to repurchase fifty percent (50%) of the Perceptive Warrant on or prior to the Funding Date on terms and conditions satisfactory to the Administrative Agent and the Lenders, and the Lenders shall have purchased the other fifty percent (50%) of the Perceptive Warrant from Perceptive Credit Holdings, LP on or prior to the Funding Date on terms and conditions satisfactory to the Administrative Agent and the Lenders.

(v) Equity Purchases. The Lenders shall have purchased (i) 73,560 Class A ordinary shares of the Borrower from Antoun Nabhan, (ii) 13,580 Class A ordinary shares of the Borrower from Marco Chacon Quiros and (iii) 80,000 Class A ordinary shares of the Borrower from Medical Device Holdings, S.A., in each case, on or prior to the Funding Date and on terms and conditions satisfactory to the Administrative Agent and the Lenders.

(w) Other. Receipt by the Administrative Agent and the Lenders of such other documents, instruments, agreements and information as reasonably requested by the Administrative Agent or any Lender, including, but not limited to, information regarding litigation, tax, accounting, labor, insurance, pension liabilities (actual or contingent), real estate leases, material contracts, debt agreements, property ownership, environmental matters, contingent liabilities and management of the Borrower and its Subsidiaries.

Without limiting the generality of the provisions of the last paragraph of Section 10.03, for purposes of determining compliance with the conditions specified in this Section 5.02, each Lender that has funded its Term A Loan on the Funding Date shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless the Administrative Agent shall have received notice from such Lender prior to the proposed Funding Date specifying its objection thereto.

5.03 Conditions to all Borrowings.

The obligation of each Lender to honor any Loan Notice is subject to the following conditions precedent:

(a) The representations and warranties of the Borrower and each other Loan Party contained in Article VI or any other Investment Document, or which are contained in any document furnished at any time under or in connection herewith or therewith, shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the date of such Borrowing, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects (and in all

respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date, and except that for purposes of this Section 5.03, the representations and warranties contained in subsections (a) and (b) of Section 6.05 shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b), respectively, of Section 7.01.

(b) No Default or Event of Default shall exist, or would result from such proposed Borrowing or from the application of the proceeds thereof.

(c) With respect to any Loan Notice requesting a Borrowing of Term B-1 Loans, the requested Borrowing shall occur during the Term B-1 Availability Period.

(d) With respect to any Loan Notice requesting a Borrowing of Term B-2 Loans, the requested Borrowing shall occur during the Term B-2 Availability Period.

(e) With respect to any Loan Notice requesting a Borrowing of Term B-3 Loans, the requested Borrowing shall occur during the Term B-3 Availability Period.

(f) With respect to any Loan Notice requesting a Borrowing of Term B-4 Loans, the requested Borrowing shall occur during the Term B-4 Availability Period.

(g) With respect to any Loan Notice requesting a Borrowing of Term C Loans, the requested Borrowing shall occur during the Term C Availability Period.

(h) The Administrative Agent shall have received a Loan Notice in accordance with the requirements hereof.

Each Loan Notice submitted by the Borrower shall be deemed to be a representation and warranty that the conditions specified in Sections 5.03(a) through (g) have been satisfied on and as of the date of the applicable Borrowing.

5.04 Additional Conditions to Term C Borrowing.

The obligation of each Lender to honor any Loan Notice requesting a Borrowing of Term C Loans is subject to the additional condition precedent that such Borrowing shall be in compliance with Section 2.14 in all respects.

Each Loan Notice submitted by the Borrower shall be deemed to be a representation and warranty that the conditions specified in Sections 5.03(a) through (g) and 5.04 have been satisfied on and as of the date of the applicable Borrowing.

## ARTICLE VI.

## REPRESENTATIONS AND WARRANTIES

On the Funding Date, and on each date thereafter on which the representations and warranties set forth herein are required to be made under any Investment Document (or deemed to be made under any Investment Document), the Loan Parties represent and warrant (in each case, on behalf of itself and, where applicable, its Subsidiaries only) to the Administrative Agent and the Lenders that:

6.01 Existence, Qualification and Power.

Each Loan Party and each Subsidiary (a) is duly incorporated, organized or formed, validly existing and in good standing under the Laws of the jurisdiction of its incorporation or organization, (b) has all requisite power and authority and all requisite governmental licenses, authorizations, consents and approvals to (i) own or lease its assets and carry on its business and (ii) execute, deliver and perform its obligations under the Investment Documents to which it is a party and (c) is duly qualified and is licensed and in good standing under the Laws of each jurisdiction where its ownership, lease or operation of properties or the conduct of its business requires such qualification or license; except in each case referred to in clauses (b)(i) or (c), to the extent that failure to do so could not reasonably be expected to have a Material Adverse Effect.

6.02 Authorization; No Contravention.

The execution, delivery and performance by each Loan Party of each Investment Document to which such Person is party have been duly authorized by all necessary corporate or other organizational action, and do not (a) contravene the terms of any of such Person's Organization Documents, (b) conflict with or result in any breach or contravention of, or the creation of any Lien under, or require any payment to be made under (i) any Contract to which such Person is a party or affecting such Person or the properties of such Person or any of its Subsidiaries or (ii) any order, injunction, writ or decree of any Governmental Authority or any arbitral award to which such Person or its property is subject or (c) violate, in any material respect, any Law (including, without limitation, Regulation U or Regulation X issued by the FRB), except with respect to any conflict, breach, contravention or payment (but not creation of Liens) referred to in clause (b) to the extent that such conflict, breach, contravention or payment could not reasonably be expected to have a Material Adverse Effect.

6.03 Governmental Authorization; Other Consents.

No approval, consent, exemption, authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person is necessary or required in connection with the execution, delivery or performance by, or enforcement against, any Loan Party of this Agreement or any other Investment Document other than (a) those that have already been obtained and are in full force and effect, (b) filings to perfect the Liens created by the Collateral Documents and (c) those approvals, consents, exemptions, authorizations, actions, notices or filings described in the Collateral Documents.

6.04 Binding Effect.

Each Investment Document has been duly executed and delivered by each Loan Party that is party thereto. Each Investment Document constitutes a legal, valid and binding obligation of each Loan Party that is party thereto, enforceable against each such Loan Party in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium and similar laws affecting the enforceability of creditors' rights generally and to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

6.05 Financial Statements; No Material Adverse Effect.

(a) The Audited Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby in accordance with GAAP consistently applied throughout the period covered thereby, except as

otherwise expressly noted therein and (iii) show all material indebtedness and other liabilities, direct or contingent, of the Borrower and its Subsidiaries as of the date thereof, including material liabilities for taxes, commitments and Indebtedness.

(b) The Interim Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby, subject, in the case of clauses (i) and (ii), to the absence of footnotes and to normal year-end audit adjustments and (iii) show all material indebtedness and other liabilities, direct or contingent, of the Borrower and its Subsidiaries as of the date thereof, including material liabilities for taxes, material commitments and Indebtedness.

(c) From the date of the Audited Financial Statements to and including the Funding Date, there has been no Disposition by any Loan Party or any Subsidiary, or any Involuntary Disposition, of any material part of the business or property of any Loan Party or any Subsidiary, and no purchase or other acquisition by any of them of any business or property (including any Equity Interests of any other Person) material to any Loan Party or any Subsidiary, in each case, which is not reflected in the foregoing financial statements or in the notes thereto and has not otherwise been disclosed in writing to the Lenders on or prior to the Funding Date.

(d) The financial statements delivered pursuant to Section 7.01(a) and (b) have been prepared in accordance with GAAP (except as may otherwise be permitted under Section 7.01(a) and (b)) and present fairly in all material respects (on the basis disclosed in the footnotes to such financial statements) the consolidated financial condition, results of operations and cash flows of the Borrower and its Subsidiaries as of the dates thereof and for the periods covered thereby.

(e) Since the date of the Audited Financial Statements, there has been no event or circumstance, either individually or in the aggregate, that has had or could reasonably be expected to have a Material Adverse Effect.

6.06 Litigation.

There are no actions, suits, proceedings, claims or disputes pending or, to the knowledge of the Loan Parties after due and diligent investigation, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against any Loan Party or any of its Subsidiaries or against any of their properties or revenues that (a) purport to affect or pertain to this Agreement or any other Investment Document, or any of the transactions contemplated hereby or (b) could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

6.07 No Default.

(a) Neither any Loan Party nor any Subsidiary is in default under or with respect to any Contract that could reasonably be expected to have a Material Adverse Effect.

(b) No Default or Event of Default has occurred and is continuing.

6.08 Ownership of Property; Liens.

(a) Each Loan Party and its Subsidiaries has good record and marketable title in fee simple to, or valid leasehold interests in, all real property necessary or used in the ordinary

conduct of its business, except for such defects in title as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The property of each Loan Party and its Subsidiaries is subject to no Liens, other than Permitted Liens.

(b) No Loan Party nor any of their respective Subsidiaries (including, for the avoidance of doubt, any Subsidiary in which a Loan Party holds a minority interest) has any direct or indirect interest in any real property located in the British Virgin Islands.

6.09 Environmental Compliance.

Except as could not reasonably be expected to have a Material Adverse Effect:

(a) Each of the Business Facilities and all operations at the Business Facilities are in compliance with all applicable Environmental Laws, and there is no violation of any Environmental Law with respect to the Business Facilities or the Businesses, and there are no conditions relating to the Business Facilities or the Businesses that could give rise to liability under any applicable Environmental Laws.

(b) None of the Business Facilities contains, or has previously contained, any Hazardous Materials at, on or under the Business Facilities in amounts or concentrations that constitute or constituted a violation of, or could give rise to liability under, Environmental Laws.

(c) Neither any Loan Party nor any Subsidiary has received any written notice of, or inquiry from any Governmental Authority regarding, any violation, alleged violation, non-compliance, liability or potential liability regarding environmental matters or compliance with Environmental Laws with regard to any of the Business Facilities or the Businesses, nor does any Responsible Officer of any Loan Party have knowledge or reason to believe that any such notice will be received or is being threatened.

(d) Hazardous Materials have not been transported or disposed of from the Business Facilities, or generated, treated, stored or disposed of at, on or under any of the Business Facilities or any other location, in each case by or on behalf of any Loan Party or any Subsidiary in violation of, or in a manner that would be reasonably likely to give rise to liability under, any applicable Environmental Law.

(e) No judicial proceeding or governmental or administrative action is pending or, to the knowledge of the Loan Parties, threatened in writing, under any Environmental Law to which any Loan Party or any Subsidiary is or will be named as a party, nor are there any consent decrees or other decrees, consent orders, administrative orders or other orders, or other administrative or judicial requirements outstanding under any Environmental Law with respect to any Loan Party, any Subsidiary, the Business Facilities or the Businesses.

(f) There has been no release or threat of release of Hazardous Materials at or from the Business Facilities, or arising from or related to the operations (including, without limitation, disposal) of any Loan Party or any Subsidiary in connection with the Business Facilities or otherwise in connection with the Businesses, in violation of or in amounts or in a manner that could give rise to liability under Environmental Laws.

6.10 Insurance.

(a) The properties of the Loan Parties and their respective Subsidiaries are insured with financially sound and reputable insurance companies that are not Affiliates of the Borrower or any Subsidiary, in such amounts, with such deductibles and covering such risks as are customarily carried by companies engaged in similar businesses and owning similar properties in localities where the applicable Loan Party or the applicable Subsidiary operates. The insurance coverage of the Loan Parties and their respective Subsidiaries as in effect on the Effective Date is outlined as to carrier, policy number, expiration date, type, amount and deductibles on Schedule 6.10 to the Disclosure Letter.

(b) The Borrower and its Subsidiaries maintain, if available, fully paid flood hazard insurance on all real property that is located in a special flood hazard area and that constitutes Collateral on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise required by the Administrative Agent.

6.11 Taxes.

The Loan Parties and their respective Subsidiaries have filed all federal, provincial, territorial and state income and other material tax returns and reports required to be filed, and have paid all federal, provincial, territorial and state income and other material taxes, assessments, fees and other governmental charges levied or imposed upon them or their properties, income or assets otherwise due and payable, except those which are being contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves have been provided in accordance with GAAP. There is no proposed tax assessment against any Loan Party or any Subsidiary that would, if made, have a Material Adverse Effect. Neither any Loan Party nor any Subsidiary thereof is party to any tax sharing agreement with any Person that is not a Loan Party.

6.12 ERISA Compliance.

(a) Each Plan is in compliance in all material respects with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state laws. Any Pension Plan that is intended to be a qualified plan under Section 401(a) of the Internal Revenue Code has received a favorable determination letter from the Internal Revenue Service to the effect that the form of such Plan is qualified under Section 401(a) of the Internal Revenue Code and any trust related thereto has been determined by the Internal Revenue Service to be exempt from federal income tax under Section 501(a) of the Internal Revenue Code or an application for such a letter will be timely submitted to the Internal Revenue Service for processing. To the best knowledge of the Loan Parties, nothing has occurred that would prevent, or cause the loss of, any such tax-qualified status.

(b) There are no pending or, to the best knowledge of the Loan Parties, threatened (in writing) claims, actions or lawsuits, or action by any Governmental Authority, with respect to any Plan that would reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect. There has been no prohibited transaction or violation of the fiduciary responsibility rules applicable with respect to any Plan that has resulted or would reasonably be expected, either individually or in the aggregate, to result in a Material Adverse Effect.

(c) (i) No ERISA Event has occurred and neither the Borrower nor any ERISA Affiliate is aware of any fact, event or circumstance that would reasonably be expected to constitute or result in an ERISA Event with respect to any Pension Plan, (ii) the Borrower and

each ERISA Affiliate has met any applicable requirements under the Pension Funding Rules in respect of any Pension Plan, and no waiver of the minimum funding standards under the Pension Funding Rules has been applied for or obtained by the Borrower or any ERISA Affiliate, (iii) as of the most recent valuation date for any Pension Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Internal Revenue Code) is sixty percent (60%) or higher and neither the Borrower nor any ERISA Affiliate knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage for any such plan to drop below sixty percent (60%) as of the most recent valuation date, (iv) neither the Borrower nor any ERISA Affiliate has incurred any liability to the PBGC with respect to any Pension Plan other than for the payment of any premiums, and there are no premium payments which have become due that are unpaid, (v) neither the Borrower nor any ERISA Affiliate has engaged in a transaction that could be subject to Section 4069 or Section 4212(c) of ERISA and (vi) no Pension Plan has been terminated by the plan administrator thereof nor by the PBGC, and no event or circumstance has occurred or exists that could reasonably be expected to cause the PBGC to institute proceedings under Title IV of ERISA to terminate any Pension Plan.

(d) Each Loan Party is not and will not be (i) an employee benefit plan subject to Title I of ERISA, (ii) a plan or account subject to Section 4975 of the Internal Revenue Code; (iii) an entity deemed to hold "plan assets" of any such plans or accounts for purposes of ERISA or the Internal Revenue Code or (iv) a "governmental plan" within the meaning of ERISA.

(e) Each Loan Party and each of its Subsidiaries is in compliance in all material respects with all applicable Laws and requirements with respect to any Employee Benefit Non-U.S. Plan, and have performed in all material respects all their obligations under any such Employee Benefit Non-U.S. Plan. No Employee Benefit Non-U.S. Plan Event has occurred or is reasonably expected to occur that would reasonably be expected to result in material liability to any Loan Party or any of its Subsidiaries. Any Employee Benefit Non-U.S. Plan has been maintained in material compliance with its terms and with the requirements of any and all applicable Laws, statutes, rules, regulations and orders and has been maintained, where required, in good standing with applicable regulatory authorities, except as would not reasonably be expected, either individually or in the aggregate, to result in a material liability to any Loan Party or any of its Subsidiaries. Any contributions required to be made with respect to a, Employee Benefit Non-U.S. Plan have been timely made. Neither the Borrower nor any of its Subsidiaries has incurred any material obligation in connection with the termination of, or withdrawal from, any Employee Benefit Non-U.S. Plan. The present value of the accrued benefit liabilities (whether or not vested) under any Employee Benefit Non-U.S. Plan, determined as of the end of the Borrower's most recently ended fiscal year on the basis of reasonable actuarial assumptions, did not exceed the current value of the assets of such Employee Benefit Non-U.S. Plan allocable to such benefit liabilities.

6.13 Subsidiaries and Capitalization.

(a) Set forth on Schedule 6.13(a) to the Disclosure Letter is a complete and accurate list as of the Effective Date of each Subsidiary (including a designation of each Subsidiary that is an Excluded Subsidiary as of the Effective Date), together with (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by any Loan Party or any Subsidiary and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto. The outstanding Equity Interests of each Subsidiary are validly issued, fully paid and non-assessable.

(b) Set forth on Schedule 6.13(b) to the Disclosure Letter is a true and complete table showing the authorized and issued capitalization of the Borrower as of the Effective Date on a fully diluted basis. All issued and outstanding Equity Interests of the Borrower and each of its Subsidiaries are duly authorized and validly issued, fully paid, non-assessable and such Equity Interests were issued in compliance with all applicable Laws. All issued and outstanding Equity Interests of each Subsidiary are free and clear of all Liens. As of the Effective Date, except as described on Schedule 6.13(b) to the Disclosure Letter, there are no outstanding commitments or other obligations of any Loan Party or any Subsidiary to issue, and no rights of any Person to acquire, any shares of any Equity Interests of any Loan Party or any of their respective Subsidiaries. Except as set forth on Schedule 6.13(b) to the Disclosure Letter, there are no statutory or contractual preemptive rights, rights of first refusal, anti-dilution rights or any similar rights held by equity holders or option holders of any Loan Party. There are no agreements (voting or otherwise) among any Loan Party's equity holders with respect to any other aspect of such Loan Party's affairs, except as set forth on Schedule 6.13(b) to the Disclosure Letter.

6.14 Margin Regulations; Investment Company Act.

(a) The Borrower is not engaged and will not engage, principally or as one of its important activities, in the business of purchasing or carrying margin stock (within the meaning of Regulation U issued by the FRB), or extending credit for the purpose of purchasing or carrying margin stock. Following the application of the proceeds of each Borrowing, not more than 25% of the value of the assets (of the Borrower only or of the Borrower and its Subsidiaries on a consolidated basis) subject to the provisions of Section 8.01 or Section 8.05 or subject to any restriction contained in any agreement or instrument between the Borrower and any Lender or any Affiliate of any Lender relating to Indebtedness and within the scope of Section 9.01(e) will be margin stock.

(b) None of any Loan Party or any Subsidiary is or is required to be registered as an "investment company" under the Investment Company Act of 1940.

6.15 Disclosure.

Each Loan Party has disclosed to the Administrative Agent and the Lenders all agreements, instruments and corporate or other restrictions to which it or any of its Subsidiaries is subject, and all other matters known to it, that, either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. No report, financial statement, certificate or other information furnished (whether written or oral) by or on behalf of any Loan Party to the Administrative Agent or any Lender in connection with the transactions contemplated hereby and the negotiation of this Agreement or delivered hereunder or under any other Loan Document (in each case, when taken as a whole, as modified or supplemented by other information so furnished) contains any material misstatement of fact or omits to state any fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, that, with respect to projected financial information, the Borrower represents only that such information was prepared in good faith based upon assumptions it believed to be reasonable at the time (it being understood that such projected financial information is not to be viewed as facts, and that actual results during the period or periods covered by such projections may differ from the projected results and such differences may be material).

6.16 Compliance with Laws.

(a) Each Loan Party and each Subsidiary is in compliance with all Laws and all orders, writs, injunctions and decrees applicable to it or to its properties, except in such instances

in which (i) such Law or order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted or (ii) the failure to comply therewith could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

(b) (i) Any physician, other licensed healthcare professional, or any other Person who is in a position to refer patients or other business to any Loan Party or any Subsidiary (each, a "Referral Source") who has a direct ownership, investment, or financial interest in any Loan Party or any Subsidiary paid fair market value for such ownership, investment or financial interest; (ii) any ownership or investment returns distributed to any Referral Source is in proportion to such Referral Source's ownership, investment or financial interest; and (iii) no preferential treatment or more favorable terms were or are offered to such Referral Source compared to investors or owners who are not in a position to refer patients or other business. Neither any Loan Party nor any Subsidiary, directly or indirectly, has guaranteed a loan, made a payment toward a loan or otherwise subsidized a loan for any Referral Source including, without limitation, any loans related to financing the Referral Source's ownership, investment or financial interest in such Loan Party or any such Subsidiary.

(c) Without limiting the generality of the foregoing, except where noncompliance individually or in the aggregate could not reasonably be expected, either individually or in the aggregate, to result in a Material Adverse Effect:

(i) any financial relationships between or among any Loan Party or any Subsidiary, on the one hand, and any Referral Source, on the other hand (A) comply with all applicable Healthcare Laws including, without limitation, the Federal Anti-Kickback Statute, the Stark Law and applicable state antikickback and self-referral laws; (B) reflect fair market value, have commercially reasonable terms and were negotiated at arm's length and (C) do not obligate the Referral Source to purchase, use, recommend or arrange for the use of any products or services of any Loan Party or any Subsidiary; and

(ii) each Loan Party and each Subsidiary have implemented policies and procedures to monitor, collect and report any payments or transfers of value to certain healthcare providers and teaching hospitals in accordance with the Affordable Care Act of 2010 and its implementing regulations and any applicable state disclosure and transparency laws.

(d) Except as set forth on Schedule 6.16(d) to the Disclosure Letter, the consummation of the transactions contemplated hereby and the exercise by the Administrative Agent or the Lenders of any right or protection set forth in this Agreement will not constitute a breach or violation of, or otherwise affect the enforceability or approval of, any (i) Device Clearance Applications, (ii) Product Authorizations or (iii) Regulatory Approvals.

6.17 Intellectual Property; Licenses, Etc.

(a) Schedule 6.17(a) to the Disclosure Letter contains, with respect to each Loan Party and each of its Subsidiaries:

(i) a complete and accurate list of all applied for, issued, or registered Patents (A) owned by, (B) constituting Material IP Rights and nonexclusively licensed to or (C) exclusively licensed to a Loan Party or one of its Subsidiaries, including the jurisdiction and patent number or patent application number;

(ii) a complete and accurate list of all material unregistered, applied for or registered Trademarks (A) owned by, (B) constituting Material IP Rights and nonexclusively licensed to or (C) exclusively licensed to a Loan Party or one of its Subsidiaries, including the jurisdiction, trademark application or registration number and the application or registration date; and

(iii) a complete and accurate list of all material applied for or registered Copyrights (A) owned by, (B) constituting Material IP Rights and nonexclusively licensed to or (C) exclusively licensed to a Loan Party or one of its Subsidiaries.

(b) Except for non-exclusive licenses granted in the ordinary course of business, each Loan Party and each of their Subsidiaries is the absolute beneficial owner of all right, title and interest in and to the Business IP Rights that it owns (including, without limitation, the Business IP Rights indicated on Schedule 6.17(b) to the Disclosure Letter as being owned by such Loan Party or Subsidiary), with good and marketable title (and no breaks in chain of title), free and clear of any Liens or claims of any kind whatsoever other than Permitted Liens and each Loan Party and Subsidiary has the right to use all its Material IP Rights. Without limiting the foregoing, and except as set forth in Schedule 6.17(b) to the Disclosure Letter:

(i) other than as permitted by Section 8.05, no Loan Party, nor any of its Subsidiaries, has transferred ownership of or exclusively licensed any of its Material IP Rights, in whole or in part, to any Person who is not a Loan Party;

(ii) other than (A) customary restrictions in in-bound licenses or out-bound non-exclusive licenses of IP Rights and non-disclosure agreements, (B) as would have been or is permitted by Sections 8.01 and 8.05 or (C) non-exclusive licenses granted in the ordinary course of business, there are no covenants not to sue, permits, grants, licenses or other agreements or arrangements relating to such Loan Party's or any of their respective Subsidiary's Material IP Rights, including any development, submission, services, research, license or support agreements, which bind, obligate or otherwise restrict such Loan Party or any of its Subsidiaries with respect to any Material IP Rights;

(iii) (A) there are no pending or, to the knowledge of any Loan Party, threatened (in writing) claims against any Loan Party or any of its Subsidiaries asserted by any other Person relating to any Business IP Rights, including any claims of adverse ownership, invalidity, infringement, misappropriation, violation or other opposition to or conflict with such Business IP Rights that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect and (B) except as could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect, there are no pending or, to the knowledge of any Loan Party, threatened (in writing) claims against any Loan Party or any of their respective Subsidiaries and no Loan Party or any of their respective Subsidiaries have received any written notice from any Person that any Loan Party's or any Subsidiary's business and/or the use of any Business IP Rights or any Product, Product Commercialization and Development Activities or Product Assets infringes upon, violates or constitutes a misappropriation of, or may infringe upon, violate or constitute a misappropriation of, or otherwise interfere with any IP Rights of any other Person or otherwise offering a license with respect to any Product;

(iv) the Loan Parties have no knowledge that any Business IP Right is being infringed, violated, misappropriated or otherwise used by any other Person without the

express authorization of the Loan Parties and, without limiting the foregoing, no Loan Party nor any Subsidiary has put any other Person on notice of actual or potential infringement, violation or misappropriation of any Business IP Rights and no Loan Party nor any Subsidiary has initiated the enforcement of any claim with respect to any Business IP Rights;

(v) all relevant current and former employees and contractors of each Loan Party and each Subsidiary who were or are involved in the creation or development of Business IP Rights have executed written confidentiality and invention assignment contracts with such Loan Party or such Subsidiary substantially in the form provided to the Administrative Agent's counsel;

(vi) the operation of each Loan Party's and each Subsidiary's business and/or the use by each Loan Party and each of their Subsidiaries of any of their respective Business IP Rights, Products, Product Commercialization and Development Activities or Product Assets does not breach, violate, infringe or interfere with or constitute a misappropriation of any valid rights arising under any IP Rights of any other Person that could reasonably be expected, either individually or in the aggregate, to result in a Material Adverse Effect.

(c) The Business IP Rights are subsisting, valid, unexpired, enforceable and have not been abandoned. With respect to the owned Business IP Rights consisting of Patents, except as set forth in Schedule 6.17(b) to the Disclosure Letter and without limiting the representations and warranties in clause (b):

(i) none of the Patents or the Inventions claimed in any such Patent have been dedicated to the public except as a result of intentional decisions made by the applicable Loan Party or Subsidiary and no Loan Party, Subsidiary nor any of their respective predecessors-in-interest has filed any disclaimer (other than a terminal disclaimer) or filed any other voluntary reduction in the scope of the Inventions claimed in such Patents;

(ii) no Loan Party, Subsidiary, nor, to the knowledge of the Loan Parties, any prior owner of any Patent or any of their respective agents or representatives have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any Patent, except as could not reasonably be expected, either individually or in the aggregate, to result in a Material Adverse Effect;

(iii) all maintenance fees, annuities, and the like due or payable on or with respect to any Patents have been timely paid, except as could not reasonably be expected, either individually or in the aggregate, to result in a Material Adverse Effect;

(iv) no Patents are or have been the subject of any re-examination, opposition, any other pre- or post-grant proceedings or of any administrative, arbitration, judicial or other proceeding, nor is any Loan Party aware of any basis for any such interference, re-examination, opposition, inter partes review, post grant review or any other pre- or post-grant proceedings, judicial proceeding or other proceeding;

(v) no Loan Party or Subsidiary has received any written notice asserting that any Patents are invalid, unpatentable or unenforceable; and

(vi) if any Patent is terminally disclaimed to another patent or patent application, all patents and patent applications subject to such terminal disclaimer are included in the Collateral.

(d) Schedule 6.17(d) to the Disclosure Letter sets forth an accurate list of all Material IP Rights, together with an indication as to whether the applicable Loan Party or applicable Subsidiary owns or has an exclusive or nonexclusive license to such Material IP Rights.

(e) None of the IP Rights are subject to any license grant by any Loan Party or any Subsidiary or similar arrangement, except for (i) license grants solely between the Loan Parties, (ii) those license grants disclosed on Schedule 6.17(e) to the Disclosure Letter and (iii) non-exclusive licenses permitted by Section 8.05 granted in the ordinary course of business.

6.18 Solvency.

The Borrower and its Subsidiaries are Solvent, on a consolidated basis.

6.19 Perfection of Security Interests in the Collateral.

The Collateral Documents create valid security interests in, and Liens on, the Collateral purported to be covered thereby, which security interests and Liens will be, upon the timely and proper filings, deliveries and other actions contemplated in the Collateral Documents perfected security interests and Liens (to the extent that such security interests and Liens can be perfected by such filings, deliveries, notations and other actions), prior to all other Liens other than Permitted Liens.

6.20 Business Locations.

Set forth on Schedule 6.20(a) to the Disclosure Letter is a list of all real property that is owned or leased by the Loan Parties as of the Effective Date (with (x) a designation of each real property that is Excluded Property and (y) a designation as to whether such real property is owned or leased). Set forth on Schedule 6.20(b) to the Disclosure Letter is the tax payer identification number (or foreign equivalent) and organizational identification number (or foreign equivalent) of each Loan Party as of the Effective Date. The exact legal name and state of organization (or foreign equivalent) of (a) the Borrower is as set forth on the signature pages hereto and (b) each Guarantor is (i) as set forth on the signature pages hereto, (ii) as set forth on the signature pages to the Joinder Agreement pursuant to which such Guarantor became a party hereto or (iii) as may be otherwise disclosed by the Loan Parties to the Administrative Agent in accordance with Section 8.12(c). Set forth on Schedule 6.20(c) to the Disclosure Letter are the locations of all inventory, equipment and other tangible personal property of each BVI Loan Party, as of the Effective Date. Set forth on Schedule 6.20(d) to the Disclosure Letter are the locations of all inventory, equipment and other tangible personal property of (x) each Belgian Loan Party and (y) each Loan Party located in the Kingdom of Belgium, in each case, as of the Effective Date. Set forth on Schedule 6.20(e) to the Disclosure Letter are the locations of all inventory, equipment and other tangible personal property of (x) each Costa Rican Loan Party and (y) each Loan Party located in the Republic of Costa Rica, in each case, as of the Effective Date. Set forth on Schedule 6.20(f) to the Disclosure Letter are the locations of all inventory, equipment and other tangible personal property of (x) each Brazilian Loan Party and (y) each Loan Party located in the Federative Republic of Brazil, in each case, as of the Effective Date. Except as set forth on Schedule 6.20(g) to the Disclosure Letter, no Loan Party has during the five years preceding the Effective Date (x) changed its legal name, (y) changed its state of organization (or foreign equivalent) or (z) been party to a continuation, merger, amalgamation, consolidation or other change in structure.

6.21 Sanctions Concerns; Anti-Corruption Laws; PATRIOT Act; Anti-Money Laundering Laws.

(a) Sanctions Concerns. No Loan Party, nor any Subsidiary, nor, to the knowledge of the Loan Parties and their respective Subsidiaries, any director, officer, employee, agent, affiliate or representative thereof, is an individual or entity that is, or is owned or controlled by, any individual or entity that is (i) the subject or target of any Sanctions, (ii) included on OFAC's List of Specially Designated Nationals, HMT's Consolidated List of Financial Sanctions Targets and the Investment Ban List, or any similar list enforced by any other relevant sanctions authority or (iii) located, organized or resident in a Designated Jurisdiction.

(b) Anti-Corruption Laws. The Loan Parties and their respective Subsidiaries have conducted their business in material compliance with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions applicable to any Loan Party or any Subsidiary, and have instituted and maintained policies and procedures designed to promote and achieve compliance with such laws.

(c) PATRIOT Act. To the extent applicable, each Loan Party and each Subsidiary is in compliance, in all material respects, with (i) the Trading with the Enemy Act, as amended, and each of the foreign assets control regulations of the United States Treasury Department (31 CFR, Subtitle B, Chapter V, as amended) and any other enabling legislation or executive order relating thereto and (ii) the Act.

(d) Anti-Money Laundering Laws. No Loan Party, nor any Subsidiary, nor, to the knowledge of the Loan Parties and their respective Subsidiaries, any director, officer, employee, agent, affiliate or representative thereof, (i) has been found in violation of, charged with, or convicted of, money laundering, drug trafficking, terrorist related activities or other money laundering predicate crimes under the Currency and Foreign Transactions Reporting Act of 1970 (otherwise known as the Bank Secrecy Act), the Act or any other United States law or regulation governing such activities (collectively, "Anti-Money Laundering Laws") or any U.S. economic sanctions violations, (ii) to each Loan Party's actual knowledge after making due inquiry, is under investigation by any Governmental Authority for possible violation of Anti-Money Laundering Laws or any Sanctions violations, (iii) has been assessed civil penalties under any Anti-Money Laundering Laws or any Sanctions or (iv) has had any of its funds seized or forfeited in an action under any Anti-Money Laundering Law. Each Loan Party has established procedures and controls which it reasonably believes are adequate (and otherwise comply in all material respects with applicable Law) to ensure that each Loan Party and each Subsidiary thereof is and will continue to be in compliance in all material respects with all applicable current and future Anti-Money Laundering Laws.

6.22 Material Contracts.

Except for Organization Documents of the Loan Parties and their respective Subsidiaries, there are no Material Contracts other than as set forth on Schedule 6.22 to the Disclosure Letter as of the Effective Date. Schedule 6.22 to the Disclosure Letter sets forth, with respect to each real estate lease agreement to which any Loan Party or any Subsidiary is a party as of the Effective Date that constitutes a Material Contract, the address of the subject property and the annual rental rate as of the Effective Date. The consummation of the transactions contemplated by the Investment Documents and the exercise by the Administrative Agent or the Lenders of any right or protection set forth in the Investment Documents will not constitute a breach or violation of, or otherwise affect the enforceability of, or give rise to a right of termination in favor of any party to any Material Contract. Except as otherwise disclosed on Schedule

6.22 to the Disclosure Letter (or pursuant to Section 7.02(a)), all Material Contracts are in full force and effect without material modification from the form in which the same were disclosed to the Administrative Agent. Except as set forth on Schedule 6.22 to the Disclosure Letter, there are no Material Contracts which are non-assignable by their terms, or as a matter of law, or which prevent the granting of a security interest therein.

6.23 Regulatory Approvals.

(a) With respect to the Products, the Loan Parties hold either directly or through licensees and agents, all Regulatory Approvals necessary or required for such Loan Party and each of its Subsidiaries to conduct all current Product Commercialization and Development Activities with respect to the Products.

(b) Set forth on Schedule 6.23(b) to the Disclosure Letter is a complete and accurate list of all Regulatory Approvals referred to in clause (a), setting forth (in reasonable detail and on a Product-by-Product basis) the Loan Party that holds such Regulatory Approval and identifying the product related to such Regulatory Approval. All such Regulatory Approvals are (i) legally and beneficially owned exclusively by such Loan Party identified on such Schedule, free and clear of all Liens other than Permitted Liens, (ii) validly registered and on file with the applicable Regulatory Authority in compliance in all material respects with all registration, filing and maintenance requirements (including any fee requirements) thereof and (iii) valid, enforceable, in good standing and in full force and effect, with the applicable Regulatory Authority.

(c) All regulatory filings required by any Regulatory Authority or in respect of any Regulatory Approval or Product Authorization with respect to any Product or any Product Commercialization and Development Activities have been made (including all required notices, registrations and listings, supplemental applications or notifications, reports (including field alerts, Device reports or other reports of adverse experiences) and all other required filings with respect to the Products or any related Product Commercialization and Development Activities), and all such filings are complete and correct in all material respects and are in compliance in all material respects with all applicable Laws.

(d) Each Loan Party and each Subsidiary and to the knowledge of the Loan Parties, each of their licensees and agents is in compliance in all material respects with all applicable Laws (including all Regulatory Approvals and Product Authorizations) with respect to each Product as to which such Person conducts, directly or indirectly, any Product Commercialization and Development Activities.

(e) Except as set forth on Schedule 6.23(e) to the Disclosure Letter, and without limiting the generality of any other representation or warranty made by any Loan Party hereunder or under any other Loan Document: (i) all Products comply in all material respects with (A) all applicable Laws of the FDA and each other applicable Regulatory Authority, whether U.S. or non-U.S. and (B) all Product Authorizations and other Regulatory Authorizations; (ii) no Loan Party nor any of their respective Subsidiaries nor, to the knowledge of any Loan Party, any of their respective agents, suppliers, licensors or licensees have received any inspection reports, warning letters or notices or similar documents with respect to any Product from any Regulatory Authority within the last three (3) years that asserts lack of compliance with any applicable Law or Regulatory Approvals or other orders, injunctions or decrees; (iii) no Loan Party nor any of their respective Subsidiaries nor, to the knowledge of any Loan Party, any of their respective agents, suppliers, licensors or licensees have received any notification from any Regulatory Authority within the last three (3) years, asserting that any Product lacks a required Regulatory

Approval or Product Authorization; (iv) there is no pending regulatory action, investigation or inquiry (other than non-material routine or periodic inspections or reviews) against any Loan Party, any of their respective Subsidiaries or, to the knowledge of any Loan Party, any of their respective suppliers, licensors or licensees with respect to any Product and, to the knowledge of any Loan Party, there is no reasonable basis for any adverse regulatory action against such Loan Party or any of their respective Subsidiaries or, to the knowledge of any Loan Party, any of their respective suppliers, agents, licensors or licensees with respect to any Product and (v) without limiting the foregoing, (A) (1) there have been no product recalls, safety alerts, corrections, withdrawals, marketing suspensions or removals conducted, undertaken or issued by any Loan Party or any Subsidiary, whether voluntary, at the request, demand or order of any Regulatory Authority or otherwise, with respect to any Product within the last three (3) years, (2) no such product recall, safety alert, correction, withdrawal, marketing suspension or removal has been requested, demanded or ordered by any Regulatory Authority within the last three (3) years, and, to the knowledge of any Loan Party, there is no reasonable basis for the issuance of any such product recall, safety alert, correction, withdrawal, marketing suspension or removal with respect to any Product 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 three (3) years with respect to or in connection with any Product, there are no consent decrees (including plea agreements) that relate to any Product and, to the knowledge of each Loan Party, there is no reasonable basis for the commencement of any criminal injunctive, seizure, detention or civil penalty action by any Regulatory Authority relating to any Product or for the issuance of any consent decree. To the knowledge of each Loan Party, no Loan Party nor any of their respective Subsidiaries nor any of their respective agents, suppliers, licensees or licensors is employing or utilizing the services of any individual who has been debarred or temporarily suspended under any applicable Law.

(f) Neither any Loan Party nor any of their respective Subsidiaries, nor, to the knowledge of the Loan Parties, any of their respective officers, employees or agents, has made an untrue statement of a material fact or fraudulent statements to the FDA or any other Regulatory Authority, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority or committed an act, made a statement or failed to make a statement that, at the time such disclosure was made (or was not made), could reasonably be expected to provide a basis for the FDA or any other Regulatory Authority to invoke its policy respecting Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities, set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy.

(g) The clinical, preclinical, safety and other studies and tests conducted by or on behalf of or sponsored by any Loan Party or any of their respective Subsidiaries, or in respect of which any Products or Product candidates under development have participated, were (and if still pending, are) being conducted materially in accordance with standard medical and scientific research procedures and all applicable Product Authorizations. No Loan Party nor any of their respective Subsidiaries has received any notices or other correspondence from the FDA or any other Regulatory Authority requiring the termination or suspension of any clinical, preclinical, safety or other studies or tests used to support regulatory clearance of, or any Product Authorization or Regulatory Approval for, any Product.

6.24 Labor Matters.

There are no existing or threatened (in writing) strikes, lockouts or other labor disputes involving any Loan Party or any Subsidiary that individually or in the aggregate could reasonably be expected to have a Material Adverse Effect. Hours worked by and payment made to employees of the Loan Parties

and their respective Subsidiaries are not in violation of the Fair Labor Standards Act or any other applicable law, rule or regulation dealing with such matters, except for any such violations as could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

6.25 EEA Financial Institutions.

No Loan Party is an EEA Financial Institution.

6.26 Representations as to Foreign Loan Parties.

Each Foreign Loan Party represents and warrants to the Administrative Agent and the Lenders that:

(a) Such Foreign Loan Party is subject to civil and commercial Laws with respect to its obligations under this Agreement and the other Investment Documents to which it is a party (collectively as to such Foreign Loan Party, the "Applicable Foreign Loan Party Documents" (it being understood and agreed that the guarantees and security interests provided and granted by any Belgian Loan Party are limited to those provided and granted in this Agreement, the Belgian Share Pledge Agreement and the Belgian Receivables Pledge Agreement)), and the execution, delivery and performance by such Foreign Loan Party of the Applicable Foreign Loan Party Documents constitute and will constitute private and commercial acts and not public or governmental acts. Neither such Foreign Loan Party nor any of its property has any immunity from jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution, execution or otherwise) under the laws of the jurisdiction in which such Foreign Loan Party is organized and existing in respect of its obligations under the Applicable Foreign Loan Party Documents.

(b) The Applicable Foreign Loan Party Documents are in proper legal form under the Laws of the jurisdiction in which such Foreign Loan Party is organized and existing for the enforcement thereof against such Foreign Loan Party under the Laws of such jurisdiction, and to ensure the legality, validity, enforceability, priority or admissibility in evidence of the Applicable Foreign Loan Party Documents. It is not necessary to ensure the legality, validity, enforceability, priority or admissibility in evidence of the Applicable Foreign Loan Party Documents that the Applicable Foreign Loan Party Documents be filed, registered or recorded with, or executed or notarized before, any court or other authority in the jurisdiction in which such Foreign Loan Party is organized and existing or that any registration charge or stamp or similar tax be paid on or in respect of the Applicable Foreign Loan Party Documents or any other document, except for (i) any such filing, registration, recording, execution or notarization as has been made or is not required to be made until the Applicable Foreign Loan Party Document or any other document is sought to be enforced and (ii) any charge or tax as has been timely paid.

(c) With respect to any Foreign Loan Party that becomes a party to this Agreement after the Effective Date as contemplated by Section 7.12, there is no tax, levy, impost, duty, fee, assessment or other governmental charge, or any deduction or withholding, imposed by any Governmental Authority in or of the jurisdiction in which such Foreign Loan Party is organized and existing either (i) on or by virtue of the execution or delivery of the Applicable Foreign Loan Party Documents or (ii) on any payment to be made by such Foreign Loan Party pursuant to the Applicable Foreign Loan Party Documents, except as has been disclosed to the Administrative Agent.

(d) The execution, delivery and performance of the Applicable Foreign Loan Party Documents executed by such Foreign Loan Party are, under applicable foreign exchange control regulations of the jurisdiction in which such Foreign Loan Party is organized and existing, not subject to any notification or authorization except (i) such as have been made or obtained or (ii) such as cannot be made or obtained until a later date (provided that any notification or authorization described in clause (ii) shall be made or obtained as soon as is reasonably practicable).

6.27 Royalty and Other Payments.

Except as set forth on Schedule 6.27 to the Disclosure Letter, as of the Effective Date, no Loan Party nor any of their respective Subsidiaries is obligated to pay any royalty, milestone payment, deferred payment or any other contingent payment in respect of any Product.

6.28 Non-Competes.

Neither the Borrower nor any other Loan Party nor any of their respective Subsidiaries, nor, to the knowledge of any Loan Party, any of their respective directors, officers or employees, is subject to a non-compete agreement that prohibits or will interfere with any of the Product Commercialization and Development Activities, including the development, commercialization or marketing of any Product.

6.29 Internal Controls.

The Borrower acknowledges that its management is responsible for the preparation and fair presentation of the financial statements of the Borrower and each of its Subsidiaries provided to the Administrative Agent or the Lenders pursuant to Sections 7.01 and 7.02, in each case, in accordance with GAAP. The Borrower has designed, implemented and maintained internal controls relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

## ARTICLE VII.

## AFFIRMATIVE COVENANTS

On the Funding Date and thereafter, so long as any Lender shall have any Commitment hereunder, any Loan or other Obligation hereunder shall remain unpaid or unsatisfied (other than contingent indemnification obligations for which no claim has been asserted), the Loan Parties shall and shall cause each Subsidiary to:

7.01 Financial Statements.

Deliver to the Administrative Agent, in form and detail reasonably satisfactory to the Administrative Agent and the Required Lenders:

(a) as soon as available, and in any event within one hundred and twenty (120) days after the end of each fiscal year of the Borrower (or, if earlier, when required to be filed with the SEC (or foreign equivalent)), a consolidated balance sheet of the Borrower and its Subsidiaries as at the end of such fiscal year, and the related consolidated statements of income or operations, changes in shareholders' equity and cash flows for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all in reasonable detail and prepared in accordance with GAAP, audited and accompanied by a report and opinion of an independent

certified public accountant of nationally recognized standing acceptable to the Required Lenders, 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 any qualification or exception as to the scope of such audit; and

(b) (i) as soon as available, and in any event within sixty (60) days after the end of each of the first three fiscal quarters of each fiscal year of the Borrower (or, if earlier, when required to be filed with the SEC (or foreign equivalent)), a consolidated balance sheet of the Borrower and its Subsidiaries as at the end of such fiscal quarter, and the related consolidated statements of income or operations and cash flows for such fiscal quarter and for the portion of the Borrower's fiscal year then ended, setting forth in each case in comparative form the figures for the corresponding fiscal quarter of the previous fiscal year and the corresponding portion of the previous fiscal year, all in reasonable detail and certified by a Responsible Officer of the Borrower as fairly presenting in all material respects the financial condition, results of operations and cash flows of the Borrower and its Subsidiaries in accordance with GAAP, subject only to normal year-end audit adjustments and the absence of footnotes, and (ii) as soon as available, and in any event within sixty (60) days after the end of the last fiscal quarter of each fiscal year of the Borrower, a consolidated balance sheet of the Borrower and its Subsidiaries as at the end of such fiscal quarter, and the related consolidated statements of income or operations for such fiscal quarter and for the Borrower's fiscal year then ended, setting forth in each case in comparative form the figures for the corresponding fiscal quarter of the previous fiscal year and the previous fiscal year, all in reasonable detail and certified by a Responsible Officer of the Borrower as presenting management's best estimate of the financial condition and results of operations of the Borrower and its Subsidiaries in accordance with GAAP, subject to normal year-end audit adjustments and the absence of footnotes.

7.02 Certificates; Other Information.

Deliver to the Administrative Agent, in form and detail reasonably satisfactory to the Administrative Agent and the Required Lenders:

(a) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b)(i), (i) a duly completed Compliance Certificate signed by a director, the chief executive officer, chief financial officer, treasurer or controller which is a Responsible Officer of the Borrower, including (A) information regarding the amount and timing of all Dispositions, Involuntary Dispositions, Debt Issuances, Extraordinary Receipts and Acquisitions that occurred during the period covered by such Compliance Certificate, (B) a certification as to whether the Loan Parties and their respective Subsidiaries have performed and observed each covenant and condition of the Loan Documents applicable to it during the period covered by the Compliance Certificate (or, if not, a listing of the conditions or covenants that have not been performed or observed and the nature and status of each such Default), (C) a certification of compliance with the financial covenants set forth in Sections 8.16 and 8.17, including financial covenant analyses and calculation for the period covered by the Compliance Certificate, (D) a listing of (I) all applications by any Loan Party, if any, for Copyrights, Patents or Trademarks made since the date of the prior certificate (or, in the case of the first such certificate, the Effective Date), (II) all issuances of registrations or letters on existing applications by any Loan Party or any of their Subsidiaries for Copyrights, Patents and Trademarks received since the date of the prior certificate (or, in the case of the first such certificate, the Effective Date), (III) all licenses of any IP Rights (other than non-exclusive licenses permitted by Section 8.05 granted in the ordinary course of business) entered into by any Loan Party or any of their Subsidiaries since the date of the prior certificate (or, in the case of the first such certificate, the Effective Date) and (IV) such

supplements to Schedules 6.17(a), 6.17(b), 6.17(d), 6.17(e) and 6.22, in each case, to the Disclosure Letter as are necessary to cause such schedules to be true and complete as of the date of such certificate, (E) the insurance binder or other evidence of insurance for any insurance coverage of any Loan Party or any Subsidiary that was renewed, replaced or modified during the period covered by such financial statements, (F) information regarding the deposit accounts and other bank accounts and securities accounts of the Loan Parties and their Subsidiaries as of the end of the period covered by such Compliance Certificate and (G) information regarding all Investments made by the Loan Parties and their Subsidiaries pursuant to Sections 8.02(c) as of the end of the period covered by such Compliance Certificate, (ii) a copy of management's discussion and analysis with respect to such financial statements, (iii) a list of all litigations, arbitrations or governmental investigations or proceedings which were instituted during the period covered by such financial statements or which, to the knowledge of any Loan Party, are threatened (in writing) against any Loan Party or any Subsidiary which, in any case, could reasonably be expected to result in losses and/or expenses (other than, for the avoidance of doubt, legal and court fees, costs and expenses) in excess of the Threshold Amount, together with a description setting forth the details thereof and stating what action the applicable Loan Party or Subsidiary has taken and proposes to take with respect thereto and (iv) information regarding, in each case, to the extent occurring during the period covered by such financial statements, (A) the termination of any Material Contract, (B) the receipt by any Loan Party or any of its Subsidiaries of any notice under any Material Contract (and a copy thereof) as to the occurrence of any material breach or default under or pursuant to such Material Contract that could result in termination thereof or a material liability in respect thereof, (C) the entering into of any new Material Contract by a Loan Party or any of its Subsidiaries (and a copy thereof) or (D) any material amendment to a Material Contract (and a copy thereof);

(b) as soon as available, and in any event within forty-five (45) days after the end of each fiscal year of the Borrower, (i) the annual budget (or equivalent) and forecast (or equivalent) of the Borrower and its Subsidiaries, on a consolidated basis, approved by the Board of Directors of the Borrower for the then current fiscal year and forecast period as then prepared by the Borrower, in each case together with such supporting materials as are required by the Administrative Agent and in form reasonably satisfactory to the Administrative Agent, comprising the balance sheets, statements of income or operations and statements of cash flows of the Borrower and its Subsidiaries on a quarterly basis for the then current fiscal year and on an annual basis for the forecast period and (ii) a certificate of the chief financial officer of the Borrower certifying that (A) such budget and forecast were prepared by the Borrower in good faith, (B) the Borrower had at the time of preparation of the budget and forecast, and at all times thereafter (including on and as of the date of delivery to the Administrative Agent of such budget and forecast) has continued to have, a reasonable basis for all of the assumptions contained in such budget and forecast and (C) such budget and forecast were prepared in accordance with, and based upon, such assumptions;

(c) promptly after the same are available, (i) copies of each annual report, proxy or financial statement or other report or communication sent to the equityholders of any Loan Party, (ii) copies of all annual, regular, periodic and special reports and registration statements which a Loan Party may file or be required to file with the SEC under Section 13 or 15(d) of the Securities Exchange Act of 1934, and not otherwise required to be delivered to the Administrative Agent pursuant hereto and (iii) copies of each Form S-1 Registration Statement filed with the SEC (together with all exhibits and amendments thereto) and all related material correspondence with the SEC;

(d) as soon as available, copies of any detailed audit reports or management letters or recommendations submitted to the Board of Directors (or the audit committee of the Board of Directors) of the Borrower or any Subsidiary by independent accountants in connection with the accounts or books of the Borrower or any Subsidiary, or any audit of any of them;

(e) as soon as available, and in any event within seven (7) Business Days of delivery to the Board of Directors of the Borrower (or any committee of such Board of Directors), copies of all statements, reports and notices (including board kits) made available to the Borrower's Board of Directors or the holders of the Borrower's Equity Interests; provided, that, any such material may be redacted by the Borrower to exclude information relating to the Administrative Agent or the Lenders (including the Borrower's strategy regarding the Loans) or material that is subject to attorney-client privilege or contractual confidentiality obligations with third parties;

(f) promptly after the furnishing thereof, copies of any statement or report furnished to any holder of debt securities of any Loan Party or any Subsidiary thereof pursuant to the terms of any indenture, loan or credit or similar agreement and not otherwise required to be furnished to the Lenders pursuant to Section 7.01 or any other clause of this Section 7.02;

(g) promptly, and in any event within five (5) Business Days after receipt thereof by any Loan Party or any Subsidiary thereof, (i) copies of each notice or other correspondence received from the SEC (or comparable agency in any applicable non-U.S. jurisdiction) concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of any Loan Party or any Subsidiary thereof and (ii) copies of any material written correspondence or any other material written communication from the FDA or any other regulatory body;

(h) as soon as practicable, and in any event not later than the last Business Day of each month, copies of the most recent monthly statements for each deposit account and other bank account or securities account of each Loan Party;

(i) promptly after the same are released, copies of all press releases;

(j) promptly after filing the relevant petition with the relevant court, notice of any decision of the board of directors or corresponding body of any Spanish Guarantor to request a voluntary insolvency ("concurso voluntario") or the filing of any notice foreseen under Article 5bis of the Spanish Insolvency Law; and

(k) promptly, such additional information regarding the business, financial or corporate affairs of any Loan Party or any Subsidiary, or compliance with the terms of the Investment Documents, as the Administrative Agent or any Lender may from time to time request.

Documents required to be delivered pursuant to Section 7.01 or Section 7.02 may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date (i) on which the Borrower posts such documents, or provides a link thereto on the Borrower's website on the Internet at the website address listed on Schedule 11.02 or (ii) on which such documents are posted on the Borrower's behalf on an Internet or intranet website, if any, to which each Lender and the Administrative Agent have access (whether a commercial, third-party website or whether sponsored by the Administrative Agent); provided, that: (x) the Borrower shall deliver paper copies of such documents to the Administrative Agent or any Lender upon its request to the Borrower to deliver such paper copies until a written request to cease delivering paper copies is given by the Administrative Agent or such

Lender and (y) the Borrower shall notify the Administrative Agent and each Lender (by facsimile or electronic mail) of the posting of any such documents and provide to the Administrative Agent by electronic mail electronic versions (i.e., soft copies) of such documents. The Administrative Agent shall have no obligation to request the delivery of or to maintain paper copies of the documents referred to above, and in any event shall have no responsibility to monitor compliance by the Borrower with any such request for delivery by a Lender, and each Lender shall be solely responsible for requesting delivery to it or maintaining its copies of such documents.

The Borrower hereby acknowledges that certain of the Lenders (each, a "Public Lender") may have personnel who do not wish to receive material non-public information with respect to the Borrower or its Affiliates, or the respective securities of any of the foregoing, and who may be engaged in investment and other market-related activities with respect to such Persons' securities. The Borrower hereby agrees that (1) it will in good faith identify that portion of the materials and/or information provided by, or to be provided by, or on behalf of the Borrower hereunder that does not constitute material non-public information with respect to the Borrower or its Affiliates or their respective securities (the "Public Materials") and (2) it will clearly and conspicuously mark all Public Materials "PUBLIC" which, at a minimum, shall mean that the word "PUBLIC" shall appear prominently on the first page thereof (it being understood that by marking Public Materials "PUBLIC," the Loan Parties shall be deemed to have authorized the Administrative Agent, any Affiliate thereof and the Lenders to treat such Public Materials as not containing any material non-public information (although it may be sensitive and proprietary) with respect to the Borrower or its securities for purposes of United States federal and state securities laws (or any foreign equivalent) (provided, however, that, to the extent such Public Materials constitute Information, they shall be treated as set forth in Section 11.07)).

7.03 Notices.

(a) Promptly (and in any event, within two (2) Business Days) notify the Administrative Agent and each Lender of the occurrence of any Default.

(b) Promptly (and in any event, within five (5) Business Days) notify the Administrative Agent and each Lender of any matter that has resulted or could reasonably be expected to result in a Material Adverse Effect.

(c) Promptly (and in any event, within five (5) Business Days) notify the Administrative Agent and each Lender of the occurrence of any ERISA Event.

(d) Promptly (and in any event, within five (5) Business Days) notify the Administrative Agent and each Lender of any material change in accounting policies or financial reporting practices by the Borrower or any Subsidiary.

(e) Promptly (and in any event, within two (2) Business Days) notify the Administrative Agent and each Lender of the occurrence of any default or event of default under any Permitted Senior Revolving Credit Document.

(f) Promptly (and in any event, within five (5) Business Days) notify the Administrative Agent and each Lender of any litigation, arbitration or governmental investigation or proceeding not previously disclosed by the Loan Parties which has been instituted or, to the knowledge of any Loan Party, is threatened (in writing) against any Loan Party or any Subsidiary or to which any of the properties of any thereof is subject which could reasonably be expected to result in losses and/or expenses in excess of the Threshold Amount.

(g) Promptly (and in any event, within five (5) Business Days) notify the Administrative Agent and each Lender of any material licensing agreement or similar arrangement entered into by any Loan Party or any of its Subsidiaries following such Loan Party or such Subsidiary receiving a written claim from the party to such license agreement alleging infringement of the IP Rights of another Person.

Each notice pursuant to clauses (a) through (g) of this Section 7.03 shall be accompanied by a statement of a Responsible Officer of the Borrower setting forth details of the occurrence referred to therein and stating what action the applicable Loan Party has taken and proposes to take with respect thereto. Each notice pursuant to Section 7.03(a) shall describe with particularity any and all provisions of this Agreement and any other Investment Document that have been breached.

7.04 Payment of Obligations.

Pay and discharge, as the same shall become due and payable, all its obligations and liabilities, including (a) all income and other material tax liabilities, assessments and governmental charges or levies upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted and adequate reserves in accordance with GAAP are being maintained by the Loan Party or such Subsidiary, (b) all lawful claims which, if unpaid, would by law become a Lien upon its property (other than Permitted Liens) and (c) all Indebtedness, as and when due and payable, but subject to any subordination provisions contained in any instrument or agreement evidencing such Indebtedness.

7.05 Preservation of Existence, Etc.

(a) Preserve, renew and maintain in full force and effect its legal existence under the Laws of the jurisdiction of its organization except in a transaction permitted by Section 8.04 or Section 8.05.

(b) Preserve, renew and maintain in full force and effect its good standing under the Laws of the jurisdiction of its organization, except to the extent the failure to do so could not reasonably be expected to have a Material Adverse Effect.

(c) Take all commercially reasonable action to maintain all rights, privileges, permits, licenses and franchises necessary or desirable in the normal conduct of its business, except to the extent that the failure to do so could not reasonably be expected to have a Material Adverse Effect.

7.06 Maintenance of Properties.

(a) Maintain, preserve and protect all of its material properties and equipment necessary in the operation of its business in good working order and condition, ordinary wear and tear excepted.

(b) Make all necessary repairs thereto and renewals and replacements thereof, except where the failure to do so could not, either individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(c) Use the standard of care typical in the industry in the operation and maintenance of its facilities.

7.07 Maintenance of Insurance.

(a) Maintain with financially sound and reputable insurance companies that are not Affiliates of any Loan Party or any Subsidiary insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons engaged in the same or similar business, of such types and in such amounts as are customarily carried under similar circumstances by such other Persons.

(b) Without limiting the foregoing, (i) maintain, if available, fully paid flood hazard insurance on all real property that is located in a special flood hazard area and that constitutes Collateral, on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise required by the Administrative Agent, (ii) furnish to the Administrative Agent evidence of the renewal (and payment of renewal premiums therefor) of all such policies prior to the expiration or lapse thereof and (iii) furnish to the Administrative Agent prompt written notice of any redesignation of any such improved real property into or out of a special flood hazard area.

(c) Cause the Administrative Agent and its successors and/or assigns to be named as lender's loss payee or mortgagee as its interest may appear, and/or additional insured with respect to any such insurance providing liability coverage or coverage in respect of any Collateral, and cause each provider or broker of any such insurance to agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Administrative Agent, that it will give the Administrative Agent fourteen (14) days (or such lesser amount as the Administrative Agent may agree) prior written notice before any such policy or policies shall be altered or canceled.

7.08 Compliance with Laws.

Comply with the requirements of all Laws and all orders, writs, injunctions and decrees applicable to it or to its business or property, except in such instances in which (a) such requirement of Law or order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted or (b) the failure to comply therewith could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

7.09 Books and Records.

(a) Maintain proper books of record and account in a manner to allow financial statements to be prepared in accordance with GAAP consistently applied in respect of all material financial transactions and matters involving the assets and business of such Loan Party or Subsidiary, as the case may be.

(b) Maintain such books of record and account in material conformity with all applicable requirements of any Governmental Authority having regulatory jurisdiction over such Loan Party or such Subsidiary, as the case may be.

7.10 Inspection Rights.

(a) Permit representatives and independent contractors of the Administrative Agent and each Lender, all at the expense of the Loan Parties: (i) to meet on a regular or other basis with any and all officers and employees of the Loan Parties and their respective Subsidiaries from time to time and upon reasonable advance notice to the applicable Loan Party or the applicable

Subsidiary and during normal business hours for the purpose of consulting with, rendering advice, recommendations and assistance to, and influencing the management of the Loan Parties or their respective Subsidiaries or obtaining information regarding the Loan Parties' or any of their respective Subsidiaries' operations, activities and prospects and expressing its views thereon and (ii) to access the premises and inspect the books, records and properties of the Loan Parties and their respective Subsidiaries upon reasonable advance notice to the Loan Parties and during normal business hours; provided, that, excluding any such visits and inspections during the continuation of an Event of Default, only one such visit and inspection per year shall be at the Loan Parties' expense (and only the Administrative Agent may exercise rights under this Section 7.10(a)); provided, further, that, when an Event of Default exists the Administrative Agent and the Lenders (or any of their respective representatives or independent contractors) may do any of the foregoing at the expense of the Loan Parties at any time during normal business hours and without advance notice.

(b) Consider, in good faith, the recommendations of the Administrative Agent and the Lenders or their respective designated representatives in connection with the matters on which they are consulted as described in clause (a) above, recognizing that the ultimate discretion with respect to all such matters shall be retained by the Loan Parties.

7.11 Use of Proceeds.

(a) Use the proceeds of the Term A Loans (i) to repay existing indebtedness on the Funding Date, (ii) for investment in clinical development programs and the expansion of commercial activities and (iii) for other general corporate purposes; provided, that, in no event shall the proceeds of the Term A Loans be used in contravention of any Law or of any Investment Document.

(b) Use the proceeds of the Term B-1 Loans, Term B-2 Loans, the Term B-3 Loans, Term B-4 Loans and Term C Loans (i) for investment in clinical development programs and the expansion of commercial activities and (ii) for other general corporate purposes; provided, that, in no event shall the proceeds of the Term B-1 Loans, Term B-2 Loans, Term B-3 Loans, Term B-4 Loans or Term C Loans be used in contravention of any Law or of any Investment Document.

7.12 Additional Subsidiaries.

(a) Within thirty (30) days after the acquisition or formation of any Subsidiary (or such later date as the Administrative Agent may agree in its sole discretion), notify the Administrative Agent thereof in writing, together with the (i) jurisdiction of organization (or foreign equivalent), (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by any Loan Party or any Subsidiary, (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto and (v) identification as to whether such Subsidiary is an Excluded Subsidiary; and

(b) Within sixty (60) days (or such later date as the Administrative Agent may agree in its sole discretion) after (i) the acquisition or formation of any Subsidiary (other than any Excluded Subsidiary) or (ii) the date on which any Subsidiary that was formerly an Excluded Subsidiary ceases to be an Excluded Subsidiary, in each case, cause such Person to (A) become a Guarantor by executing and delivering to the Administrative Agent a Joinder Agreement or such other documents as the Administrative Agent shall reasonably request for such purpose and (B) deliver to the Administrative Agent documents of the types referred to in Sections 5.02(f) and (g)

(in each case, with respect to any such Person that is a Foreign Subsidiary, unless waived by the Administrative Agent in its sole discretion) and favorable opinions of counsel to such Person (or, with respect to any such Person that is a Foreign Subsidiary, if customary in the jurisdiction of organization of such Person, favorable opinions of counsel to the Administrative Agent) (which, in each case, shall cover, among other things, the legality, validity, binding effect and enforceability of the documentation referred to in clause (A)), all in form, content and scope reasonably satisfactory to the Administrative Agent.

(c) on the Funding Date, cause each Subsidiary (other than any Excluded Subsidiary) that was formed or acquired after the Effective Date but prior to the Funding Date to (i) become a Guarantor by executing and delivering to the Administrative Agent a Joinder Agreement or such other documents as the Administrative Agent shall reasonably request for such purpose and (ii) deliver to the Administrative Agent documents of the types referred to in Sections 5.02(f) and (g) and favorable opinions of counsel to such Person (which shall cover, among other things, the legality, validity, binding effect and enforceability of the documentation referred to in clause (i)), all in form, content and scope reasonably satisfactory to the Administrative Agent.

7.13 ERISA Compliance.

Do, and cause each of its ERISA Affiliates to do, each of the following: (a) maintain each Plan in compliance in all material respects with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state law, (b) cause each Plan that is qualified under Section 401(a) of the Internal Revenue Code to maintain such qualification, and (c) make any required contributions to any Plan subject to Section 412, Section 430 or Section 431 of the Internal Revenue Code.

7.14 Pledged Assets.

(a) Equity Interests. Cause 100% of the issued and outstanding Equity Interests of each Subsidiary directly owned by a Loan Party to be subject at all times to a first priority, perfected Lien in favor of the Administrative Agent (including as a parallel debt creditor), for the benefit of the Secured Parties, pursuant to the terms and conditions of the Collateral Documents, together with opinions of counsel and any filings and deliveries necessary in connection therewith to perfect the security interests therein, all in form and substance satisfactory to the Administrative Agent. It is understood and agreed that the Loan Parties shall have thirty (30) days after the acquisition of any Foreign Subsidiary after the Funding Date to comply with this Section 7.14(a) with respect to such Loan Party's pledge of its Equity Interests in such Foreign Subsidiary.

(b) Other Property. (i) Cause all property (other than Excluded Property) of each Loan Party to be subject at all times to first priority perfected Liens, which Liens are superior in right to any other Person (subject to Permitted Liens) (and, in the case of owned real property, title insured Liens), in each case, in favor of the Administrative Agent (including as a parallel debt creditor) to secure the Obligations pursuant to the Collateral Documents (and subject to the terms and conditions of the Collateral Documents) or, with respect to any such property acquired subsequent to the Funding Date, such other additional security documents as the Administrative Agent shall request and, in connection with the foregoing, deliver to the Administrative Agent such other documentation as the Administrative Agent may request including filings and deliveries necessary to perfect such Liens, Organization Documents, resolutions, Real Property Security Documents and favorable opinions of counsel to such Person, all in form, content and scope reasonably satisfactory to the Administrative Agent; and (ii) use commercially reasonable efforts to obtain and deliver to the Administrative Agent Collateral Access Agreements with

respect to leased real property to the extent required by this Agreement and the Collateral Documents.

(c) Material Contracts. Ensure, and cause each of their respective Subsidiaries to ensure, that at all times the exercise of the rights of the Administrative Agent or any Lender under any Loan Document (including the realization, sale or assignment by the Administrative Agent or a Lender of any Equity Interests in any Subsidiary directly owned by such Loan Party) would not conflict with (i) any Material Contract to which any Loan Party or any of its respective Subsidiaries is a party or which is binding upon such Loan Party or such Subsidiary or any of such Loan Party's or such Subsidiary's assets or (ii) any Loan Party's Organization Documents.

7.15 Compliance with Material Contracts.

Comply in all respects with each Material Contract of such Person except where the failure to comply, either individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect.

7.16 Maintenance of Regulatory Approvals, Contracts, IP Rights, Etc.

Each Loan Party will, and will cause each of its Subsidiaries (to the extent applicable) to, (a) maintain in full force and effect all Regulatory Approvals (including the Product Authorizations), contracts, or other rights necessary for the operations of such Loan Party's or such Subsidiary's business, as the case may be, including in respect of all related Product Commercialization and Development Activities, (b) promptly after any Loan Party has knowledge thereof, notify the Administrative Agent of any product recalls, safety alerts, corrections, withdrawals, marketing suspensions or removals conducted, to be undertaken or issued by such Loan Party, any of their respective Subsidiaries or any of their respective agents, suppliers, licensors or licensees, as the case may be, whether voluntary or at the request, demand or order of any Regulatory Authority or otherwise with respect to any Product, or the occurrence of any act, event or omission that is reasonably likely to result in the undertaking or issuing of any such action or item, (c) maintain in full force and effect, and pay all costs and expenses relating to (i) all Material Contracts, (ii) all IP Rights owned or controlled by such Loan Party or any such Subsidiary that is related to any Product or Product Commercialization and Development Activities or otherwise useful in or material, either individually or in the aggregate, to the business of any Loan Party or Subsidiary and (iii) all Product Assets owned or controlled by such Loan Party or any Subsidiary that are used in or necessary for related Product Commercialization and Development Activities, (d) promptly after learning thereof, notify the Administrative Agent of any infringement or other violation by any Person of such Loan Party's or any of its Subsidiaries' IP Rights, and diligently pursue any such infringement or other violation, except in any specific circumstance where both (i) the Loan Parties are able to demonstrate that it is not commercially reasonable to do so and (ii) where not doing so does not materially adversely affect any Product or the Product Commercialization and Development Activities related to such Product, (e) use commercially reasonable efforts to pursue and maintain in full force and effect legal protection for all new IP Rights developed or controlled by such Loan Party or any of its Subsidiaries, as the case may be, that is related to any Product or Product Commercialization and Development Activities or otherwise useful in or material, either individually or in the aggregate, to the business of any Loan Party or Subsidiary and (f) promptly after learning thereof, notify the Administrative Agent of any claim by any Person that such Loan Party or any of its Subsidiaries, including in connection with any Product Commercialization and Development Activities, has infringed upon any IP Rights of such Person.

7.17 Anti-Corruption Laws.

Conduct its business in compliance in all material respects with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions and maintain policies and procedures designed to promote and achieve compliance with such laws.

7.18 Cash Management.

(a) Maintain all deposit accounts (including, without limitation, the Specified Deposit Account), disbursement accounts, securities accounts, investment accounts (and other similar accounts) and lockboxes located in the United States or the British Virgin Islands, in each case, with a bank or financial institution that is acceptable to the Administrative Agent and ensure that each such account or lockbox is subject to a Qualifying Control Agreement (each such deposit account, disbursement account, securities account, investment account (or similar account) and lockbox (a "Controlled Account")), with all cash, checks and other similar items of payment in such account or lockbox securing payment of the Obligations and such Loan Party shall have granted a Lien to the Administrative Agent, for the benefit of the Secured Parties, over such Controlled Accounts;

(b) Deposit promptly (and in any event no later than five (5) Business Days) 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 of each BVI Loan Party and each U.S. Loan Party (including pursuant to clause (c) below) into Controlled Accounts;

(c) To the extent that any Loan Party or any Subsidiary holds cash on hand (other than cash maintained in a Controlled Account) in excess of (i) $5,000,000 on an individual basis for each such Person or (ii) $10,000,000 in the aggregate when taken together with all other Loan Parties and Subsidiaries, in each case, such excess amount shall, within five (5) Business Days be (x) deposited into a Controlled Account or (y) in the case of Establishment Labs Sociedad Anonima, deposited into the Specified Deposit Account, in each case, in compliance with clauses (a) and (b) above; and

(d) At any time after the occurrence and during the continuance of an Event of Default, at the request of the Administrative Agent, cause all payments constituting proceeds of accounts of each BVI Loan Party, each U.S. Loan Party and each Costa Rican Loan Party to be directed into lockbox accounts that are subject to Qualifying Control Agreements.

7.19 Post-Closing Obligations.

(a) Within five (5) Business Days of the Funding Date (or such longer period of time as may be agreed to by the Administrative Agent in its sole discretion), arrange for the filing of the particulars of a cessation of (i) that certain charge in respect of the property of the Borrower registered on September 29, 2016 with identification number MTE6TZ and Perceptive Credit Holdings, LP as the trustee and (ii) that certain charge in respect of the property of the Borrower registered on September 14, 2015 with identification number VPHPR3 and CPH TU, LP as the chargee, in each case with the registrar of corporate affairs in the British Virgin Islands in accordance with section 165 of the BVI Business Companies Act, 2004.

(b) Within the time periods set forth therefor on Schedule 7.19 (or such longer periods of time as may be agreed to by the Administrative Agent in its sole discretion), deliver to

the Administrative Agent such other documents, instruments, certificates or agreements as are listed on Schedule 7.19 or take such other actions as are described on Schedule 7.19, in each case in form and substance reasonably satisfactory to the Administrative Agent.

7.20 Compliance with Securities Laws.

Comply in all material respects with the Securities Act and the Exchange Act.

ARTICLE VIII.

NEGATIVE COVENANTS

On the Funding Date and thereafter, so long as any Lender shall have any Commitment hereunder, any Loan or other Obligation (other than contingent indemnification obligations for which no claim has been asserted) hereunder shall remain unpaid or unsatisfied, no Loan Party shall, nor shall it permit any Subsidiary to, directly or indirectly:

8.01 Liens.

Create, incur, assume or suffer to exist any Lien upon any of its property, assets or revenues, whether now owned or hereafter acquired, other than the following:

(a) Liens pursuant to any Loan Document;

(b) Liens existing on the Effective Date and listed on Schedule 8.01 to the Disclosure Letter;

(c) Liens (other than any Liens imposed under ERISA) for taxes, assessments or governmental charges or levies not yet due or which are being contested in good faith and by appropriate proceedings diligently conducted, if adequate reserves with respect thereto are maintained on the books of the applicable Person in accordance with GAAP;

(d) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law or pursuant to customary reservations or retentions of title arising in the ordinary course of business; provided, that, such Liens secure only amounts not yet due and payable or, if due and payable, are unfiled and no other action has been taken to enforce the same or are being contested in good faith by appropriate proceedings for which adequate reserves determined in accordance with GAAP have been established;

(e) pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation, other than any Lien imposed by ERISA;

(f) deposits to secure the performance of bids, trade contracts and leases (other than Indebtedness), statutory obligations, surety and appeal bonds, performance bonds and other obligations of a like nature incurred in the ordinary course of business;

(g) easements, rights-of-way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, 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 the applicable Person;

(h) Liens securing judgments for the payment of money (or appeal or other surety bonds relating to such judgments) not constituting an Event of Default under Section 9.01(h);

(i) Liens securing Indebtedness permitted under Section 8.03(e); provided, that: (i) such Liens do not at any time encumber any property other than the property financed by such Indebtedness, (ii) the Indebtedness secured thereby does not exceed the cost of acquiring, purchasing, constructing or improving such property (negotiated on an arm's length basis) and (iii) such Liens attach to such property concurrently with or within one hundred eighty (180) days after the acquisition thereof (or, in the case of any such property owned by such Loan Party or such Subsidiary as of the Effective Date, within one hundred eighty (180) days of the Effective Date);

(j) licenses, sublicenses, leases or subleases (other than relating to intellectual property) granted to others in the ordinary course of business not interfering in any material respect with the business of any Loan Party or any Subsidiary;

(k) bankers' liens, rights of setoff and similar Liens incurred on deposits made in the ordinary course of business;

(l) Liens of a Permitted Senior Revolving Credit Lender on Permitted Senior Revolving Credit Priority Collateral securing only the Permitted Senior Revolving Credit Indebtedness owing to such Permitted Senior Revolving Credit Lender, subject to compliance with the terms and provisions of Section 8.03(g) and the definition of "Permitted Senior Revolving Credit Indebtedness";

(m) solely until the Funding Date, Liens securing Indebtedness under the Existing Credit Agreement;

(n) Liens on fee owned real property of the Loan Parties securing Indebtedness permitted by Section 8.03(h);

(o) any Lien existing on any property or asset prior to the acquisition thereof by the Borrower or any Subsidiary after the Effective Date or existing on any property or asset prior to the merger, consolidation or becoming a Subsidiary of any Person that is merged or consolidated with or into the Borrower or any of its Subsidiaries after the Effective Date or that becomes a Subsidiary after the Effective Date; provided, that, (i) such Lien is not created in contemplation of or in connection with such acquisition or such Person becoming a Subsidiary, as the case may be, (ii) such Lien shall not apply to any other property or assets of the Borrower or any Subsidiary (other than improvements, accessions, proceeds, dividends or distributions in respect thereof and assets fixed or appurtenant thereto) and (iii) such Lien shall secure only those obligations which it secures on the date of such acquisition or the date such Person becomes a Subsidiary, as the case may be;

(p) Liens in favor of a seller solely on any cash earnest money deposits made by the Borrower or any of its Subsidiaries in connection with any letter of intent or purchase agreement with respect to any Permitted Acquisition or other Investment permitted hereunder;

(q) (i) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code on items in the course of collection and (ii) Liens securing cash management obligations and any obligations under cash management agreements (in each case, that do not constitute Indebtedness) in the ordinary course of business;

(r) licenses and sublicenses of intellectual property permitted by Section 8.19(b); and

(s) additional Liens incurred by the Borrower and its Subsidiaries so long as the aggregate outstanding principal amount of Indebtedness and other obligations secured thereby do not exceed $1,000,000 at any time.

Notwithstanding anything to the contrary in this Section 8.01, no Lien permitted under clauses (b) through (q), or clause (s) shall apply to any Material IP Rights.

8.02 Investments.

Make any Investments, except:

(a) Investments held by any Loan Party or any Subsidiary in the form of cash or Cash Equivalents;

(b) Investments existing as of the Effective Date and set forth in Schedule 8.02 to the Disclosure Letter;

(c) (i) Investments by Loan Parties in any Person that is a Qualified Loan Party prior to giving effect to such Investment, (ii) Investments by (A) Loan Parties (that are not Brazilian Loan Parties) in Brazilian Loan Parties, in an aggregate amount not to exceed $25,000,000 (provided, that, such amount shall increase by $0.25 for each $1.00 of cash and Cash Equivalents received by the Borrower from the issuance of its Qualified Equity Interests (other than in connection with any Specified Cure Contribution) on or after July 1, 2018 (so long as such cash and Cash Equivalents are not otherwise applied to any other permitted use under this Agreement); provided, however, that, in no event shall such amount exceed $40,000,000) at any one time outstanding and (B) Brazilian Loan Parties in Brazilian Loan Parties, (iii) Investments by Subsidiaries that are not Loan Parties in (A) Loan Parties and (B) any other Subsidiary that is not a Loan Party, (iv) Investments by Qualified Loan Parties in (A) Loan Parties that are not Qualified Loan Parties (other than Brazilian Loan Parties), in an aggregate amount not to exceed $10,000,000 at any one time outstanding; provided, that, the aggregate amount of any Investment made pursuant to clause (ii)(A) that indirectly flows through a Loan Party that is not a Qualified Loan Party (other than a Brazilian Loan Party) shall not be deemed to apply to this clause (iv)(A), and (B) Subsidiaries that are not Loan Parties, in an aggregate amount not to exceed, together with all Investments made pursuant to clause (c)(v)(B), $5,000,000 at any one time outstanding and (v) Investments by Loan Parties that are not Qualified Loan Parties in (A) other Loan Parties that are not Qualified Loan Parties (other than Brazilian Loan Parties) and (B) Subsidiaries that are not Loan Parties, in an aggregate amount not to exceed, together with all Investments made pursuant to clause (c)(iv)(B), $5,000,000 at any one time outstanding;

(d) extensions of credit to non-Affiliates in the nature of accounts receivable or notes receivable arising from the sales of goods or services in the ordinary course of business;

(e) Permitted Acquisitions and Approved Strategic Investments;

(f) Swap Contracts permitted under Section 8.03(d);

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of security deposits with utilities and other like Persons made in the ordinary course of business;

(i) employee loans, travel advances and guarantees in accordance with the Loan Parties' usual and customary practices with respect thereto (if permitted by applicable Law), which in the aggregate shall not exceed $250,000 outstanding at any time;

(j) Investments received in connection with any insolvency proceedings in respect of any customers, suppliers or clients and in settlement of delinquent obligations of, and other disputes with, customers, suppliers or clients;

(k) Guarantees permitted by Section 8.03 (other than by reference to this Section 8.02 (or any subclause hereof)); and

(l) other Investments not permitted by any of the foregoing clauses of this Section 8.02, in an aggregate amount not to exceed $1,000,000 at any one time outstanding.

8.03 Indebtedness.

Create, incur, assume or suffer to exist any Indebtedness, except:

(a) Indebtedness under the Loan Documents;

(b) Indebtedness (other than by reference to this Section 8.03 (or any sub-clause hereof)) existing on the Effective Date and described on Schedule 8.03 to the Disclosure Letter and Permitted Refinancings thereof;

(c) (i) intercompany Indebtedness permitted under Section 8.02 (other than by reference to this Section 8.03 (or any sub-clause hereof)) and (ii) Guarantees permitted by Section 8.02 (other than by reference to this Section 8.03 (or any subclause hereof));

(d) obligations (contingent or otherwise) of any Loan Party or any Subsidiary existing or arising under any Swap Contract; provided, that, (i) such obligations are (or were) entered into by such Person in the ordinary course of business for the purpose of directly mitigating risks associated with liabilities, commitments, investments, assets, or property held or reasonably anticipated by such Person, or changes in the value of securities issued by such Person, and not for purposes of speculation or taking a "market view" and (ii) such Swap Contract does not contain any provision exonerating the non-defaulting party from its obligation to make payments on outstanding transactions to the defaulting party;

(e) purchase money Indebtedness (including obligations in respect of Capital Leases or Synthetic Leases) incurred by any Loan Party or any of their respective Subsidiaries to finance the acquisition, purchase, construction or improvement of fixed assets, and renewals, refinancings and extensions thereof; provided, that, (i) such Indebtedness when incurred shall not exceed the cost of acquiring, purchasing, constructing or improving such asset(s), (ii) no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon, plus any fees and expenses incurred in connection with such refinancing and any reasonable

premium paid in connection with such refinancing, (iii) the aggregate outstanding principal amount of all Indebtedness outstanding in reliance on this clause (e) shall not exceed $4,000,000 at any one time outstanding and (iv) the aggregate outstanding principal amount of all Indebtedness outstanding in reliance on this clause (e), Section 8.03(g) and Section 8.03(h), when taken together, shall not exceed $12,000,000 at any one time outstanding;

(f) unsecured Indebtedness in respect of netting services, overdraft protections, employee credit card programs, automatic clearinghouse arrangements and similar arrangements in each case in connection with deposit accounts and Indebtedness arising from the honoring of a bank or other financial institution of a check, draft or similar instrument drawn against insufficient funds in the ordinary course of business; provided, that, (x) any such Indebtedness is extinguished within thirty (30) days and (y) the aggregate outstanding principal amount of such Indebtedness shall not exceed $1,000,000 at any one time outstanding;

(g) Permitted Senior Revolving Credit Indebtedness in an aggregate principal amount not to exceed at any one time outstanding $4,000,000 pursuant to one or more revolving credit facilities; provided, that, (x) no Default or Event of Default shall have occurred and be continuing both immediately before and immediately after the effectiveness of any Permitted Senior Revolving Credit Documents, (y) prior to the incurrence of any such Indebtedness, (i) the Administrative Agent, the Loan Parties and the applicable Permitted Senior Revolving Credit Lender shall have entered into an intercreditor agreement reasonably satisfactory to the Administrative Agent pursuant to which (A) such Permitted Senior Revolving Credit Lender may be granted a first priority security interest only in the accounts receivable and/or inventory of Establishment Labs Sociedad Anonima and proceeds thereof (collectively, the "Permitted Senior Revolving Credit Priority Collateral"), (B) the Administrative Agent, on behalf of the Secured Parties, shall be granted a second priority security interest in the Permitted Senior Revolving Credit Priority Collateral, (C) the Administrative Agent, on behalf of the Secured Parties, shall maintain its first priority security interest in all other assets of the Loan Parties (other than Excluded Property) and (D) such Permitted Senior Revolving Credit Lender shall not be granted a security interest in any property of the Loan Parties other than the Permitted Senior Revolving Credit Priority Collateral and (ii) the Administrative Agent and the Loan Parties shall have entered into amendments, in each case in form and substance reasonably satisfactory to the Administrative Agent, to this Agreement and such other Loan Documents as required to, among other things, include in the Loan Documents such additional representations, warranties, covenants and defaults as are included in the applicable Permitted Senior Revolving Credit Documents (but not included in the Loan Documents at such time) and (z) the aggregate outstanding principal amount of all Indebtedness incurred in reliance on this clause (g), Section 8.03(e) and Section 8.03(h), when taken together, shall not exceed $12,000,000 at any one time outstanding;

(h) Indebtedness hereafter incurred by any Loan Party or any of their respective Subsidiaries to finance the purchase, construction or improvement of real property, and renewals and extensions thereof; provided, that, (i) such Indebtedness shall be secured only by real property (and, for the avoidance of doubt, by no other assets of any Loan Party or any Subsidiary), (ii) no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing, plus any fees and expenses incurred in connection with such refinancing and any reasonable premium paid in connection with such refinancing, (iii) the aggregate outstanding principal amount of all Indebtedness incurred in reliance on this clause (h) shall not exceed $10,000,000 at any one time outstanding and (iv) the aggregate outstanding principal amount of all Indebtedness incurred in reliance on

this clause (h), Section 8.03(e) and Section 8.03(g), when taken together, shall not exceed $12,000,000 at any one time outstanding;

(i) solely until the Funding Date, Indebtedness under the Existing Credit Agreement;

(j) accounts payable to trade creditors for goods and services and current operating liabilities (not the result of the borrowing of money) incurred in the ordinary course of the Loan Parties and their respective Subsidiaries' business in accordance with customary terms and paid within the specified time, unless contested in good faith by appropriate proceedings and reserved for in accordance with GAAP;

(k) Indebtedness consisting of guarantees resulting from the endorsement of negotiable instruments for collection in the ordinary course of business;

(l) other unsecured Indebtedness not permitted by any of the other clauses of this Section 8.03, in an aggregate principal amount not to exceed $1,000,000 at any one time outstanding;

(m) Indebtedness of any Person that becomes a Subsidiary after the Effective Date; provided, that, (i) such Indebtedness exists at the time such Person becomes a Subsidiary and is not created in contemplation of or in connection with such Person becoming a Subsidiary and (ii) the aggregate principal amount of all such Indebtedness outstanding in reliance on this clause (m) shall not exceed $500,000 at any one time outstanding;

(n) unsecured Earn Out Obligations in connection with Permitted Acquisitions; and

(o) unsecured Indebtedness of the Borrower owing to (i) solely until August 1, 2019, JW Partners, LP pursuant to that certain Warrant Payment Agreement dated as of August 24, 2017 between the Borrower and JW Partners, LP in an aggregate amount not to exceed $1,589,488.64 at any one time outstanding, (ii) solely until August 1, 2019, JW Opportunities Master Fund, Ltd. pursuant to that certain Warrant Payment Agreement dated as of August 24, 2017 between the Borrower and JW Opportunities Master Fund, Ltd. in an aggregate amount not to exceed $529,829.55 at any one time outstanding, (iii) solely until August 1, 2019, Relativity Healthcare Fund, LLC pursuant to that certain Warrant Cancellation Agreement dated as of August 24, 2017 between the Borrower and Relativity Healthcare Fund, LLC in an aggregate amount not to exceed $141,287.55 at any one time outstanding and (iv) solely until September 30, 2017, Perceptive Credit Holdings, LP pursuant to that certain Warrant Repurchase Agreement dated as of August 24, 2017 between the Borrower and Perceptive Credit Holdings, LP in an aggregate amount not to exceed $2,400,000 at any one time outstanding.

8.04 Fundamental Changes.

Merge, dissolve, liquidate, amalgamate or consolidate with or into another Person, or Dispose of (whether in one transaction or in a series of transactions) all or substantially all of its assets (whether now owned or hereafter acquired) to or in favor of any Person; provided, that, notwithstanding the foregoing provisions of this Section 8.04 but subject to the terms of Sections 7.12 and 7.14, (a) the Borrower may merge or consolidate with any of its Subsidiaries, provided, that, the Borrower shall be the continuing or surviving corporation, (b) any Qualified Loan Party (other than the Borrower) may merge, amalgamate or consolidate with any other Qualified Loan Party (other than the Borrower), (c) any Loan Party that is not a Qualified Loan Party may merge, amalgamate or consolidate with any Loan Party (other than the Borrower), provided, that, if a Qualified Loan Party is a party to such transaction, such Qualified Loan

Party shall be the continuing or surviving Person, (d) any Subsidiary that is not a Loan Party may be merged or consolidated with or into any Loan Party, provided, that, such Loan Party shall be the continuing or surviving Person, (e) any Subsidiary that is not a Loan Party may be merged or consolidated with or into any other Subsidiary that is not a Loan Party, (f) any Subsidiary that is not a Loan Party 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 its assets and business are transferred to a Loan Party prior to or concurrently with such dissolution, liquidation or winding up and (g) the Borrower and its Subsidiaries may consummate Permitted Acquisitions and Approved Strategic Investments, provided, that, (x) to the extent applicable, such transaction complies with clauses (a) through (f) of the first proviso in this Section 8.04 and (y) to the extent such transaction involves a merger, amalgamation or consolidation with a Person other than the Borrower or any Subsidiary, either (A) the Borrower or such Subsidiary shall be the continuing or surviving Person or (B) the continuing or surviving Person shall comply with the requirements of Section 7.12 and Section 7.14.

8.05 Dispositions.

Make any Disposition unless (a) the consideration paid in connection therewith shall be cash or Cash Equivalents paid contemporaneous with consummation of the transaction and shall be in an amount not less than the fair market value of the property disposed of, (b) no Default or Event of Default shall have occurred and be continuing both immediately prior to and after giving effect to such Disposition, (c) such transaction does not involve the sale or other disposition of a minority equity interest in any Subsidiary and (d) the aggregate net book value of all of the assets sold or otherwise disposed of in such Disposition together with the aggregate net book value of all assets sold or otherwise disposed of by the Loan Parties and their respective Subsidiaries in all such transactions occurring during the term of this Agreement does not exceed $1,000,000.

8.06 Restricted Payments.

Declare or make, directly or indirectly, any Restricted Payment, except that:

(a) each Subsidiary may make Restricted Payments to any Loan Party;

(b) each Loan Party and each Subsidiary may declare and make dividend payments or other distributions payable solely in the Qualified Capital Stock of such Person;

(c) (i) the Borrower may purchase, redeem, retire or otherwise acquire its Qualified Capital Stock solely to the extent such purchase, redemption, retirement or acquisition is made with proceeds received from a substantially concurrent issuance of new Qualified Capital Stock of the Borrower, (ii) to the extent constituting Restricted Payments, the Borrower may repay Indebtedness permitted by Section 8.03(o) to the extent not prohibited by Section 8.11 and (iii) the Borrower may purchase, redeem, retire or otherwise acquire shares of its Qualified Capital Stock from Global Silicone SRL for aggregate consideration not to exceed $2,845,990; provided, that, with respect to this clause (iii), such purchase occurs within thirty (30) days of the Funding Date;

(d) the Borrower may (i) purchase or pay cash in lieu of fractional shares of its Qualified Capital Stock arising out of dividends, splits, or business combinations or in connection with the issuance of its Qualified Capital Stock pursuant to mergers, consolidations or other acquisitions, in each case, permitted by this Agreement, (ii) pay cash in lieu of fractional shares upon the exercise of warrants, options or other securities convertible into or exercisable for

Qualified Capital Stock of the Borrower and (iii) make payments in connection with the retention of Qualified Capital Stock in payment of withholding taxes in connection with equity-based compensation plans to the extent that net share settlement arrangements are deemed to be repurchases; and

(e) the Borrower may make other Restricted Payments not to exceed (i) $600,000 in the fiscal year of the Borrower ending December 31, 2017 and (ii) $500,000 in any fiscal year of the Borrower ending thereafter.

8.07 Change in Nature of Business.

Engage in any material line of business substantially different from those lines of business conducted by the Borrower and its Subsidiaries on the Effective Date or any business substantially related or incidental thereto.

8.08 Transactions with Affiliates and Insiders.

Enter into or permit to exist any transaction or series of transactions with any officer, director, employee or Affiliate of such Person other than (a) advances of working capital to any Loan Party, (b) transfers of cash and assets to any Loan Party, (c) intercompany transactions expressly permitted by Section 8.02, Section 8.03, Section 8.04, Section 8.05 or Section 8.06, (d) customary compensation and indemnification of, and other employment arrangements with, directors, officers and employees in the ordinary course of business, (e) issuances of Qualified Capital Stock of the Borrower to Affiliates in exchange for cash; provided, that, (i) no Default or Event of Default shall have occurred and be continuing (or could reasonably be expected to occur as a result of such issuance) and (ii) the terms of each such issuance are no less favorable (including the amount of cash received by the Borrower) to the Borrower than those that would be obtained in a comparable arm's-length transaction with a Person who is not an Affiliate of the Borrower and (f) except as otherwise specifically limited in this Agreement, other transactions which are entered into in the ordinary course of such Person's business on terms and conditions substantially as favorable to such Person as would be obtainable by it in a comparable arms-length transaction with a Person other than an officer, director or Affiliate.

8.09 Burdensome Agreements.

Enter into, or permit to exist, any Contract that encumbers or restricts the ability of any such Person to (a) make Restricted Payments to any Loan Party, (b) pay any Indebtedness or other obligations owed to any Loan Party, (c) make loans or advances to any Loan Party, (d) transfer any of its property to any Loan Party, (e) pledge its property pursuant to the Loan Documents or any renewals, refinancings, exchanges, refundings or extension thereof or (f) act as a Loan Party pursuant to the Loan Documents or any renewals, refinancings, exchanges, refundings or extension thereof, except (in respect of any of the matters referred to in clauses (a) through (e) above) for (i) this Agreement and the other Loan Documents, (ii) any document or instrument governing Indebtedness incurred pursuant to Section 8.03(b), Section 8.03(e), Section 8.03(h); provided, that, any such restriction contained therein relates only to the asset or assets constructed or acquired in connection therewith, (iii) customary restrictions and conditions contained in any agreement relating to the sale of any property permitted under Section 8.05 pending the consummation of such sale, (iv) any Permitted Senior Revolving Credit Documents, (v) requires the grant of any security for any obligation if such property is given as security for the Obligations, (vi) prohibitions, restrictions and conditions existing on the Effective Date identified on Schedule 8.09 to the Disclosure Letter, (vii) customary provisions contained in leases, subleases, licenses and sublicenses and other contracts restricting the assignment, subletting or encumbrance thereof, customary net worth provisions or similar financial maintenance provisions contained therein and other customary provisions

contained in leases, subleases, licenses and sublicenses and other contracts entered into in the ordinary course of business, (viii) prohibitions, restrictions and conditions that are binding on a Subsidiary at the time such Subsidiary first becomes a Subsidiary, so long as such restrictions were not entered into solely in contemplation of such Person becoming a Subsidiary and (ix) customary restrictions under any arrangement with any Governmental Authority imposed on any Subsidiary in connection with governmental grants, financial aid, tax holidays or similar benefits or economic interests.

8.10 Use of Proceeds.

Use the proceeds of any Loan, whether directly or indirectly, and whether immediately, incidentally or ultimately, to purchase or carry margin stock (within the meaning of Regulation U of the FRB) or to extend credit to others for the purpose of purchasing or carrying margin stock or to refund indebtedness originally incurred for such purpose.

8.11 Payment of Other Indebtedness.

Make (or give any notice with respect thereto) any voluntary or optional payment or prepayment or redemption or acquisition for value of (including without limitation, by way of depositing money or securities with the trustee with respect thereto before due for the purpose of paying when due), refund, refinance or exchange of any Indebtedness of any Loan Party or any Subsidiary (other than (i) any of the foregoing payments or transactions relating to (x) Indebtedness arising under the Loan Documents, (y) any Permitted Senior Revolving Credit Indebtedness and (z) the repayment of all Indebtedness owing under the Existing Credit Agreement on the Funding Date, (ii) such payments or transactions that do not exceed an aggregate amount of $1,000,000 per fiscal year, (iii) Permitted Refinancings expressly permitted hereby and (iv) prepayments by the Borrower of Indebtedness permitted by Section 8.03(o); provided, that, with respect to this clause (iv), (x) the funds utilized by the Borrower for any such payments shall consist solely of (A) proceeds received from a substantially concurrent issuance of new Qualified Capital Stock of the Borrower and (B) not more than $1,750,000 of internally generated cash and Cash Equivalents of the Loan Parties and their Subsidiaries and (y) no proceeds of any Loans or any other Indebtedness shall be used for any such payments).

8.12 Organization Documents; Fiscal Year; Legal Name, State of Formation and Form of Entity; Certain Amendments.

(a) Amend, modify or change its Organization Documents in a manner materially adverse to the Administrative Agent or the Lenders, in their capacity as the Administrative Agent or as Lenders, as applicable, under the Loan Documents.

(b) Change its fiscal year or any fiscal quarter.

(c) Without providing ten (10) days prior written notice to the Administrative Agent, change its name, jurisdiction of organization or form of organization (or foreign equivalent).

(d) Amend, modify or change (or permit the amendment, modification or change of) any of the terms or provisions of any Permitted Senior Revolving Credit Document in a manner adverse to the Administrative Agent or any Secured Party or in violation of the terms and provisions of any intercreditor agreement entered into by the Administrative Agent with respect thereto (for the avoidance of doubt, any amendment, modification or change that is permitted pursuant to any applicable intercreditor agreement shall not be adverse to the Administrative Agent or any Secured Party).

(e) Make any change in accounting policies or reporting practices, except as required by GAAP.

8.13 Ownership of Subsidiaries.

Notwithstanding any other provisions of this Agreement to the contrary, (a) permit any Person (other than any Loan Party or any Wholly Owned Subsidiary) to own any Equity Interests of any Subsidiary, except to qualify directors where required by applicable law or to satisfy other requirements of applicable law with respect to the ownership of Equity Interests of Foreign Subsidiaries, (b) permit any Loan Party or any Subsidiary to issue or have outstanding any shares of Disqualified Capital Stock or (c) create, incur, assume or suffer to exist any Lien on any Equity Interests of any Subsidiary, except for Permitted Liens.

8.14 Sale Leasebacks.

Enter into any Sale and Leaseback Transaction (other than any Permitted Sale and Leaseback Transaction).

8.15 Sanctions; Anti-Corruption Laws.

(a) Directly or indirectly, use the proceeds of any Loan, or lend, contribute or otherwise make available the proceeds of any Loan to any Person, to fund any activities of or business with any Person, or in any Designated Jurisdiction, that, at the time of such funding, is the subject of Sanctions, or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as Lender, Administrative Agent, or otherwise) of Sanctions.

(b) Directly or indirectly, use the proceeds of any Loan for any purpose which would breach the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions.

(c) Any provision of this Section 8.15 or Section 6.21(a) shall not apply to or in favor of any Person if and to the extent that it would result in a breach, by or in respect of that Person, of any applicable Blocking Law.

8.16 Minimum Product Revenues.

(a) Minimum Product Revenues. Permit Product Revenues for any four consecutive fiscal quarter period to be less than (i) $20,000,000, for the four consecutive fiscal quarter period ending September 30, 2017, (ii) $30,000,000, for any four consecutive fiscal quarter period ending during the period from December 31, 2017 through and including September 30, 2018, (iii) $45,000,000, for any four consecutive fiscal quarter period ending during the period from December 31, 2018 through and including September 30, 2019, (iv) $60,000,000, for any four consecutive fiscal quarter period ending during the period from December 31, 2019 through and including September 30, 2021, (v) $120,000,000, for any four consecutive fiscal quarter period ending during the period from December 31, 2021 through and including September 30, 2022 and (vi) $150,000,000, for any four consecutive fiscal quarter period ending thereafter.

(b) Cure Right.

(i) Notwithstanding anything to the contrary contained in Section 8.16(a), in the event that any Loan Party would otherwise be in default of the financial covenant set forth in Section 8.16(a) for any period, on or before the tenth ($10^{th}$) Business Day subsequent to the due date for delivery of the financial statements for such period pursuant to Section 7.01(a) or (b), as applicable (such period, the "Cure Period"), the Borrower shall have the right to issue its Qualified Capital Stock for cash in an aggregate amount not to exceed the amount necessary to cure the relevant failure to comply with Section 8.16(a) (such contribution, a "Specified Cure Contribution"), and upon the receipt by the Borrower of such Specified Cure Contribution within the Cure Period, the financial covenant set forth in Section 8.16(a) shall be recalculated giving effect to the following pro forma adjustments (collectively, the "Cure Right"):

(A) Product Revenues shall be increased for the final fiscal quarter of such period (the "Applicable Quarter") and any period of four consecutive fiscal quarters that includes the Applicable Quarter, solely for the purpose of measuring the financial covenant set forth in Section 8.16(a), and not for any other purpose under this Agreement, by an amount equal to the Specified Cure Contribution; and

(B) If, after giving effect to the foregoing recalculation, the Loan Parties shall then be in compliance with the requirements of the financial covenant set forth in Section 8.16(a), the Loan Parties shall be deemed to have satisfied the requirements of the financial covenant set forth in Section 8.16(a) 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 or default of the covenant set forth in Section 8.16(a) that had occurred shall be deemed cured for the purposes of this Agreement.

(ii) Notwithstanding anything herein to the contrary, (A) the Loan Parties shall provide notice to the Administrative Agent of their intention to exercise the Cure Right no later than the date of delivery of the financial statements evidencing such noncompliance pursuant to Section 7.01(a) or (b), as applicable, (B) in each four fiscal quarter period, there shall be a period of at least two (2) fiscal quarters in respect of which no Cure Right is exercised, (C) the Cure Right may not be exercised with respect to consecutive fiscal quarters, (D) the Specified Cure Contribution shall be no greater than the amount required for purposes of complying with the financial covenant in Section 8.16(a), (E) the Specified Cure Contribution received pursuant to any exercise of the Cure Right shall be disregarded for purposes of determining any available basket under any covenant in this Agreement, (F) the Cure Right may be exercised no more than three (3) times during the term of this Agreement and (G) the provisions of this Section 8.16(b) shall in no way limit the Borrower's ability to issue its Qualified Capital Stock at any time and for the avoidance of doubt, any limitation with respect to amount of the Specified Cure Contribution is only a limitation with respect to the amount of Product Revenue that may count as a Specified Cure Contribution pursuant to the terms of this Section 8.16(b).

8.17 Liquidity.

(a) Permit Liquidity of the Loan Parties to be less than $10,000,000; and

(b) Permit Liquidity of the Loan Parties held in Controlled Accounts to be less than $5,000,000.

8.18 Modifications and Terminations of Material Contracts.

Except to the extent such action or omission could not reasonably be expected, either individually or in the aggregate, to have or result in a Material Adverse Effect, take or omit to take any action that results in the termination of, or permits any other Person to terminate, any Material Contract or Material IP Rights, other than any bona fide dispute that is being contested in good faith.

8.19 Inbound and Outbound Licenses.

(a) Except as set forth on Schedule 8.19(a) to the Disclosure Letter, no Loan Party shall, nor shall it permit any of its Subsidiaries to, enter into or become or remain bound by (x) any Material Contract or (y) any material inbound license agreement, unless no Default or Event of Default has occurred and is continuing (or would reasonably be expected to occur as a result thereof) and the Loan Parties have (i) provided prior written notice to the Administrative Agent of the material terms of such agreement with a description of its anticipated and projected impact on the relevant Loan Party's business or financial condition and (ii) taken such commercially reasonable actions as the Administrative Agent may reasonably request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for the Administrative Agent to be granted a valid and perfected Lien on such agreement and the right to fully exercise its rights under any of the Loan Documents in the event of a disposition or liquidation (including in connection with a foreclosure) of the rights, assets or property that is the subject of such agreement; provided, that, inbound license agreements in the nature of over the counter software that are commercially available to the public shall not be prohibited by this clause (a).

(b) Except as set forth on Schedule 8.19(b) to the Disclosure Letter, no Loan Party shall, nor shall it permit any of its Subsidiaries to, enter into or become or remain bound by any outbound license of IP Rights unless such outbound license (i) is duly authorized by the Loan Parties (pursuant to their customary approval process) and entered into on an arm's-length basis, (ii) is entered into for the purpose of Product Commercialization and Development Activities with respect to a Product, (iii) does not otherwise constitute a Disposition prohibited pursuant to this Agreement, (iv) to the extent such IP Rights constitute Collateral, (x) could not reasonably be expected to result in a Material Adverse Effect and (y) does not impair the Administrative Agent from fully exercising its rights under any of the Loan Documents in the event of a disposition or liquidation (including in connection with a foreclosure) of the rights, assets or property that is the subject of such license, (v) is not an exclusive license (whether as to use, geography or otherwise) and (vi) is not perpetual or irrevocable.

## ARTICLE IX.

## EVENTS OF DEFAULT AND REMEDIES

9.01 Events of Default.

Any of the following shall constitute an Event of Default:

(a) Non-Payment. The Borrower or any other Loan Party fails to pay (i) when and as required to be paid herein, any amount of principal of any Loan, (ii) within three (3) Business Days after the same becomes due, any interest on any Loan, or any fee or prepayment premium

due hereunder or (iii) within five (5) Business Days after the same becomes due, any other amount payable hereunder or under any other Investment Document; or

(b) Specific Covenants. Any Loan Party fails to perform or observe any term, covenant or agreement contained in any of Section 7.01, 7.02, 7.03, 7.05, 7.10, 7.11, 7.12, 7.14, 7.15, 7.16, 7.17, 7.18, 7.19 or Article VIII; or

(c) Other Defaults. Any Loan Party fails to perform or observe any other covenant or agreement (not specified in subsection (a) or (b) above) contained in any Investment Document on its part to be performed or observed and such failure continues for thirty (30) days after the earlier of the date on which (i) a Responsible Officer of any Loan Party becomes aware of such failure and (ii) written notice thereof shall have been given to the Borrower by the Administrative Agent or any Lender; or

(d) Representations and Warranties. Any representation, warranty, certification or statement of fact made or deemed made by or on behalf of the Borrower or any other Loan Party herein, in any other Investment Document, or in any document delivered in connection herewith or therewith shall be incorrect or misleading in any material respect when made or deemed made; or

(e) Cross-Default. (i) Any Loan Party or any Subsidiary (A) fails to make any payment when due (whether by scheduled maturity, required prepayment, acceleration, demand or otherwise), but only after the expiration of any grace period applicable thereto, in respect of any Indebtedness or Guarantee (other than Indebtedness hereunder and Indebtedness under Swap Contracts) having an aggregate principal amount (including undrawn committed or available amounts and including amounts owing to all creditors under any combined or syndicated credit arrangement) of more than the Threshold Amount or (B) fails to observe or perform any other agreement or condition relating to any such Indebtedness or Guarantee or contained in any instrument or agreement evidencing, securing or relating thereto, or any other event occurs, the effect of which default or other event is to cause, or to permit the holder or holders of such Indebtedness or the beneficiary or beneficiaries of such Guarantee (or a trustee or agent on behalf of such holder or holders or beneficiary or beneficiaries) to cause (after the expiration of any applicable grace or cure period applicable thereto), with the giving of notice if required, such Indebtedness to be demanded or to become due or to be repurchased, prepaid, defeased or redeemed (automatically or otherwise), or an offer to repurchase, prepay, defease or redeem such Indebtedness to be made, prior to its stated maturity, or such Guarantee to become payable or cash collateral in respect thereof to be demanded or (ii) there occurs under any Swap Contract an Early Termination Date (as defined in such Swap Contract) resulting from (A) any event of default under such Swap Contract as to which any Loan Party or any Subsidiary is the Defaulting Party (as defined in such Swap Contract) or (B) any Termination Event (as so defined) under such Swap Contract as to which any Loan Party or any Subsidiary is an Affected Party (as so defined) and, in either event, the Swap Termination Value owed by such Loan Party or such Subsidiary as a result thereof is greater than the Threshold Amount; or

(f) Insolvency Proceedings, Etc. (i) Any Loan Party or any of its Subsidiaries institutes or consents to the institution of any proceeding (including, in respect of any Loan Party or any of its Subsidiaries that is a German Person, insolvency proceedings (Insolvenzfahren)) under any Debtor Relief Law, or makes an assignment for the benefit of creditors; or applies for or consents to the appointment of any receiver, administrative receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer for it or for all or any material part of its property; or any receiver, administrative receiver, trustee, custodian, conservator, liquidator,

rehabilitator or similar officer is appointed without the application or consent of such Person and the appointment continues undischarged or unstayed for sixty (60) calendar days or any proceeding under any Debtor Relief Law relating to any such Person or to all or any material part of its property is instituted without the consent of such Person and continues undismissed or unstayed for sixty (60) calendar days, or an order for relief is entered in any such proceeding (provided, that, in respect of a German Person, "receiver", "administrative receiver", "trustee", "custodian", "conservator", "liquidator", "rehabilitator" or "similar officer" includes an "Insolvenzverwalter", a "Vorläufiger Insolvenzverwalter" or a "Sachwalter"); (ii) any BVI Loan Party ceases to be "solvent" as such term is defined in the Insolvency Act, 2003 of the British Virgin Islands; (iii) any action is taken by any Spanish Guarantor, any of its directors or any third party aiming to the declaration of insolvency ("concurso") of such Spanish Guarantor, including any "solicitud de concurso voluntario" or the occurrence of any of the situations described in Articles 5.2 and 5 bis of the Spanish Insolvency Law; or (iv) in respect of a French Loan Party, such French Loan Party shall be in a state of cessation des paiements within the meaning of the French Code de commerce (as used in this clause (f), a reference to a "similar officer" shall include a provisional administrator, conciliateur, mandataire ad hoc, administrateur judiciaire, mandataire judiciaire, liquidateur judiciaire, commissaire à l'exécution du plan, mandataire à l'exécution de l'accord or any person appointed as a result of any proceedings described in this clause (f), and "any proceeding" shall include any Loan Party applying for mandat ad hoc or conciliation in accordance with articles L. 611-3 to L. 611-16 of the French Code de commerce, the entry of a judgment opening sauvegarde, sauvegarde accélérée, sauvegarde financière accélérée, redressement judiciaire or liquidation judiciaire proceedings or ordering a cession totale ou partielle de l'entreprise under articles L. 620-1 to L. 670-8 of the French Code de commerce); or

(g) Inability to Pay Debts; Attachment. (i) Any Loan Party or any of its Subsidiaries becomes unable or admits in writing its inability or fails generally to pay its debts as they become due (provided, that, with respect to a German Person, "unable or admits its inability to pay its debts generally as they fall due" shall include illiquidity (Zahlungsunfähigkeit) within the meaning of section 17 German Insolvency Act (Insolvenzordnung – InsO ("InsO")) and over-indebtedness (Überschuldung) within the meaning of section 19 InsO) or (ii) any writ or warrant of attachment or execution or similar process is issued or levied against all or any material part of the property of any such Person and is not released, vacated or fully bonded within thirty (30) days after its issue or levy; or

(h) Judgments. There is entered against any Loan Party or any Subsidiary (i) one or more final judgments or orders for the payment of money in an aggregate amount exceeding the Threshold Amount (to the extent not covered by independent third-party insurance as to which the insurer does not dispute coverage) or (ii) any one or more non-monetary final judgments that have, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect and, in either case, (A) enforcement proceedings are commenced by any creditor upon such judgment or order or (B) there is a period of thirty (30) consecutive days during which a stay of enforcement of such judgment, by reason of a pending appeal or otherwise, is not in effect; or

(i) ERISA. (i) An ERISA Event occurs with respect to any Pension Plan or Multiemployer Plan which has resulted or would reasonably be expected to result in liability of any Loan Party under Title IV of ERISA to the Pension Plan, Multiemployer Plan or the PBGC in an aggregate amount in excess of the Threshold Amount or (ii) any Loan Party or any ERISA Affiliate fails to pay when due, after the expiration of any applicable grace period, any

installment payment with respect to its withdrawal liability, if any, under Section 4201 of ERISA under a Multiemployer Plan in an aggregate amount in excess of the Threshold Amount; or

(j) Employee Benefit Non-U.S. Plans. (i) There shall occur one or more Employee Benefit Non-U.S. Plan Events which individually or in the aggregate results in or would reasonably be expected to result in liability of the Borrower and its Subsidiaries in excess of the Threshold Amount during the term hereof; or (ii) there exists any fact or circumstance that reasonably would be expected to result in the imposition of a Lien or security interest under any applicable Laws, statutes, rules, regulations and orders to which any Employee Benefit Non-U.S. Plan is subject, on assets of the Borrower or any of its Subsidiaries; or

(k) Invalidity of Investment Documents. Any Investment Document, at any time after its execution and delivery and for any reason other than as expressly permitted hereunder or thereunder, ceases to be in full force and effect; or any Loan Party or any other Person contests in any manner the validity or enforceability of any Investment Document; or any Loan Party denies that it has any or further liability or obligation under any Investment Document, or purports to revoke, terminate or rescind any Investment Document; or

(l) Change of Control. There occurs any Change of Control; or

(m) Invalidity of Subordination Provisions. Any subordination provision in any document or instrument governing Indebtedness that is purported to be subordinated to the Obligations or any subordination provision in any subordination agreement that relates to any Indebtedness that is to be subordinated to the Obligations, or any subordination provision in any guaranty by any Loan Party of any such Indebtedness, shall cease to be in full force and effect, or any Person (including the holder of any such Indebtedness) shall contest in any manner the validity, binding nature or enforceability of any such provision; or

(n) Permitted Senior Revolving Credit Indebtedness. There occurs an "Event of Default" (or any comparable term) under, and as defined in, any Permitted Senior Revolving Credit Document; or

(o) Regulatory Matters, Etc. There occurs any of the following: (i) the FDA or any other Regulatory Authority initiates an enforcement action against, or issues a warning letter with respect to, any Loan Party or any of their respective Subsidiaries, any Product or any manufacturing facilities for any Product that causes any Loan Party or any of their respective Subsidiaries to discontinue or withdraw, or would reasonably be expected to cause any Loan Party to discontinue or withdraw, marketing or sales of any Product that has generated or is expected to generate at least $1,000,000 in revenue for the Loan Parties and their respective Subsidiaries on a consolidated basis over any period of twelve (12) consecutive months, or causes a delay in the manufacture or sale of any such Product, which discontinuance or delay would reasonably be expected to last for more than thirty (30) days, (ii) a recall of any Product that has generated or is expected to generate at least $1,000,000 in revenue for the Loan Parties and their respective Subsidiaries on a consolidated basis over any period of twelve (12) consecutive months or (iii) any Loan Party enters into a settlement agreement with the FDA or any other Regulatory Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, in excess of $1,000,000; or

(p) Material Adverse Effect. There occurs any circumstance or circumstances that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

9.02 Remedies Upon Event of Default.

If any Event of Default occurs and is continuing, the Administrative Agent shall, at the request of, or may, with the consent of, the Required Lenders, take any or all of the following actions:

(a) declare the commitment of each Lender to make Loans to be terminated, whereupon such commitments and obligation shall be terminated;

(b) declare the unpaid principal amount of all outstanding Loans, all interest accrued and unpaid thereon and all other amounts owing or payable hereunder or under any other Loan Document to be immediately due and payable, without presentment, demand, protest or other notice of any kind, all of which are hereby expressly waived by the Loan Parties; and

(c) exercise on behalf of itself and the Lenders all rights and remedies available to it and the Lenders under the Loan Documents;

provided, however, that, upon the occurrence of an actual or deemed entry of an order for relief with respect to the Borrower under the Bankruptcy Code of the United States, the obligation of each Lender to make Loans shall automatically terminate, the unpaid principal amount of all outstanding Loans and all interest and other amounts as aforesaid shall automatically become due and payable, in each case without further act of the Administrative Agent or any Lender.

If the Obligations are accelerated for any reason, the prepayment premium required by Section 2.03(d) will also be due and payable as though such Obligations were voluntarily prepaid and any discount on the Loans shall be deemed earned in full and, in each case, shall constitute part of the Obligations, in view of the impracticability and extreme difficulty of ascertaining actual damages and by mutual agreement of the parties as to a reasonable calculation of each Lender's lost profits as a result thereof. Any prepayment premium required by Section 2.03(d) payable pursuant to the preceding sentence shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination and the Borrower and the other Loan Parties agree that it is reasonable under the circumstances currently existing. The prepayment premium required by Section 2.03(d) shall also be payable and any discount on the Loans shall be deemed earned in full, in each case, in the event that 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. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE BORROWER AND THE OTHER LOAN PARTIES EXPRESSLY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING PREPAYMENT PREMIUM AND ANY DISCOUNT ON THE LOANS IN CONNECTION WITH ANY SUCH ACCELERATION. The Borrower and the other Loan Parties expressly agree that (i) the prepayment premium required by Section 2.03(d) and any discount on the Loans provided for herein is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel, (ii) the prepayment premium required by Section 2.03(d) and any discount on the Loans 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 Borrower and the other Loan Parties giving specific consideration in this transaction for such agreement to pay the prepayment premium required by Section 2.03(d) and any discount on the Loans, (iv) the Borrower and the other Loan Parties shall be estopped hereafter from claiming differently than as agreed to in this paragraph and (v) the prepayment premium required by Section 2.03(d) and any discount on the Loans represent a good faith, reasonable estimate and calculation of the lost profits or 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 any early termination. The Borrower and the other Loan Parties expressly acknowledge that their agreement to pay the prepayment

premium required by Section 2.03(d) and any discount on the Loans to the Lenders as herein described is a material inducement to the Lenders to make the Loans hereunder.

9.03 Application of Funds.

After the exercise of remedies provided for in Section 9.02 (or after the Loans have automatically become immediately due and payable as set forth in the proviso to Section 9.02), any amounts received by any Lender or the Administrative Agent on account of the Obligations shall be applied by the Administrative Agent in the following order:

First, to payment of that portion of the Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Administrative Agent and amounts payable under Article III) payable to the Administrative Agent in its capacity as such;

Second, to payment of that portion of the Obligations constituting fees, indemnities and other amounts (other than principal and interest) payable to the Lenders (including fees, charges and disbursements of counsel to the respective Lenders) arising under the Loan Documents and amounts payable under Article III, ratably among them in proportion to the respective amounts described in this clause Second payable to them;

Third, to payment of that portion of the Obligations constituting accrued and unpaid interest on and prepayment premium with respect to the Loans, ratably among the Lenders in proportion to the respective amounts described in this clause Third held by them;

Fourth, to payment of that portion of the Obligations constituting accrued and unpaid principal of the Loans, ratably among the Secured Parties in proportion to the respective amounts described in this clause Fourth held by them; and

Last, the balance, if any, after all of the Obligations have been indefeasibly paid in full, to the Borrower or as otherwise required by Law.

## ARTICLE X.

## ADMINISTRATIVE AGENT

10.01 Appointment and Authority.

(a) Each of the Lenders hereby irrevocably appoints Madryn Health Partners, LP to act on its behalf as the Administrative Agent hereunder and under the other Loan Documents and authorizes the Administrative Agent to take such actions on its behalf and to exercise such powers as are delegated to the Administrative Agent by the terms hereof or thereof, together with such actions and powers as are incidental thereto. The provisions of this Article X are solely for the benefit of the Administrative Agent and the Lenders, and neither the Borrower nor any other Loan Party shall have rights as a third party beneficiary of any of such provisions. It is understood and agreed that the use of the term "agent" herein or in any other Loan Documents (or any other similar term) with reference to the Administrative Agent is not intended to connote any fiduciary or other implied (or express) obligations arising under agency doctrine of any applicable Law. Instead such term is used as a matter of market custom, and is intended to create or reflect only an administrative relationship between contracting parties.

(b) The Administrative Agent shall also act as the "collateral agent" and parallel debt creditor under the Loan Documents, and each of the Lenders hereby irrevocably appoints and authorizes the Administrative Agent to act as the agent of such Lender for purposes of acquiring, holding and enforcing (including in its capacity as parallel debt creditor) any and all Liens on Collateral granted by any of the Loan Parties to secure any of the Obligations, together with such powers and discretion as are incidental thereto. In this connection, the Administrative Agent, as "collateral agent" and any co-agents, sub-agents and attorneys-in-fact appointed by the Administrative Agent pursuant to Section 10.05 for purposes of holding or enforcing any Lien on the Collateral (or any portion thereof) granted under the Collateral Documents, or for exercising any rights and remedies thereunder at the direction of the Administrative Agent, shall be entitled to the benefits of all provisions of this Article X and Article XI (including Section 11.04(c), as though such co-agents, sub-agents and attorneys-in-fact were the "collateral agent" under the Loan Documents) as if set forth in full herein with respect thereto.

(c) In connection with the ratification and raising of any Loan Document into the status of a Spanish Public Document, the Administrative Agent shall act as the agent and representative of each Loan Party and is hereby authorised on behalf of each Loan Party to enter into, enforce the rights of each Loan Party under and represent each Loan Party in respect of the granting of any Spanish Public Document.

(d) Notwithstanding the foregoing clause (c), the Administrative Agent, acting at its discretion and to the extent reasonably possible, may invite the Loan Parties to enter into and/or to enforce the rights of each Loan Document (including any Collateral Document governed by Spanish law) jointly with the Administrative Agent. For the avoidance of doubt, this clause (d) does not grant any right to the Loan Parties to enter into and/or to enforce the rights.

(e) Each of the Lenders:

(i) appoints the Administrative Agent (acting as the "collateral agent") to act as agent (mandataire) pursuant to article 1984 of the French Code Civil for the purpose of executing any Collateral Documents governed by French law (collectively, the "French Transaction Security Documents") in its name;

(ii) confirms its approval of the French Transaction Security Documents creating or expressed to create a Lien for its benefit and any Lien created or to be created pursuant thereto; and

(iii) irrevocably authorizes, empowers and directs the Administrative Agent, acting as the "collateral agent" (by itself or by such person(s) as it may nominate) on its behalf, to perform the duties and to exercise the rights, powers, authorities and discretions that are specifically delegated to it under or in connection with the French Transaction Security Documents, and to take any action and exercise any right, power, authority and discretion upon the terms and conditions set out in this Agreement under or in connection with the French Transaction Security Documents, in each case together with any other rights, powers, authorities and discretions which are incidental thereto, it being understood that each Lender shall issue special powers of attorney in all cases where the exercise of powers granted under this Agreement requires the issuance of any such special powers of attorney, and the Administrative Agent accepts such appointment, it being agreed that notwithstanding any other provision of this Agreement to the contrary, the provisions of this clause (e) are governed by the laws of France.

(f) Each of the Lenders:

(i) appoints the Administrative Agent (acting as the "collateral agent") to act as security agent (agent des sûretés) pursuant to articles 2488-6 et seq. of the French Code civil in respect of the French Transaction Security Documents;

(ii) irrevocably authorizes the Administrative Agent acting in such capacity within the meaning of article 2488-6 of the French Code civil without limitation and notwithstanding any other rights conferred upon the Administrative Agent under this Agreement:

(A) to negotiate, accept and execute in its name and for the benefit of each Lender the French Transaction Security Documents (and any ancillary document in connection therewith);

(B) to take, register, administer and enforce any Lien created or expressed to be created pursuant to a French Transaction Security Document;

(C) to perform the duties and to exercise the rights, powers and discretions that are specifically delegated to it under or in connection with the French Transaction Security Documents, and more generally to take any action and exercise any right, power, prerogative and discretion upon the terms and conditions set out in this Agreement or under or in connection with the French Transaction Security Documents and to protect the rights of the Lenders under or in connection with any Lien created thereunder, in each case together with any other right, power, prerogative and discretion which is incidental thereto;

(D) to release the Liens granted under the French Transaction Security Documents in accordance with the provisions of this Agreement; and

(E) to take any action and exercise any right, power, authority and discretion in accordance with the Loan Documents.

The Administrative Agent accepts its appointment as "agent des sûretés" pursuant to this clause (f) for so long as this Agreement is in force or any French Transaction Security Document or claim in respect thereof exists, and declares that it holds in its own name the Lien created or expressed to be created pursuant to the French Transaction Security Documents in its capacity as security Agent (agent des sûretés) pursuant to articles 2488-6 et seq. of the French Code civil for the benefit of the Lenders on the terms contained in this Agreement, and accordingly any action taken by the Administrative Agent in such capacity in connection with or for the purposes of the Liens governed by French law and the French Transaction Security Documents in accordance with this Agreement and the French Transaction Security Documents shall be deemed to be taken by the Administrative Agent acting as "agent des sûretés" in its own name and for the benefit of the Lenders (other than where the Administrative Agent specifies that it is acting in its capacity as creditor of the Parallel Debt).

(g) Each Lender acknowledges that (i) the Administrative Agent (acting in such capacity) shall not be liable on its own estate (patrimoine propre) for the payment of any soulte that would be payable to a Loan Party as a result of the enforcement of a Lien created pursuant to

a French Transaction Security Document and (ii) the payment of any sums in respect of a soulte (if any) shall be borne by each Lender in accordance with this Agreement.

(h) To the fullest extent permitted by applicable Law, the Administrative Agent appointed as agent des sûretés pursuant to this Section 10.01 shall be entitled to exercise all rights and benefit from all protections conferred upon the Administrative Agent under this Agreement or any other Loan Document.

(i) Any change of the Administrative Agent acting as agent des sûretés (remplacement conventionnel or remplacement judiciaire) appointed pursuant to this Section 10.01 shall be made in accordance with Section 10.06 and article 2488-11 of the French Code civil.

(j) Notwithstanding any other provision of this Agreement to the contrary, clauses (f) through (i) of this Section 10.01, insofar as they relate to the French Transaction Security Documents and the role of the Administrative Agent acting as agent des sûretés in respect thereof, shall be governed by French law.

(k) Each of the Secured Parties (other than the Administrative Agent):

(i) appoints, with the express consent pursuant to article 1395 of the Italian Civil Code, the Administrative Agent as mandatario con rappresentanza (common representative) for the purposes of executing in its name and on its behalf any Collateral Document which is expressed to be or construed to be governed by Italian Law (the "Italian Law Security Documents") and security agent (the "Security Agent") under and for the purposes of any Italian Law Security Documents

(ii) grants the Administrative Agent the power to, in its name and on its behalf, enter into any and each Italian Law Security Document (including any amendment or extension thereof), execute any other agreement or instrument, give or receive any notice, to collect any and all amounts due to the Secured Parties under each such Italian Law Security Document and take any other action in relation to the creation, perfection, maintenance, enforcement and release of the Lien created thereunder in the name and on behalf of the Secured Parties, including (without limitation and for the avoidance of doubt) any confirmation and extension of the Lien created thereunder;

(iii) authorizes the Administrative Agent to, in its name and on its behalf, exercise such rights, powers and discretions as are specifically delegated to the Administrative Agent by the terms hereof, the other Loan Documents and the Italian Law Security Documents together with all rights, powers and discretions as are reasonably incidental thereto or necessary to give effect to the provisions contained herein;

(iv) hereby confirms that, in the event that any Lien created under the Italian Law Security Documents remains registered in the name of a Secured Party after it has ceased to be a Secured Party, then the Administrative Agent shall remain empowered under this paragraph to execute a release of such Lien in its name and on its behalf; and

(v) undertakes to ratify and approve any such action taken in the name and on behalf of the Secured Parties by the Administrative Agent acting in its appointed capacity.

(l) Each Secured Party other than the Administrative Agent acknowledges and agrees that the Administrative Agent may enter in its name and on its behalf as direct representative into contractual arrangements pursuant to or in connection with the Italian Law Security Documents to which the Security Agent is also a party (in its capacity as common representative or otherwise) and expressly authorizes the Administrative Agent, pursuant to article 1395 of the Italian Civil Code. The Secured Parties expressly waive any right they may have under article 1394 of the Italian Civil Code in respect of contractual arrangements entered into by the Administrative Agent in their name and on their behalf pursuant to or in connection with the Italian Law Security Documents.

(m) The above notwithstanding, the Administrative Agent in its quality as mandatario con rappresentanza, acting at its discretion and to the extent reasonably possible, may invite the other Secured Parties to enter into and/or to enforce the rights of each Loan Document jointly with the Administrative Agent. For the avoidance of doubt, the provision above does not grant any right to the other Secured Parties to enter into and/or to enforce the rights under any Loan Document jointly with the Administrative Agent.

10.02 Rights as a Lender.

The Person serving as the Administrative Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Administrative Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Administrative Agent hereunder in its individual capacity. Such Person and its Affiliates may accept deposits from, lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with any Loan Party or any Subsidiary or other Affiliate thereof as if such Person were not the Administrative Agent hereunder and without any duty to account therefor to the Lenders.

10.03 Exculpatory Provisions.

The Administrative Agent shall not have any duties or obligations except those expressly set forth herein and in the other Loan Documents, and its duties hereunder shall be administrative in nature. Without limiting the generality of the foregoing, the Administrative Agent:

(a) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default has occurred and is continuing;

(b) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Administrative Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in the other Loan Documents); provided, that, the Administrative Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Administrative Agent to liability or that is contrary to any Loan Document or applicable law, including for the avoidance of doubt any action that may be in violation of the automatic stay under any Debtor Relief Law or that may affect a forfeiture, modification or termination of property of a Defaulting Lender in violation of any Debtor Relief Law; and

(c) shall not, except as expressly set forth herein 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 Loan Party 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.

The Administrative Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Administrative Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.01 and Section 9.02) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment. The Administrative Agent shall be deemed not to have knowledge of any Default unless and until notice describing such Default is given in writing to the Administrative Agent by the Borrower or a Lender.

The Administrative Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Article V or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Administrative Agent.

10.04 Reliance by Administrative Agent.

The Administrative Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, Internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Administrative Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. 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 notice to the contrary from such Lender prior to the making of such Loan. The Administrative Agent may consult with legal counsel (who may be counsel for the Loan Parties), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.

10.05 Delegation of Duties.

The Administrative Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Administrative Agent. The Administrative Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Article X shall apply to any such sub-agent and to the Related Parties of the Administrative Agent and any such sub-agent, and shall apply to their respective activities in connection with the syndication of the Facilities provided for herein as well as 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.

10.06 Resignation of Administrative Agent.

The Administrative Agent may resign as Administrative Agent at any time by giving thirty (30) days advance notice thereof to the Lenders and the Borrower and, thereafter, the retiring Administrative Agent shall be discharged from its duties and obligations hereunder. Upon any such resignation, the Required Lenders shall have the right, subject to the approval of the Borrower (so long as no Event of Default has occurred and is continuing; such approval not to be unreasonably withheld), to appoint a successor Administrative Agent. If no successor Administrative Agent shall have been so appointed by the Required Lenders, been approved (so long as no Event of Default has occurred and is continuing) by the Borrower or have accepted such appointment within thirty (30) days after the Administrative Agent's giving of notice of resignation, then the Administrative Agent may, on behalf of the Lenders, appoint a successor Administrative Agent reasonably acceptable to the Borrower (so long as no Default or Event of Default has occurred and is continuing). Upon the acceptance of any appointment as Administrative Agent hereunder by a successor Administrative Agent, such successor Administrative Agent shall thereupon succeed to and become vested with all rights, powers, privileges and duties of the retiring Administrative Agent. After any retiring Administrative Agent's resignation hereunder as Administrative Agent, the provisions of this Section 10.06 shall continue in effect for its benefit in respect of any actions taken or omitted to be taken by it while it was acting as Administrative Agent. If no successor has accepted appointment as Administrative Agent by the date which is thirty (30) days following a retiring Administrative Agent's notice of resignation, the retiring Administrative Agent's resignation shall nevertheless thereupon become effective and the Required Lenders shall perform all of the duties of the Administrative Agent hereunder until such time, if any, as the Required Lenders appoint a successor agent as provided for above.

Any successor Administrative Agent and each of the other parties hereto shall have the same rights and obligations amongst themselves as they would have had if such successor Administrative Agent had been an original party hereto, including the capacity to represent any Loan Party for the purposes of raising any Loan Document to the status of a Spanish Public Document.

10.07 Non-Reliance on Administrative Agent and Other Lenders.

Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement. Each Lender also acknowledges that it will, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

10.08 Administrative Agent May File Proofs of Claim.

In case of the pendency of any receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition or other judicial proceeding relative to any Loan Party, 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) shall be entitled and empowered, by intervention in 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 11.04) 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 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 the Administrative Agent under Section 11.04.

Nothing contained herein shall be deemed to authorize the Administrative Agent to authorize or consent to or accept or adopt on behalf of any Lender any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Lender or to authorize the Administrative Agent to vote in respect of the claim of any Lender in any such proceeding.

10.09 Collateral and Guaranty Matters.

The Lenders irrevocably authorize the Administrative Agent, at its option and in its discretion,

(a) to release any Lien on any Collateral granted to or held by the Administrative Agent under any Loan Document (i) upon termination of all unused Commitments and payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted), (ii) that is sold or otherwise disposed of or to be sold or otherwise disposed of as part of or in connection with any sale or other Disposition permitted hereunder or under any other Loan Document or any Involuntary Disposition or (iii) as approved in accordance with Section 11.01;

(b) to subordinate any Lien on any property granted to or held by the Administrative Agent under any Loan Document to the holder of any Lien on such property that is permitted by Section 8.01(i); and

(c) to release any Guarantor from its obligations under the Guaranty if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Loan Documents.

Upon request by the Administrative Agent at any time, the Required Lenders will confirm in writing the Administrative Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor from its obligations under the Guaranty, pursuant to this Section 10.09.

The Administrative Agent shall not be responsible for or have a duty to ascertain or inquire into any representation or warranty regarding the existence, value or collectability of the Collateral, the existence, priority or perfection of the Administrative Agent's Lien thereon, or any certificate prepared by any Loan Party in connection therewith, nor shall the Administrative Agent be responsible or liable to the Lenders for any failure to monitor or maintain any portion of the Collateral.

ARTICLE XI.

MISCELLANEOUS

11.01 Amendments, Etc.

No amendment or waiver of any provision of this Agreement or any other Loan Document, and no consent to any departure by the Borrower or any other Loan Party therefrom, shall be effective unless in writing signed by the Required Lenders and the Borrower or the applicable Loan Party, as the case may be, and acknowledged by the Administrative Agent, and each such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; provided, further, that:

(a) no such amendment, waiver or consent shall:

(i) extend or increase the Commitment of a Lender (or reinstate any Commitment terminated pursuant to Section 9.02) without the written consent of such Lender whose Commitment is being extended or increased (it being understood and agreed that a waiver of any condition precedent set forth in Section 5.03 or of any Default or a mandatory reduction in Commitments is not considered an extension or increase in Commitments of any Lender);

(ii) postpone any date fixed by this Agreement or any other Loan Document for any payment of principal (excluding mandatory prepayments), interest, prepayment premiums, fees or other amounts due to the Lenders (or any of them) or any scheduled or mandatory reduction of the Commitments hereunder or under any other Loan Document without the written consent of each Lender entitled to receive such payment or whose Commitments are to be reduced;

(iii) reduce the principal of, the rate of interest specified herein on or the prepayment premium specified herein on any Loan, or any fees or other amounts payable hereunder or under any other Loan Document without the written consent of each Lender entitled to receive such payment of principal, interest, fees or other amounts; provided, however, that, only the consent of the Required Lenders shall be necessary to amend the definition of "Default Rate" or to waive any obligation of the Borrower to pay interest at the Default Rate;

(iv) change any provision of this Section 11.01(a) or the definition of "Required Lenders" without the written consent of each Lender directly affected thereby;

(v) except in connection with a Disposition permitted under Section 8.05, release all or substantially all of the Collateral without the written consent of each Lender directly affected thereby;

(vi) release the Borrower or, except in connection with a merger or consolidation permitted under Section 8.04 or a Disposition permitted under Section 8.05, all or substantially all of the Guarantors without the written consent of each Lender directly affected thereby, except to the extent the release of any Guarantor is permitted pursuant to Section 10.09 (in which case such release may be made by the Administrative Agent acting alone); and

(b) unless also signed by the Administrative Agent, no amendment, waiver or consent shall affect the rights or duties of the Administrative Agent under this Agreement or any other Loan Document;

provided, however, that, notwithstanding anything to the contrary herein, (i) 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 Commitments 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, (ii) each Lender is entitled to vote as such Lender sees fit on any bankruptcy reorganization plan that affects the Loans and each Lender acknowledges that the provisions of Section 1126(c) of the Bankruptcy Code of the United States supersedes the unanimous consent provisions set forth herein and (iii) the Required Lenders shall determine whether or not to allow a Loan Party to use cash collateral in the context of a bankruptcy or insolvency proceeding and such determination shall be binding on all of the Lenders. Notwithstanding anything to the contrary set forth herein, in order to implement the Term C Facility, this Agreement may be amended for such purpose by the Loan Parties, the Administrative Agent and the Term C Lenders.

It is understood and agreed that, following the Funding Date, subject to the written consent of the Administrative Agent and the Required Lenders (such consent not to be unreasonably withheld or delayed) effectuated in accordance with this Section 11.01, the Loan Parties shall be permitted to convey the Business IP Rights to a Qualified Loan Party in order to facilitate the Borrower's intellectual property strategy.

Notwithstanding any provision herein to the contrary, the Administrative Agent and the Borrower may make amendments contemplated by Section 3.05.

11.02 Notices and Other Communications; Facsimile Copies.

(a) Notices Generally. Except in the case of notices and other communications expressly permitted to be given by telephone (and except as provided in subsection (b) below), all notices and other communications provided for herein shall be in writing and shall be delivered by hand or overnight courier service, mailed by certified or registered mail or sent by facsimile as follows, and all notices and other communications expressly permitted hereunder to be given by telephone shall be made to the applicable telephone number, as follows:

(i) if to the Borrower or any other Loan Party or the Administrative Agent, to the address, facsimile number, electronic mail address or telephone number specified for such Person on Schedule 11.02; and

(ii) if to any other Lender, to the address, facsimile number, electronic mail address or telephone number of its Lending Office (whether specified on Schedule 11.02 or separately specified to the Borrower and the Administrative Agent).

Notices and other communications sent by hand or overnight courier service, or mailed by certified or registered mail, shall be deemed to have been given when received; notices and other communications sent by facsimile shall be deemed to have been given when sent (except that, if not given during normal business hours for the recipient, shall be deemed to have been given at the opening of business on the next Business Day for the recipient). Notices and other

communications delivered through electronic communications to the extent provided in subsection (b) below, shall be effective as provided in such subsection (b).

(b) Electronic Communications. Notices and other communications to the Lenders hereunder may be delivered or furnished by electronic communication (including e-mail and Internet or intranet websites) pursuant to procedures approved by the Administrative Agent; provided, that, the foregoing shall not apply to notices to any Lender pursuant to Article II if such Lender has notified the Administrative Agent that it is incapable of receiving notices under such Article by electronic communication. The Administrative Agent or the Borrower may each, in their respective discretion, agree to accept notices and other communications to it hereunder by electronic communications pursuant to procedures approved by it; provided, that, approval of such procedures may be limited to particular notices or communications.

Unless the Administrative Agent otherwise prescribes, (i) notices and other communications sent to an e-mail address shall be deemed received upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested" function, as available, return e-mail or other written acknowledgement) and (ii) notices or communications posted to an Internet or intranet website shall be deemed received upon the deemed receipt by the intended recipient at its e-mail address as described in the foregoing clause (i) of notification that such notice or communication is available and identifying the website address therefor; provided, that, for both clauses (i) and (ii), if such notice, email or other communication is not sent during the normal business hours of the recipient, such notice, email or communication shall be deemed to have been sent at the opening of business on the next business day for the recipient.

(c) Change of Address, Etc. Each of the Borrower, the Lenders and the Administrative Agent may change its address, facsimile or telephone number for notices and other communications hereunder by notice to the other parties hereto. In addition, each Lender agrees to notify the Administrative Agent from time to time to ensure that the Administrative Agent has on record (i) an effective address, contact name, telephone number, facsimile number and electronic mail address to which notices and other communications may be sent and (ii) accurate wire instructions for such Lender.

(d) Reliance by Administrative Agent and Lenders. The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic Loan Notices) purportedly given by or on behalf of any Loan Party even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Loan Parties shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of a Loan Party. All telephonic notices to and other telephonic communications with the Administrative Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.

11.03 No Waiver; Cumulative Remedies; Enforcement.

No failure by any Lender or the Administrative Agent to exercise, and no delay by any such Person in exercising, any right, remedy, power or privilege hereunder or under any other Loan Document shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right,

remedy, power or privilege. The rights, remedies, powers and privileges herein provided, and provided under each other Loan Document, are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

Notwithstanding anything to the contrary contained herein or in any other Loan Document, the authority to enforce rights and remedies hereunder and under the other Loan Documents against the Loan Parties or any of them shall be vested exclusively in, and all actions and proceedings at law in connection with such enforcement shall be instituted and maintained exclusively by, the Administrative Agent in accordance with Section 10.01 for the benefit of all the Secured Parties; provided, however, that, the foregoing shall not prohibit (a) the Administrative Agent from exercising on its own behalf the rights and remedies that inure to its benefit (solely in its capacity as Administrative Agent) hereunder and under the other Loan Documents, (b) any Lender from exercising setoff rights in accordance with Section 11.08 (subject to the terms of Section 2.11) or (c) any Lender from filing proofs of claim or appearing and filing pleadings on its own behalf during the pendency of a proceeding relative to any Loan Party under any Debtor Relief Law; and provided, further, that, if at any time there is no Person acting as Administrative Agent hereunder and under the other Loan Documents, then (i) the Required Lenders shall have the rights otherwise ascribed to the Administrative Agent pursuant to Section 10.01 and (ii) in addition to the matters set forth in clauses (b) and (c) of the preceding proviso and subject to Section 2.11, any Lender may, with the consent of the Required Lenders, enforce any rights and remedies available to it and as authorized by the Required Lenders.

11.04 Expenses; Indemnity; and Damage Waiver.

(a) Costs and Expenses. The Loan Parties shall pay (i) all out-of-pocket expenses incurred by the Administrative Agent and its Affiliates (including the fees, charges and disbursements of one primary counsel and, as reasonably necessary, one local counsel in each relevant jurisdiction for the Administrative Agent and one specialty counsel in each relevant specialty for the Administrative Agent), in connection with the preparation, negotiation, execution, delivery and administration of this Agreement and the other Investment Documents or any amendments, modifications or waivers of the provisions hereof or thereof (whether or not the transactions contemplated hereby or thereby shall be consummated) or the administration of this Agreement and the other Investment Documents and (ii) all out-of-pocket expenses incurred by the Administrative Agent or any Lender (including the fees, charges and disbursements of one primary counsel for the Administrative Agent and the Lenders and, as reasonably necessary, one local counsel for the Administrative Agent and the Lenders in any relevant jurisdiction and one specialty counsel in each relevant specialty for the Administrative Agent and the Lenders (and of such other counsel as necessary in the event of a conflict), and shall pay all fees and time charges for attorneys who may be employees of the Administrative Agent or any Lender, in connection with the enforcement or protection of its rights (A) in connection with this Agreement and the other Investment Documents, including its rights under this Section 11.04 or (B) in connection with the Loans made hereunder, including all such out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Loans.

(b) Indemnification by the Loan Parties. The Loan Parties shall indemnify the Administrative Agent (and any sub-agent thereof) and each Lender, and each Related Party of any of the foregoing Persons (each such Person being called an "Indemnitee") against, and hold each Indemnitee harmless from, any and all losses, claims, damages, liabilities and related expenses (including the fees, charges and disbursements of any counsel for any Indemnitee), and shall indemnify and hold harmless each Indemnitee from all fees and time charges and disbursements for attorneys who may be employees of any Indemnitee, incurred by any Indemnitee or asserted against any Indemnitee by any Person (including the Borrower or any

other Loan Party) arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Investment Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, or, in the case of the Administrative Agent (and any sub-agent thereof) and its Related Parties only, the administration of this Agreement and the other Investment Documents, (ii) any Loan or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of Hazardous Materials on or from any property owned or operated by a Loan Party or any of its Subsidiaries, or any Environmental Liability related in any way to a Loan Party or any of its Subsidiaries, (iv) any actual or prospective claim, litigation, investigation or proceeding relating to an allegation that the use, advertisement, display, importation, manufacture, marketing, offering for sale, performance, preparation of derivative works based upon, promotion, reproduction, sale, use and/or other distribution of a Product by any Loan Party, any Subsidiary or any of their respective licensees, or the conduct of the Businesses, constitutes the infringement, violation or misappropriation of the rights of any Person or (v) any actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by a third party or by the Borrower or any other Loan Party, and regardless of whether any Indemnitee is a party thereto, in all cases, whether or not caused by or arising, in whole or in part, out of the comparative, contributory or sole negligence of the Indemnitee; provided, that, such indemnity shall not, as to any Indemnitee, be available to the extent that such losses, claims, damages, liabilities or related expenses (x) are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from the gross negligence or willful misconduct of such Indemnitee, if such Borrower or such Loan Party has obtained a final and nonappealable judgment in its favor on such claim as determined by a court of competent jurisdiction or (y) arise solely from a dispute between or among Indemnitees and (1) do not involve any action or inaction by any Loan Party or any of their respective Affiliates or (2) do not relate to any action of such Indemnitee in its capacity as the Administrative Agent as determined by a court of competent jurisdiction in a final and nonappealable judgment. This Section 11.04(b) shall not apply with respect to taxes other than any taxes that represent losses, claims, damages, etc. arising from any non-tax claim.

(c) Reimbursement by Lenders. To the extent that the Loan Parties for any reason fail to indefeasibly pay any amount required under subsection (a) or (b) of this Section 11.04 to be paid by them to the Administrative Agent (or any sub-agent thereof) or any Related Party thereof, each Lender severally agrees to pay to the Administrative Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's pro rata share (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought based on each Lender's share of the Total Credit Exposure at such time) of such unpaid amount (including any such unpaid amount in respect of a claim asserted by such Lender), such payment to be made severally among them based on such Lenders' Applicable Percentages (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought); provided, further, that, the unreimbursed expense or indemnified loss, claim, damage, liability or related expense, as the case may be, was incurred by or asserted against the Administrative Agent (or any such sub-agent), or against any Related Party thereof acting for the Administrative Agent (or any such sub-agent) in connection with such capacity. The obligations of the Lenders under this subsection (c) are subject to the provisions of Section 2.10(b).

(d) Waiver of Consequential Damages, Etc. To the fullest extent permitted by applicable law, no Loan Party shall assert, and each Loan Party hereby waives, and acknowledges that no other Person shall have, any claim against any Indemnitee, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages)

arising out of, in connection with, or as a result of, this Agreement, any other Investment Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Loan or the use of the proceeds thereof. No Indemnitee referred to in subsection (b) above shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Investment Documents or the transactions contemplated hereby or thereby.

(e) Payments. All amounts due under this Section 11.04 shall be payable not later than ten (10) Business Days after demand therefor.

(f) Survival. The agreements in this Section 11.04 and the indemnity provisions of Section 11.02(d) shall survive the resignation of the Administrative Agent, the replacement of any Lender, the termination of the Commitments and the repayment, satisfaction or discharge of all the other Obligations.

11.05 Payments Set Aside.

To the extent that any payment by or on behalf of any Loan Party is made to the Administrative Agent or any Lender, or the Administrative Agent or any Lender exercises its right of setoff, 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 or such Lender in its discretion) to be repaid to a trustee, receiver or any other party, in connection with any proceeding under any Debtor Relief Law or otherwise, then (a) 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 (b) 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 Rate from time to time in effect. The obligations of the Lenders under clause (b) of the preceding sentence shall survive the payment in full of the Obligations and the termination of this Agreement.

11.06 Successors and Assigns.

(a) Successors and Assigns Generally. The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the parties hereto and thereto and their respective successors and assigns permitted hereby, except that the Borrower may not assign or otherwise transfer any of their rights or obligations hereunder or thereunder without the prior written consent of the Administrative Agent and each Lender and no Lender may assign or otherwise transfer any of its rights or obligations hereunder except (i) to an assignee in accordance with the provisions of subsection (b) of this Section 11.06, (ii) by way of participation in accordance with the provisions of subsection (d) of this Section 11.06 or (iii) by way of pledge or assignment of a security interest subject to the restrictions of subsection (e) of this Section 11.06 (and any other attempted assignment or transfer by any party hereto shall be null and void). 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 subsection (e) of this Section 11.06 and, to the extent expressly contemplated hereby, the Related Parties of each of the Administrative Agent and the Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) Assignments by Lenders. Any Lender may at any time assign to one or more assignees all or a portion of its rights and obligations under this Agreement and the other Loan Documents (including all or a portion of its Commitments under any Facility and the Loans at the time owing to it (in each case with respect to any Facility)); provided, that, any such assignment shall be subject to the following conditions:

(i) Minimum Amounts.

(A) in the case of an assignment of the entire remaining amount of the assigning Lender's Commitment with respect to any Facility and/or the Loans with respect to any Facility at the time owing to it or contemporaneous assignments to related Approved Funds that equal at least the amount specified in subsection (b)(i)(B) of this Section 11.06 in the aggregate or in the case of an assignment to a Lender, an Affiliate of a Lender or an Approved Fund, no minimum amount need be assigned; and

(B) in any case not described in subsection (b)(i)(A) of this Section 11.06, the aggregate amount of the applicable Commitment (which for this purpose includes Loans outstanding thereunder) or, if the applicable Commitment is not then in effect, the principal outstanding balance of the Loans with respect to such Facility of the assigning Lender subject to each such assignment, determined as of the date the Assignment and Assumption with respect to such assignment is delivered to the Administrative Agent or, if "Trade Date" is specified in the Assignment and Assumption, as of the Trade Date, shall not be less than $1,000,000 unless each of the Administrative Agent and, so long as no Event of Default has occurred and is continuing, the Borrower otherwise consents (each such consent not to be unreasonably withheld or delayed);

(ii) Proportionate Amounts. Each partial assignment shall be made as an assignment of a proportionate part of all of the assigning Lender's rights and obligations under this Agreement with respect to the Loans or the Commitment assigned.

(iii) Required Consents. No consent shall be required for any assignment except to the extent required by subsection (b)(i)(B) of this Section 11.06 and, in addition:

(A) the consent of the Borrower (such consent not to be unreasonably withheld or delayed) shall be required unless (1) an Event of Default has occurred and is continuing at the time of such assignment or (2) such assignment is to a Lender, an Affiliate of a Lender or an Approved Fund; provided, 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 notice thereof;

(B) the consent of the Administrative Agent (such consent not to be unreasonably withheld or delayed) shall be required for assignments in respect of (i) any unfunded Commitment if such assignment is to a Person that is not a Lender with a Commitment in respect of the applicable Facility, an Affiliate of such Lender or an Approved Fund with respect to such Lender or (ii) any Loan to a Person that is not a Lender, an Affiliate of a Lender or an Approved Fund;

(iv) Assignment and Assumption. The parties to each assignment shall execute and deliver to the Administrative Agent an Assignment and Assumption. The assignee, if it is not a Lender, shall deliver to the Administrative Agent such information, including notice information, as the Administrative Agent shall reasonably require.

(v) No Assignment to Certain Persons. No such assignment shall be made (A) to the Borrower or any of the Borrower's Affiliates or Subsidiaries, (B) to any Defaulting Lender or any of its Subsidiaries or any Person who, upon becoming a Lender hereunder, would constitute any of the foregoing Persons described in this clause (B) or (C) to a natural Person.

(vi) 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 pro rata 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 pro rata share of all Loans in accordance with its Applicable Percentage. 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.

(vii) Spanish Public Documents. At the request of the Administrative Agent or the assignee, the parties to an assignment shall promptly raise the duly completed Assignment and Assumption to the status of Spanish Public Document in the form of "escritura pública". For this purpose, the assignee will appoint the Administrative Agent as its Administrative Agent and representative in connection with the ratification and raising such Assignment and Assumption to the status of a Spanish Public Document. For the avoidance of doubt, any costs arising from the notarization of the Assignment and Assumption shall be paid, as applicable, by the assigning Lender and the assignee.

(viii) French Law Provisions. To the extent that an assignment of rights and obligations by a Lender referred to in this clause (b) could be construed as a novation within the meaning of articles 1329 et seq. of the French Code civil, each party hereto agrees that for the purposes of articles 1334 et seq. of the French Code civil and upon such an assignment, the Liens created under the French Security Documents shall be preserved and maintained for the benefit of the Secured Parties. An assignee may, in the case of an assignment of rights by an existing Lender hereunder, if it considers it necessary to make the assignment effective as against a French Loan Party, arrange for such assignment to be notified to or acknowledged by such French Loan Party in accordance with article 1324 of the French Code civil.

Subject to acceptance and recording thereof by the Administrative Agent pursuant to subsection (c) of this Section 11.06, from and after the effective date specified in each Assignment and Assumption, 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 a Lender under this Agreement, and the assigning Lender thereunder 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 assigning Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) but shall continue to be entitled to the benefits of Sections 3.01, 3.02, 3.04 and 11.04 with respect to facts and circumstances occurring prior to the effective date of such assignment. Upon request, the Borrower (at its expense) shall execute and deliver a Note to the assignee Lender. Any assignment or transfer by a Lender of rights or obligations under this Agreement that does not comply with this subsection 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 subsection (d) of this Section 11.06.

(c) Register. The Administrative Agent, acting solely for this purpose as an agent of the Borrower (and such agency being solely for tax purposes), shall maintain at the Administrative Agent's Office a copy of each Assignment and Assumption delivered to it (or the equivalent thereof in electronic form) and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts (and stated interest) of 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 notice.

(d) Participations. Any Lender may at any time, without the consent of, or notice to, the Borrower or the Administrative Agent, sell participations to any Person (other than a natural Person, a Defaulting Lender or the Borrower or any of the Borrower's Affiliates or Subsidiaries) (each, a "Participant") in all or a portion of such Lender's rights and/or obligations under this Agreement (including all or a portion of its Commitment and/or the Loans owing to it); provided, that, (i) such Lender's obligations under this Agreement 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, the Administrative Agent and the other Lenders shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations under this Agreement. For the avoidance of doubt, each Lender shall be responsible for the indemnity under Section 11.04(c) without regard to the existence of any participation.

Any agreement or instrument pursuant to which a Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, modification or waiver of any provision of this Agreement; provided, that, such agreement or instrument may provide that such Lender will not, without the consent of the Participant, agree to any amendment, waiver or other modification described in clauses (i) through (vi) of Section 11.01(a) that affects such Participant. The Borrower agrees that each Participant shall be entitled to the benefits of Sections 3.01, 3.02 and 3.04 (subject to the requirements and limitations therein (it being understood that the documentation required under Section 3.01(c) 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 subsection (b) of this Section 11.06; provided, that, such Participant (A) agrees to be subject to the provisions of Sections 3.03 and 11.13 as if it were an assignee under paragraph (b) of this Section; and (B) shall not be entitled to receive any greater payment under Section 3.01 or 3.02, 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. Each Lender that sells a participation agrees, at the Borrower's request and expense, to use reasonable efforts to cooperate with the Borrower to effectuate the provisions of Section 11.13 with respect to any Participant. To the fullest extent permitted by law, each Participant also shall be entitled to the benefits of Section 11.08 as though it were a Lender; provided, that, such Participant agrees to be subject to Section 2.11 as though it were a Lender.

(e) Certain Pledges. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement (including under its Note, if any) 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.

11.07 Treatment of Certain Information; Confidentiality.

Each of the Administrative Agent and the Lenders agrees to maintain the confidentiality of the Information (as defined below), except that Information may be disclosed (a) to its Affiliates and to its Related Parties (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and will be instructed to keep such Information confidential), (b) to the extent required or requested by 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), (c) to the extent required by applicable laws or regulations or by any subpoena or similar legal process, (d) to any other party hereto, (e) as may be reasonably necessary in connection with the exercise of any remedies hereunder or under any other Investment Document or any action or proceeding relating to this Agreement or any other Investment Document or the enforcement of rights hereunder or thereunder, (f) subject to an agreement containing provisions substantially the same as those of this Section 11.07, to (i) any assignee of or Participant in, or any prospective assignee of or Participant in, any of its rights and obligations under this Agreement or (ii) any actual or prospective party (or its Related Parties) to any swap, derivative or other transaction under which payments are to be made by reference to a Loan Party and its obligations, this Agreement or payments hereunder, (g) on a confidential basis to (i) any rating agency in connection with rating any Loan Party or its Subsidiaries or the credit facilities provided hereunder or (ii) the CUSIP Service Bureau or any similar agency in connection with the issuance and monitoring of CUSIP numbers or other market identifiers with respect to the credit facilities provided hereunder, (h) with the consent of the Borrower, (i) to the members of its investment committee and its limited partners (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and instructed to keep such Information confidential) or (j) to the extent such Information (x) becomes publicly available other than as a result of a breach of this Section 11.07 or (y) becomes available to the Administrative Agent, any Lender or any of their respective Affiliates on a nonconfidential basis from a source other than the Borrower.

For purposes of this Section 11.07, "Information" means all information received from a Loan Party or any Subsidiary relating to the Loan Parties or any Subsidiary or any of their respective businesses, other than any such information that is available to the Administrative Agent or any Lender

on a nonconfidential basis prior to disclosure by such Loan Party or any Subsidiary; provided, that, in the case of information received from a Loan Party or any Subsidiary after the date hereof, such information is clearly identified at the time of delivery as confidential. Any Person required to maintain the confidentiality of Information as provided in this Section 11.07 shall be considered to have complied with its obligation to do so if such Person has exercised the same degree of care to maintain the confidentiality of such Information as such Person would accord to its own confidential information.

11.08 Set-off.

If an Event of Default shall have occurred and be continuing, each Lender and each of their respective Affiliates is hereby authorized at any time and from time to time, after obtaining the prior written consent of the Administrative Agent, to the fullest extent permitted by applicable law, to set off and apply any and all deposits (general or special, time or demand, provisional or final, in whatever currency) at any time held and other obligations (in whatever currency) at any time owing by such Lender or any such Affiliate to or for the credit or the account of the Borrower or any other Loan Party against any and all of the obligations of the Borrower or such Loan Party now or hereafter existing under this Agreement or any other Loan Document to such Lender or its Affiliates, irrespective of whether or not such Lender or Affiliate shall have made any demand under this Agreement or any other Loan Document and although such obligations of the Borrower or such Loan Party may be contingent or unmatured or are owed to a branch office or Affiliate of such Lender different from the branch office or Affiliate holding such deposit or obligated on such indebtedness; 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 2.12 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. The rights of each Lender and their respective Affiliates under this Section 11.08 are in addition to other rights and remedies (including other rights of setoff) that such Lender or their respective Affiliates may have. Each Lender agrees to notify the Borrower and the Administrative Agent promptly after any such setoff and application; provided, that, the failure to give such notice shall not affect the validity of such setoff and application.

11.09 Interest Rate Limitation.

Notwithstanding anything to the contrary contained in any Investment Document, the interest (actual or deemed) paid or agreed to be paid under the Investment Documents shall not exceed the maximum rate of non-usurious interest permitted by applicable Law (the "Maximum Rate"). If the Administrative Agent or any Lender shall receive interest (including, without limitation, all charges, fees, exactions or other sums which may at any time be deemed to be interest) in an amount that exceeds the Maximum Rate, the excess interest shall be applied to the principal of the Loans or, if it exceeds such unpaid principal, refunded to the Borrower. In determining whether the interest contracted for, charged, or received by the Administrative Agent or a Lender exceeds the Maximum Rate, such Person may, to the extent permitted by applicable Law, (a) characterize any payment that is not principal as an expense, fee, or premium rather than interest, (b) exclude voluntary prepayments and the effects thereof and (c) amortize, prorate, allocate, and spread in equal or unequal parts the total amount of interest throughout the contemplated term of the Obligations hereunder.

11.10 Counterparts; Integration; Effectiveness.

This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. This Agreement, the other Investment Documents, and any separate letter agreements with respect to fees payable to the Administrative Agent, constitute the entire contract among the parties relating to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof. Except as provided in Section 5.01, this Agreement shall become effective when it shall have been executed by the Administrative Agent and when the Administrative Agent shall have received counterparts hereof that, when taken together, bear the signatures of each of the other parties hereto. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

11.11 Survival of Representations and Warranties.

All representations and warranties made hereunder and in any other Investment Document or other document delivered pursuant hereto or thereto or in connection herewith or therewith shall survive the execution and delivery hereof and thereof and shall continue in full force and effect as long as any Loan or other Obligation hereunder shall remain unpaid or unsatisfied. Such representations and warranties have been or will be relied upon by the Administrative Agent and each Lender, regardless of any investigation made by the Administrative Agent or any Lender or on their behalf and notwithstanding that the Administrative Agent or any Lender may have had notice or knowledge of any Default at the time of any Borrowing, and shall continue in full force and effect as long as any Loan or any other Obligation hereunder shall remain unpaid or unsatisfied.

11.12 Severability.

If any provision of this Agreement or the other Investment Documents is held to be illegal, invalid or unenforceable, (a) the legality, validity and enforceability of the remaining provisions of this Agreement and the other Investment Documents shall not be affected or impaired thereby and (b) the parties shall endeavor in good faith negotiations to replace the illegal, invalid or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the illegal, invalid or unenforceable provisions. The invalidity of a provision in a particular jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. Without limiting the foregoing provisions of this Section 11.12, if and to the extent that the enforceability of any provisions in this Agreement relating to Defaulting Lenders shall be limited by Debtor Relief Laws, 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.

11.13 Replacement of Lenders.

If the Borrower is entitled to replace a Lender pursuant to the provisions of Section 3.03, or if any Lender is a Defaulting Lender or a Non-Consenting Lender, then the Borrower may, at its 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 11.06), all of its interests, rights (other than its existing rights to payments pursuant to Sections 3.01 and 3.02) and obligations under this Agreement and the related Loan Documents to an Eligible Assignee that shall assume such obligations (which assignee may be another Lender, if a Lender accepts such assignment), provided, that:

(a) such Lender shall have received payment of an amount equal to one hundred percent (100%) of (x) the outstanding principal of its Loans, accrued interest thereon and all other amounts payable to it hereunder and under the other Loan Documents (other than prepayment premium) from the assignee (to the extent of such outstanding principal and accrued interest) or the Borrower (in the case of all other amounts) and (y) the prepayment premium required by Section 2.03(d) from the Borrower, as if such assignment was a prepayment of one hundred percent (100%) of the outstanding principal amount of such assignor's Loans on the effective date of such assignment;

(b) in the case of any such assignment resulting from a claim for compensation under Section 3.02 or payments required to be made pursuant to Section 3.01, such assignment will result in a reduction in such compensation or payments thereafter;

(c) such assignment does not conflict with applicable Laws; and

(d) in the case of any such assignment resulting from a Non-Consenting Lender's failure to consent to a proposed change, waiver, discharge or termination with respect to any Loan Document, the applicable replacement bank, financial institution or Fund consents to the proposed change, waiver, discharge or termination; provided, that, the failure by such Non-Consenting Lender to execute and deliver an Assignment and Assumption shall not impair the validity of the removal of such Non-Consenting Lender and the mandatory assignment of such Non-Consenting Lender's Commitments and outstanding Loans pursuant to this Section 11.13 shall nevertheless be effective without the execution by such Non-Consenting Lender of an Assignment and Assumption.

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.

11.14 Governing Law; Jurisdiction; Etc.

(a) GOVERNING LAW. THIS AGREEMENT AND THE OTHER INVESTMENT DOCUMENTS (EXCEPT, AS TO ANY OTHER INVESTMENT DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER INVESTMENT DOCUMENT (EXCEPT, AS TO ANY OTHER INVESTMENT DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

(b) SUBMISSION TO JURISDICTION. THE BORROWER AND EACH OTHER LOAN PARTY 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 IN TORT OR OTHERWISE, AGAINST THE ADMINISTRATIVE AGENT, ANY LENDER OR ANY RELATED PARTY OF THE FOREGOING IN ANY WAY RELATING TO THIS AGREEMENT OR ANY OTHER INVESTMENT DOCUMENT OR THE TRANSACTIONS RELATING HERETO OR THERETO, IN ANY OTHER FORUM OTHER THAN THE COURTS OF THE STATE OF NEW YORK AND ANY UNITED STATES DISTRICT COURT IN THE STATE OF NEW YORK, IN EACH CASE LOCATED IN NEW YORK

COUNTY, NEW YORK, AND ANY APPELLATE COURT FROM ANY THEREOF, AND EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY SUBMITS TO THE 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 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. NOTHING IN THIS AGREEMENT OR IN ANY OTHER INVESTMENT DOCUMENT SHALL AFFECT ANY RIGHT THAT THE ADMINISTRATIVE AGENT OR ANY LENDER MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER INVESTMENT DOCUMENT AGAINST THE BORROWER OR ANY OTHER LOAN PARTY OR ITS PROPERTIES IN THE COURTS OF ANY JURISDICTION. NOTWITHSTANDING THE FOREGOING, THE PRECEDING SENTENCE SHALL NOT APPLY IN RELATION TO ANY PROCEEDINGS RELATING TO THIS AGREEMENT COMMENCED BY THE ADMINISTRATIVE AGENT OR ANY LENDER AGAINST ANY FRENCH LOAN PARTY (INCLUDING WHERE A FRENCH LOAN PARTY IS A JOINT DEFENDANT WITH ANY OTHER LOAN PARTY) AND ANY SUCH PROCEEDINGS SHALL BE COMMENCED IN THE COURTS OF THE STATE OF NEW YORK AND ANY UNITED STATES DISTRICT COURT IN THE STATE OF NEW YORK, IN EACH CASE LOCATED IN NEW YORK COUNTY, NEW YORK, AND ANY APPELLATE COURT FROM ANY THEREOF PURSUANT TO THIS PARAGRAPH.

(c) WAIVER OF VENUE. THE BORROWER AND EACH OTHER LOAN PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER INVESTMENT DOCUMENT IN ANY COURT REFERRED TO IN SUBSECTION (B) OF THIS SECTION 11.14. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(d) SERVICE OF PROCESS. EACH PARTY HERETO IRREVOCABLY CONSENTS TO SERVICE OF PROCESS IN THE MANNER PROVIDED FOR NOTICES IN SECTION 11.02. NOTHING IN THIS AGREEMENT WILL AFFECT THE RIGHT OF ANY PARTY HERETO TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY APPLICABLE LAW.

(e) EXECUTIVE PROCEEDINGS SPAIN.

(i) Upon enforcement, the sum payable by a Spanish Guarantor shall be the aggregate amount of the balance of the accounts maintained by the Administrative Agent (or the relevant Lender, as the case may be) pursuant to Section 2.09. For the purposes of Articles 571 et seq. of the Spanish Civil Procedural Law, the Parties agree that such balances shall be considered as due, liquid and payable and may be claimed pursuant to that law.

(ii) For the purposes of the provisions of Art. 571 et seq. of the Spanish Civil Procedural Law, the parties hereto agree that the amount of debt to be claimed through executive proceedings shall be determined by the Administrative Agent (or a Lender, as the case may be) in a certificate evidencing the balances shown in the relevant account(s) referred to in the foregoing clause (e)(i). For the Administrative Agent or a Lender to exercise executive action it must present:

(A) an original notarial first or authentic copy of this Agreement;

(B) the notarial document ("acta notarial") which (1) incorporates (I) the certificate of amounts due by the Spanish Guarantor issued by the Administrative Agent (or the relevant Lender, as the case may be) and (II) an excerpt of the credits and debits, including the interest applied, which appears in the relevant account(s) referred to in clause (e)(i), and (2) evidences that the amounts due and payable by the Spanish Guarantor have been calculated in accordance with this Agreement and that such amounts match the balance of the accounts; and

(C) a notarial document ("acta notarial") or a confirmatory fax ("burofax") evidencing that the Spanish Guarantor has been served notice for the amount that is due and payable.

(iii) Clause (e)(ii) of this Section 11.14 is also applicable to any Lender with regard to its Commitment. Such Lender may issue the appropriate certification of the balances of the relevant account(s) referred to in clause (e)(i) of and the certification of the balances of such accounts may be legalised by a notary.

(iv) The amount of the balances determined in accordance with this clause (e) shall be notified to the relevant Spanish Guarantor in an attestable manner at least three (3) days in advance of exercising any executive action.

(v) The Spanish Guarantor hereby authorises the Administrative Agent (and each Lender, as appropriate) to request and obtain certificates and documents issued by the notary which has formalised this Agreement in order to evidence its compliance with the entries of his registry-book and the relevant entry date for the purpose of number 4 of Article 517, of the Spanish Civil Procedural Law. The cost of such certificate and documents will be for the account of the Spanish Guarantor.

(vi) This Agreement shall be raised to public by means of a Spanish Public Document by the Spanish Guarantor for the purposes contemplated in Article 517 et seq. of the Spanish Civil Procedural Law.

11.15 Waiver of Right to Trial by Jury.

EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER INVESTMENT DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR

OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE OTHER INVESTMENT DOCUMENTS BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 11.15.

11.16 Electronic Execution of Assignments and Certain Other Documents.

The words "execute," "execution," "signed," "signature" and words of like import in any Assignment and Assumption or in any amendment or other modification hereof (including waivers and consents) 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.

11.17 USA PATRIOT Act.

Each Lender that is subject to the Act (as hereinafter defined) and the Administrative Agent (for itself and not on behalf of any Lender) hereby notifies the Loan Parties that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "Act"), it is required to obtain, verify and record information that identifies the Loan Parties, which information includes the name and address of the Loan Parties, information concerning its direct and indirect holders of Equity Interests and other Persons exercising Control over it, and its and their respective directors and officers, and other information that will allow such Lender or the Administrative Agent, as applicable, to identify the Loan Parties in accordance with the Act. The Loan Parties shall, promptly following a request by the Administrative Agent or any Lender, provide all documentation and other information that the Administrative Agent or such Lender reasonably requests in order to comply with its ongoing obligations under applicable "know your customer" and anti-money laundering laws, rules and regulations, including the Act.

11.18 No Advisory or Fiduciary Relationship.

In connection with all aspects of each transaction contemplated hereby (including in connection with any amendment, waiver or other modification hereof or of any other Investment Document), each Loan Party acknowledges and agrees, and acknowledges its Affiliates' understanding, that: (a)(i) the arranging and other services regarding this Agreement provided by the Administrative Agent and the Lenders are arm's-length commercial transactions between the Loan Parties and their Affiliates, on the one hand, and the Administrative Agent, the Lenders and their respective Affiliates on the other hand, (ii) the Loan Parties have consulted their own legal, accounting, regulatory and tax advisors to the extent they have deemed appropriate and (iii) each Loan Party is capable of evaluating, and understands and accepts, the terms, risks and conditions of the transactions contemplated hereby and by the other Investment Documents; (b)(i) the Administrative Agent, each Lender and each of their respective Affiliates is and has been acting solely as a principal and, except as expressly agreed in writing by the relevant parties, has not been, is not and will not be acting as an advisor, agent or fiduciary for any Loan Party or any Loan Party's Affiliates or any other Person and (ii) neither the Administrative Agent, any Lender nor any of their respective Affiliates has any obligation to the Loan Parties or any of their Affiliates with respect to the transactions contemplated hereby except those obligations expressly set forth herein and in the other Investment Documents; and (c) the Administrative Agent, the Lenders and their respective Affiliates may

be engaged in a broad range of transactions that involve interests that differ from those of the Loan Parties and their Affiliates, and neither the Administrative Agent nor any Lender nor any of their respective Affiliates has any obligation to disclose any of such interests to the Loan Parties or their Affiliates. To the fullest extent permitted by law, the Loan Parties hereby waive and release any claims that they may have against the Administrative Agent, any Lender or any of their respective Affiliates with respect to any breach or alleged breach of agency or fiduciary duty in connection with any aspect of any transaction contemplated hereby.

11.19 Acknowledgement and Consent to Bail-In of EEA Financial Institutions.

Solely to the extent any Lender that is an EEA Financial Institution is a party to this Agreement and notwithstanding anything to the contrary in any Investment Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Lender that is an EEA Financial Institution arising under any Investment Document, to the extent such liability is unsecured, may be subject to the write-down and conversion powers of an EEA 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 an EEA Resolution Authority to any such liabilities arising hereunder which may be payable to it by any Lender 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 EEA 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 Investment 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 EEA Resolution Authority.

11.20 Funding Date.

The parties hereto agree that if the Funding Date does not occur on or before August 24, 2017, this Agreement and all other Loan Documents shall be automatically terminated.

11.21 Parallel Debt.

Each Loan Party hereby irrevocably and unconditionally undertakes to pay to the Administrative Agent (acting in its capacity as the "collateral agent") amounts equal to any amounts owing from time to time by such Loan Party to any Secured Party under any Loan Document as and when such amounts are due.

Each Loan Party and the Administrative Agent (acting in its capacity as the "collateral agent") acknowledge that the obligations of each Loan Party under the preceding paragraph are several and are separate and independent from, and shall not in any way limit or affect, the corresponding obligations of such Loan Party to any Secured Party under any Loan Document (the "Corresponding Debt"), nor shall

the amounts for which each Loan Party is liable under the preceding paragraph (the "Parallel Debt") be limited or affected in any way by such Loan Party's Corresponding Debt; provided, that:

(a) the Parallel Debt of each Loan Party shall be decreased to the extent that such Loan Party's Corresponding Debt has been irrevocably paid or (in the case of guarantee obligations) discharged;

(b) the Corresponding Debt of each Loan Party shall be decreased to the extent that such Loan Party's Parallel Debt has been irrevocably paid or (in the case of guarantee obligations) discharged; and

(c) the amount of the Parallel Debt of each Loan Party shall at all times be equal to the amount of such Loan Party's Corresponding Debt.

For the purpose of this Section 11.21, the Administrative Agent (acting in its capacity as the "collateral 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 Liens granted under the Loan Documents to the Administrative Agent (acting in its capacity as the "collateral agent") to secure the Parallel Debt are granted to the Administrative Agent in its capacity as creditor of the Parallel Debt and shall not be held on trust.

All monies received or recovered by the Administrative Agent (acting in its capacity as the "collateral agent") pursuant to this Section, and all amounts received or recovered by the Administrative Agent acting in such capacity from or by the enforcement of any Lien granted to secure the Parallel Debt, shall be applied in accordance with Section 9.03.

Without limiting or affecting the rights of the Administrative Agent (acting in its capacity as the "collateral agent") against the Loan Parties (whether under this Section or under any other provision of the Loan Documents), each Loan Party acknowledges that:

(x) nothing in this Section shall impose any obligation on the Administrative Agent (acting in its capacity as the "collateral agent") to advance any sum to any Loan Party or otherwise under any Loan Document; and

(y) for the purpose of any vote taken under any Loan Document, the Administrative Agent (acting in its capacity as the "collateral agent") shall not be regarded as having any participation or commitment other than those which it has in its capacity as a Lender.

For Spanish Law purposes, no obligation shall be deemed to be included nor shall it be secured under any Collateral Document granted pursuant to Spanish Law if such obligation constitutes or is included in the definition of Parallel Debt.

11.22 Enforcement Through Administrative Agent Only.

The Secured Parties shall not have any independent power to enforce, or have recourse to, any of the Liens or to exercise any right, power, authority or discretion arising under the Loan Documents except through the Administrative Agent.

SCHEDULE 2

EXHIBIT E TO AMENDED CREDIT AGREEMENT

See Attached.

SCHEDULE 2

EXHIBIT E

FORM OF COMPLIANCE CERTIFICATE

Financial Statement Date:[_____, 20__]

To: Madryn Health Partners, LP, as Administrative Agent

Re: Credit Agreement dated as of August 24, 2017 (as amended, modified, restated, supplemented or extended from time to time, the "Credit Agreement"), among Establishment Labs Holdings Inc., a BVI business company, limited by shares and incorporated under the laws of the British Virgin Islands (the "Borrower"), the Guarantors from time to time party thereto, the Lenders from time to time party thereto and Madryn Health Partners, LP, as Administrative Agent. Capitalized terms used but not otherwise defined herein have the meanings provided in the Credit Agreement.

Date:[_____, 20__]

Ladies and Gentlemen:

The undersigned Responsible Officer hereby certifies as of the date hereof that [he/she] is the [Chief Executive Officer, Chief Financial Officer, Treasurer or Controller] of the Borrower, and that, in [his/her] capacity as such, [he/she] is authorized to execute and deliver this Compliance Certificate to the Administrative Agent on the behalf of the Borrower, and that:

[Use following paragraph 1 for financial statements delivered pursuant to Section 7.01(a) of the Credit Agreement:]

[1. [Attached hereto as Schedule 1 are the year-end audited financial statements of the Borrower and its Subsidiaries, together with the report and opinion of an independent certified public accountant in satisfaction of their requirements under Section 7.01(a) of the Credit Agreement for the fiscal year of the Borrower ended as of the Financial Statement Date.]

[Use following paragraph 1 for financial statements delivered pursuant to Section 7.01(b) of the Credit Agreement:]

[1. [Attached hereto as Schedule 1 are the unaudited financial statements of the Borrower and its Subsidiaries in satisfaction of their requirements under Section 7.01(b) of the Credit Agreement for the fiscal quarter of the Borrower ended as of the Financial Statement Date. Such financial statements fairly present in all material respects the financial condition, results of operations, shareholders' equity and cash flows of the Borrower and its Subsidiaries in accordance with GAAP as at such date and for such period, subject only to normal year end audit adjustments and the absence of footnotes.]

2. The undersigned has reviewed and is familiar with the terms of the Credit Agreement and has made, or has caused to be made, a reasonably detailed review of the transactions and condition (financial or otherwise) of the Loan Parties during the accounting period covered by such financial statements.

3. A review of the activities of the Loan Parties and their respective Subsidiaries during the accounting period covered by such financial statements has been made under the supervision of the undersigned with a view to determining whether during such fiscal period the Loan Parties and their

respective Subsidiaries performed and observed all of their respective obligations under the Loan Documents, and

[select one:]

[to the knowledge of the undersigned during such fiscal period, the Loan Parties and their respective Subsidiaries performed and observed each covenant and condition of the Loan Documents applicable to them, and no Default has occurred and is continuing.]

[or:]

[the following covenants or conditions have not been performed or observed and the following is a list of each such Default and its nature and status:]

4. The financial covenant analyses and calculation of (i) Product Revenues for the four consecutive fiscal quarter period most recently ended on or prior to the date of this Compliance Certificate and (ii) Liquidity, in each case, set forth on Schedule 2 attached hereto are true and accurate on and as of the date of this Compliance Certificate.

5. Attached hereto as Schedule 3 is a supplement setting forth information regarding the amount and timing of all Dispositions, Involuntary Dispositions, Debt Issuances, Extraordinary Receipts and Acquisitions that occurred during the period covered by the attached financial statements.

6. Attached hereto as Schedule 4 is a list of (i) all applications by any Loan Party, if any, for Copyrights, Patents or Trademarks made since [the Effective Date] [the date of the prior Compliance Certificate], (ii) all issuances of registrations or letters on existing applications by any Loan Party for Copyrights, Patents and Trademarks received since [the Effective Date] [the date of the prior Compliance Certificate], (iii) licenses of any IP Rights (other than non-exclusive licenses permitted by Section 8.05 of the Credit Agreement granted in the ordinary course of business) entered into by any Loan Party since [the Effective Date] [the date of the prior Compliance Certificate] and (iv) such supplements to Schedules 6.17(a), 6.17(b), 6.17(d) and 6.17(e) of the Disclosure Letter as are necessary to cause such schedules to be true and complete in all material respects as of the date of this Compliance Certificate.

7. Attached hereto as Schedule 5 is the insurance binder or other evidence of insurance for any insurance coverage of any Loan Party or any Subsidiary that was renewed, replaced or modified during the period covered by the attached financial statements.

8. Attached hereto as Schedule 6 is a copy of management's discussion and analysis with respect to such financial statements.

9. Attached hereto as Schedule 7 is a list of all litigations, arbitrations or governmental investigations or proceedings which were instituted during the period covered by such financial statements or which, to the knowledge of any Loan Party, are threatened (in writing) against any Loan Party or any Subsidiary which, in any case, could reasonably be expected to result in losses and/or expenses (other than, for the avoidance of doubt, legal and court fees, costs and expenses) in excess of the Threshold Amount, together with a description setting forth the details thereof and stating what action the applicable Loan Party or Subsidiary has taken and proposes to take with respect thereto.

10. Attached hereto as Schedule 8 is information regarding, in each case, to the extent occurring during the period covered by such financial statements, (i) the termination of any Material Contract, (ii) the receipt by any Loan Party or any of its Subsidiaries of any notice under any Material Contract (and a

copy thereof) as to the occurrence of any material breach or default under or pursuant to such Material Contract that could result in termination thereof or a material liability in respect thereof, (iii) the entering into of any new Material Contract by a Loan Party or any of its Subsidiaries (and a copy thereof) or (iv) any material amendment to a Material Contract (and a copy thereof).

11. Attached hereto as Schedule 9 is a listing of all deposit accounts and other bank accounts and securities accounts of the Loan Parties and their Subsidiaries (including, for the avoidance of doubt, the Controlled Accounts) as of the Financial Statement Date (which listing shall include the location of each such account and the balance of each such account as of the Financial Statement Date).

12. Attached hereto as Schedule 10 is a listing of all Investments made by any Loan Party or any Subsidiary thereof pursuant to Section 8.02(c) of the Credit Agreement as of the Financial Statement Date.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the undersigned has executed this Compliance Certificate as of _____, 20__.

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

By:_____
Name:
Title:

Schedule 1

[Audited][Unaudited] Financial Statements of the Borrower and its Subsidiaries

Schedule 2

1. Product Revenues.

A. For the four fiscal quarter period most recently ended as of the date of this Compliance Certificate, all amounts paid to and received by the Borrower and its Subsidiaries in the ordinary course of business that, in accordance with GAAP, would be classified as net revenue, excluding upfront payments, milestones, royalties and other similar one-time payments received by the Borrower and its Subsidiaries that are not related to the sale of products or services[1]: $_____

B. Minimum amount required by Section 8.16 of the Credit Agreement for such period: $_____

Compliance: [Yes] [No]

2. Liquidity.

A. Aggregate Unrestricted Cash maintained by the Loan Parties (without duplication) for each day during the four fiscal quarter period most recently ended as of the date of this Compliance Certificate: $_____

B. Minimum amount required by Section 8.17(a) of the Credit Agreement: $10,000,000

Compliance: [Yes] [No]

C. Aggregate Unrestricted Cash maintained by the Loan Parties (without duplication) for each day during the four fiscal quarter period most recently ended as of the date of this Compliance Certificate and which is held in a Controlled Account: $_____

D. Minimum amount required by Section 8.17(b) of the Credit Agreement: $5,000,000

[1] "Product Revenues" shall exclude the revenues generated by any Subsidiary to the extent that the declaration or payment of dividends or similar distributions by that Subsidiary of the income resulting from such revenue is not at the time permitted by operation of the terms of its Organization Documents or any agreement, instrument, judgment, decree, order, statute, rule, or governmental regulation applicable to that Subsidiary.

Compliance: [Yes] [No]

Schedule 3

Dispositions, Involuntary Dispositions, Debt Issuances Extraordinary Receipts and Acquisitions

Schedule 4

IP Schedule Updates

# Schedule 5

## Insurance Binders

Schedule 6

Management's Discussion and Analysis

Schedule 7

Litigations, Arbitrations, or Governmental Investigations or Proceedings

## Schedule 8

Material Contracts

Schedule 9

Listing of Deposit Accounts, Other Bank Accounts and Securities Accounts

Schedule 10

Listing of Investments in Loan Parties and Subsidiaries

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Juan Jose Chacon Quiros, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: August 7, 2020

*/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, Renee M. Gaeta, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: August 7, 2020

*/s/ Renee M. Gaeta*

Renee M. Gaeta

*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 Jose Chacon Quiros, as Chief Executive Officer, and Renee M. Gaeta, 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 Quarterly Report on Form 10-Q for the period ended June 30, 2020, 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: August 7, 2020

*/s/ Juan José Chacón Quirós*
Juan José Chacón Quirós

*Chief Executive Officer and Director*
*(Principal Executive Officer)*

Date: August 7, 2020

*/s/ Renee M. Gaeta*
Renee M. Gaeta
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.