

# 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, 2019**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-35280

### VERICEL CORPORATION

(Exact name of registrant as specified in its charter)

**Michigan** **94-3096597**  
(State or other jurisdiction of (I.R.S. employer  
incorporation or organization) identification no.)

**64 Sidney Street**

**Cambridge MA 02139**

(Address of principal executive offices, including zip code)

(Registrant's telephone number, including area code) **(800) 556-0311**

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class

Trading Symbol(s)

Name of each exchange on which registered

Common Stock, no par value

VCEL

NASDAQ

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 - x No - o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes - x No - o

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 | <input type="checkbox"/> | Accelerated filer         | <input checked="" type="checkbox"/> |
| Non-accelerated filer   | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                          | Emerging growth company   | <input type="checkbox"/>            |

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. o

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

**COMMON STOCK, NO PAR VALUE**

44,136,896

(Class)

Outstanding at July 31, 2019

**VERICEL CORPORATION**  
**QUARTERLY REPORT ON FORM 10-Q**  
**TABLE OF CONTENTS**

**PART I — FINANCIAL INFORMATION**

|         |  |                    |
|---------|--|--------------------|
| Item 1. | <a href="#">Financial Statements (Unaudited):</a>  | <a href="#">3</a>  |
|         | <a href="#">Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018</a>  | <a href="#">3</a>  |
|         | <a href="#">Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2019 and 2018</a>                                    | <a href="#">4</a>  |
|         | <a href="#">Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2019 and 2018</a>                            | <a href="#">5</a>  |
|         | <a href="#">Consolidated Statements of Shareholders Equity (Deficit) from December 31, 2017 to June 30, 2018 and from December 31, 2018 to June 30, 2019</a> | <a href="#">6</a>  |
|         | <a href="#">Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018</a>  | <a href="#">7</a>  |
|         | <a href="#">Notes to Condensed Consolidated Financial Statements</a>   | <a href="#">8</a>  |
| Item 2. | <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>  | <a href="#">19</a> |
| Item 3. | <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>   | <a href="#">23</a> |
| Item 4. | <a href="#">Controls and Procedures</a>  | <a href="#">23</a> |

**PART II — OTHER INFORMATION**

|          |   |                    |
|----------|---|--------------------|
| Item 1.  | <a href="#">Legal Proceedings</a>   | <a href="#">25</a> |
| Item 1A. | <a href="#">Risk Factors</a>  | <a href="#">25</a> |
| Item 1B. | <a href="#">Unresolved Staff Comments</a>                                   | <a href="#">27</a> |
| Item 2.  | <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a> | <a href="#">27</a> |
| Item 6.  | <a href="#">Exhibits</a>  | <a href="#">27</a> |
|          | <a href="#">Exhibit Index</a>   | <a href="#">28</a> |
|          | <a href="#">Signature</a>   | <a href="#">30</a> |

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

VERICEL CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited, amounts in thousands)

|   | June 30,<br>2019 | December 31,<br>2018 |
|---|------------------|----------------------|
| <b>ASSETS</b>   |                  |                      |
| Current assets:   |                  |                      |
| Cash and cash equivalents   | \$ 13,962        | \$ 18,286            |
| Short-term investments  | 52,047           | 64,638               |
| Accounts receivable (net of allowance for doubtful accounts of \$748 and \$514, respectively)                           | 21,084           | 23,454               |
| Inventory   | 4,788            | 3,558                |
| Other current assets  | 2,167            | 2,847                |
| Total current assets  | 94,048           | 112,783              |
| Property and equipment, net   | 6,963            | 5,906                |
| Right-of-use assets   | 24,815           | —                    |
| Total assets  | \$ 125,826       | \$ 118,689           |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>   |                  |                      |
| Current liabilities:  |                  |                      |
| Accounts payable  | \$ 5,250         | \$ 7,108             |
| Accrued expenses  | 4,701            | 6,930                |
| Current portion of operating lease liabilities  | 2,558            | —                    |
| Other liabilities   | 34               | 754                  |
| Total current liabilities   | 12,543           | 14,792               |
| Operating lease liabilities   | 24,607           | —                    |
| Other long-term liabilities   | 134              | 1,666                |
| Total liabilities   | 37,284           | 16,458               |
| <b>COMMITMENTS AND CONTINGENCIES</b>  |                  |                      |
| Shareholders' equity:   |                  |                      |
| Common stock, no par value; shares authorized — 75,000; shares issued and outstanding — 44,066 and 43,578, respectively | 480,050          | 471,180              |
| Other comprehensive gain (loss)   | 38               | (39)                 |
| Warrants  | 104              | 104                  |
| Accumulated deficit   | (391,650)        | (369,014)            |
| Total shareholders' equity  | 88,542           | 102,231              |
| Total liabilities and shareholders' equity  | \$ 125,826       | \$ 118,689           |

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

**VERICEL CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited, amounts in thousands except per share amounts)

|  | Three Months Ended June 30, |            | Six Months Ended June 30, |             |
|--|-----------------------------|------------|---------------------------|-------------|
|  | 2019                        | 2018       | 2019                      | 2018        |
| Product sales, net   | \$ 26,151                   | \$ 19,011  | \$ 47,961                 | \$ 37,038   |
| Cost of product sales  | 9,022                       | 7,727      | 17,662                    | 15,393      |
| Gross profit   | 17,129                      | 11,284     | 30,299                    | 21,645      |
| Research and development   | 21,070                      | 3,739      | 24,078                    | 7,468       |
| Selling, general and administrative                                      | 16,259                      | 11,791     | 29,779                    | 22,745      |
| Total operating expenses   | 37,329                      | 15,530     | 53,857                    | 30,213      |
| Loss from operations   | (20,200)                    | (4,246)    | (23,558)                  | (8,568)     |
| Other income (expense):  |                             |            |                           |             |
| Increase in fair value of warrants                                       | —                           | (37)       | —                         | (2,944)     |
| Interest income  | 428                         | 83         | 908                       | 83          |
| Interest expense   | (2)                         | (448)      | (4)                       | (880)       |
| Other income (expense)   | (18)                        | (3)        | 18                        | (1)         |
| Total other income (expense)   | 408                         | (405)      | 922                       | (3,742)     |
| Net loss   | \$ (19,792)                 | \$ (4,651) | \$ (22,636)               | \$ (12,310) |
| Net loss per share (Basic and Diluted)                                   | \$ (0.45)                   | \$ (0.12)  | \$ (0.52)                 | \$ (0.33)   |
| Weighted average number of common shares outstanding (Basic and Diluted) | 43,956                      | 38,349     | 43,841                    | 37,251      |

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

**VERICEL CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(Unaudited, amounts in thousands)

|                                | Three Months Ended June 30, |            | Six Months Ended June 30, |             |
|--------------------------------|-----------------------------|------------|---------------------------|-------------|
|                                | 2019                        | 2018       | 2019                      | 2018        |
| Net loss                       | \$ (19,792)                 | \$ (4,651) | \$ (22,636)               | \$ (12,310) |
| Other comprehensive loss:      |                             |            |                           |             |
| Unrealized gain on investments | 35                          | —          | 38                        | —           |
| Comprehensive loss             | \$ (19,757)                 | \$ (4,651) | \$ (22,598)               | \$ (12,310) |

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

**VERICEL CORPORATION**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**  
(Unaudited, amounts in thousands)

|  | Common Stock |            | Warrants<br>Amounts | Accumulated Other<br>Comprehensive<br>Income (Loss) | Accumulated<br>Deficit | Total<br>Shareholders'<br>Equity |
|--|--------------|------------|---------------------|---|------------------------|----------------------------------|
|  | Shares       | Amount     |                     |   |                        |                                  |
| BALANCE, DECEMBER 31, 2018   | 43,578       | \$ 471,180 | \$ 104              | \$ (39)   | \$ (369,014)           | \$ 102,231                       |
| Net loss   |              |            |                     |   | (2,844)                | (2,844)                          |
| Compensation expense related to stock options and restricted stock units, net of forfeitures |              | 2,628      |                     |   |                        | 2,628                            |
| Stock option exercises   | 228          | 780        |                     |   |                        | 780                              |
| Shares issued under the Employee Stock Purchase Plan   | 19           | 218        |                     |   |                        | 218                              |
| Change in unrealized gain(loss) on investments   |              |            |                     | 42  |                        | 42                               |
| BALANCE, MARCH 31, 2019  | 43,825       | \$ 474,806 | \$ 104              | \$ 3  | \$ (371,858)           | \$ 103,055                       |
| Net loss   |              |            |                     |   | (19,792)               | (19,792)                         |
| Compensation expense related to stock options and restricted stock units, net of forfeitures |              | 4,183      |                     |   |                        | 4,183                            |
| Stock option exercises   | 227          | 850        |                     |   |                        | 850                              |
| Shares issued under the Employee Stock Purchase Plan   | 14           | 211        |                     |   |                        | 211                              |
| Change in unrealized gain (loss) on investments  |              |            |                     | 35  |                        | 35                               |
| BALANCE, JUNE 30, 2019   | 44,066       | \$ 480,050 | \$ 104              | \$ 38   | \$ (391,650)           | \$ 88,542                        |

|   | Common Stock |            | Warrants<br>Amounts | Accumulated Other<br>Comprehensive<br>Income | Accumulated<br>Deficit | Total<br>Shareholders'<br>Equity |
|---|--------------|------------|---------------------|--|------------------------|----------------------------------|
|   | Shares       | Amount     |                     |  |                        |                                  |
| BALANCE, DECEMBER 31, 2017  | 35,861       | \$ 383,020 | \$ 397              | \$ —   | \$ (360,877)           | \$ 22,540                        |
| Net loss  |              |            |                     |  | (7,659)                | (7,659)                          |
| Compensation expense related to stock options granted, net of forfeitures |              | 1,348      |                     |  |                        | 1,348                            |
| stock option exercises  | 253          | 851        |                     |  |                        | 851                              |
| Shares issued under the Employee Stock Purchase Plan                      | 28           | 127        |                     |  |                        | 127                              |
| Exercise of warrants resulting in the issuance of common stock            | 360          | 1,727      |                     |  |                        | 1,727                            |
| Net change in warrant valuation of exercised warrants                     |              | 2,001      |                     |  |                        | 2,001                            |
| BALANCE, MARCH 31, 2018   | 36,502       | \$ 389,074 | \$ 397              | \$ —   | \$ (368,536)           | \$ 20,935                        |
| Net loss  |              |            |                     |  | (4,651)                | (4,651)                          |
| Compensation expense related to stock options granted, net of forfeitures |              | 2,465      |                     |  |                        | 2,465                            |
| Issuance of common stock, net of issuance costs                           | 5,750        | 70,090     |                     |  |                        | 70,090                           |
| Stock option exercises  | 306          | 964        |                     |  |                        | 964                              |
| Shares issued under the Employee Stock Purchase Plan                      | 31           | 148        |                     |  |                        | 148                              |
| Exercise of warrants resulting in the issuance of common stock            | 95           | 333        | (95)                |  |                        | 238                              |
| Net change in warrant valuation of exercised warrants                     |              | 409        |                     |  |                        | 409                              |
| BALANCE, JUNE 30, 2018  | 42,684       | \$ 463,483 | \$ 302              | \$ —   | \$ (373,187)           | \$ 90,598                        |

**VERICEL CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited, amounts in thousands)

|  | Six Months Ended June 30, |                  |
|--|---------------------------|------------------|
|  | 2019                      | 2018             |
| <b>Operating activities:</b>   |                           |                  |
| Net loss   | \$ (22,636)               | \$ (12,310)      |
| Adjustments to reconcile net loss to net cash used for operating activities: |                           |                  |
| Depreciation and amortization expense  | 698                       | 813              |
| Stock compensation expense   | 6,810                     | 3,807            |
| Change in fair value of warrants   | —                         | 2,944            |
| Loss on sale of fixed assets   | —                         | 23               |
| Foreign currency translation loss  | 13                        | 49               |
| Amortization of premiums and discounts on marketable securities              | (408)                     | —                |
| Non-cash lease cost  | 1,139                     | —                |
| Change in operating assets and liabilities:                                  |                           |                  |
| Inventory  | (1,230)                   | 68               |
| Accounts receivable  | 2,370                     | 771              |
| Prepaid and other current assets   | 680                       | 254              |
| Accounts payable   | (2,238)                   | (1,049)          |
| Accrued expenses   | (2,229)                   | (462)            |
| Operating lease liabilities  | (1,007)                   | —                |
| Other assets and liabilities, net  | (187)                     | 56               |
| Net cash used in operating activities  | <u>(18,225)</u>           | <u>(5,036)</u>   |
| <b>Investing activities:</b>   |                           |                  |
| Purchases of short-term investments  | (32,402)                  | —                |
| Maturities of short-term investments   | 45,477                    | —                |
| Expenditures for property, plant and equipment                               | (1,224)                   | (979)            |
| Net cash provided by (used in) investing activities                          | <u>11,851</u>             | <u>(979)</u>     |
| <b>Financing activities:</b>   |                           |                  |
| Net proceeds from equity offering  | —                         | 70,090           |
| Net proceeds from common stock issuance due to stock option exercises        | 2,059                     | 2,096            |
| Proceeds from exercise of warrants   | —                         | 1,965            |
| Other  | (9)                       | (29)             |
| Net cash provided by financing activities                                    | <u>2,050</u>              | <u>74,122</u>    |
| Net increase (decrease) in cash and cash equivalents                         | <u>(4,324)</u>            | <u>68,107</u>    |
| Cash and cash equivalents at beginning of period                             | 18,286                    | 26,862           |
| Cash and cash equivalents at end of period                                   | <u>\$ 13,962</u>          | <u>\$ 94,969</u> |

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE QUARTER ENDED JUNE 30, 2019 (UNAUDITED)**

**1. Organization**

Vericel Corporation, a Michigan corporation (together with its consolidated subsidiaries referred to herein as the Company, Vericel, we, us or our), was incorporated in March 1989 and began employee-based operations in 1991. On May 30, 2014, Vericel completed the acquisition of certain assets and assumed certain liabilities of Sanofi, a French *société anonyme* (Sanofi), including all of the outstanding equity interests of Genzyme Biosurgery ApS (Genzyme Denmark or the Danish subsidiary) (now known as Vericel Denmark ApS), a wholly-owned subsidiary of Sanofi, and a portfolio of patents and patent applications of Sanofi and certain of its subsidiaries for purposes of acquiring the portion of the cell therapy and regenerative medicine business related to the MACI<sup>®</sup>, Epicel<sup>®</sup> and Carticel<sup>®</sup> products. The Company is a fully integrated, commercial-stage biopharmaceutical company and currently markets MACI and Epicel in the U.S. and holds exclusive rights to commercialize NexoBrid<sup>®</sup> in all countries of North America. The Company is a leader in advanced cell therapies for the sports medicine and severe burn care markets.

MACI (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. At the end of the second quarter of 2017, the Company removed Carticel (autologous cultured chondrocytes), an earlier generation autologous chondrocyte implant (ACI) product, from the market. The Company also markets Epicel (cultured epidermal autografts), a permanent skin replacement Humanitarian Use Device (HUD) for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns greater than or equal to 30 percent of total body surface area (TBSA). The Company also entered into exclusive license and supply agreements with MediWound Ltd. (MediWound) to commercialize NexoBrid<sup>®</sup> in all countries in North America. NexoBrid is a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns. NexoBrid is currently in clinical development in North America, and a U.S. Biologics License Application (BLA) currently is targeted for submission to the U.S. Food and Drug Administration (FDA) in the second quarter of 2020. The Company operates its business primarily in the U.S. in one reportable segment — the research, product development, manufacture and distribution of advanced therapies for use in the treatment of specific diseases.

The accompanying condensed consolidated financial statements have been prepared on a basis, which assumes that the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of June 30, 2019, the Company has an accumulated deficit of \$391.7 million and had a net loss of \$19.8 million and \$22.6 million during the three and six months ended June 30, 2019. The Company had cash and cash equivalents of \$14.0 million, and short-term investments of \$52.0 million as of June 30, 2019. The Company expects that existing cash, cash equivalents and short-term investments will be sufficient to support the Company's current operations through at least 12 months from the issuance of these financial statements. The Company may seek additional funding through debt or equity financings. However, the Company may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders.

**2. Basis of Presentation**

The condensed consolidated financial statements included herein have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). The preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (U.S. GAAP) requires management to make estimates, judgments, and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. The financial statements reflect, in the opinion of management, all adjustments (consisting only of normal, recurring adjustments) necessary to state fairly the financial position and results of operations as of and for the periods indicated. The results of operations for the three and six months ended June 30, 2019, are not necessarily indicative of the results to be expected for the full year or for any other period. The June 30, 2019 condensed consolidated balance sheet data was derived from the Company's audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on February 26, 2019 (Annual Report).



## Consolidated Statement of Cash Flows

The following table presents certain supplementary cash flows information for the six months ended June 30, 2019 and 2018:

| (In thousands)   | Six Months Ended June 30, |          |
|--|---------------------------|----------|
|  | 2019                      | 2018     |
| Supplementary Cash Flows information:                          |                           |          |
| Warrants exercised for common stock                            | \$ —                      | \$ 2,409 |
| Interest paid (net of interest capitalized)                    | 4                         | 754      |
| Additions to equipment in process included in accounts payable | 365                       | 459      |
| Right-of-use asset and lease liability recognized              | 560                       | —        |

### 3. Recent Accounting Pronouncements

#### Accounting for Leases

The FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In accordance with the updated guidance, lessees are required to recognize the assets and liabilities arising from operating leases on the balance sheet. The guidance is effective for annual reporting periods beginning after December 15, 2018. The leasing Accounting Standard Update 2016-02, became effective for the Company on January 1, 2019, and was adopted using the modified retrospective method. See note 7 for further discussion.

#### Measuring Credit Losses on Financial Instruments

The FASB issued updated guidance on measuring credit losses on financial instruments. The guidance removes the thresholds that companies apply to measure credit losses on financial instruments measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities. Prior to the updated guidance, credit losses are recognized when it is probable that the loss has been incurred. The revised guidance removes all recognition thresholds and requires companies to recognize an allowance for credit losses for the difference between the amortized cost basis of a financial instrument and the amount of amortized cost that a company expected to collect over the instrument's contractual life. The guidance is effective for annual reporting periods beginning after December 15, 2019. The Company is currently in the process of evaluating the impact to its consolidated financial statements.

### 4. Revenue

#### Revenue Recognition and Net Product Sales

The Company recognizes product revenue from sales of MACI kits, MACI implants and Epicel grafts following the five step model in Accounting Standards Codification 606 *Revenue Recognition* (ASC 606).

##### MACI Kits

MACI kits are sold directly to hospitals based on contracted rates in the approved contract or sales order. The Company recognizes MACI kit revenue upon delivery of the biopsy kit at which time the customer (the doctor) is in control of the kit. The kit provides the doctor the ability to biopsy a sampling of cells to provide to the Company that can be used later to manufacture the implant. The ordering of the kit does not obligate the Company to manufacture an implant nor does the receipt of the cell tissue. The customer's order of an implant is separate from the process of ordering the kit. Therefore, the sale of the kit and any subsequent sale of an implant are distinct contracts and are accounted for separately.

##### MACI Implants

The Company recognizes product revenues from sales of MACI implants upon delivery at which time the customer is in control of the implant and the claim is billable. Prior authorization or confirmation of coverage level by the patient's private insurance plan, hospital or government payer is a prerequisite to the shipment of product to a patient. Depending upon the type of contract and payer for the MACI implant, the Company's net product revenues are either based on contracted rates or estimated based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs. Net product revenues from sales to distributors may include a prompt pay discount.

On July 25, 2018 and August 10, 2018, the Company entered into amendments to its distribution agreement with Orsini Pharmaceutical Services, Inc. (Orsini). The amendments modified certain payment terms for surgeries after June 15, 2018. In addition, under the revised agreement, the parties agreed to limit Orsini's right to serve as the Company's exclusive distributor for MACI to a specified set of payers as the Company moved to a limited expanded network of distributors. The agreement with Orsini includes a provision whereby the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. Orsini performs the collection activities. The net product revenues for these cases are based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period in which such change occurs.

On April 18, 2019, the Company entered into an amendment with Orsini that extended the term of the agreement until May 2022, modified the per case dispensing fee, and eliminated Orsini's exclusivity for all payers.

On July 26, 2018, the Company entered into a Dispensing Agreement (Dispensing Agreement) with AllCare Plus Pharmacy, Inc. (AllCare). Pursuant to the Dispensing Agreement, the Company appoints AllCare as a non-exclusive specialty pharmacy provider of MACI. The Company pays AllCare a fee for each patient to whom MACI is dispensed. Under the Dispensing Agreement, the Company retains the credit and collection risk from the end customer on all implants. Depending upon the type of contract and payer for the MACI implant, the Company's net product revenues are based on contracted rates or estimated based on expected payments from the insurance provider, hospital or patient. The estimates of such payment amounts vary by customer and payer and are based on either contracted rates, publicly available rates or past payer precedents. Changes in estimates are recorded through revenue in the period such change occurs. On May 1, 2019, the Company entered into an amendment with AllCare that extended the term of the Dispensing Agreement until May 2022 and modified the per case dispensing fee.

### *Epicel*

The Company sells Epicel directly to hospitals based on contracted rates stated in the approved contract or purchase order. Similar to MACI, there is no obligation to manufacture skin grafts upon receipt of a skin biopsy, and Vericel has no contractual right to receive payment until the product is delivered to the hospital. The Company recognizes product revenues from sales of Epicel upon delivery to the hospital at which time the customer is in control of the skin grafts and the claim is billable to the hospital.

## Revenue by Product and Customer

The following table and description below reflect the products from which the Company generated its revenue:

| Revenue by product (in thousands)   | Three Months Ended June 30, |                  | Six Months Ended June 30, |                  |
|---|-----------------------------|------------------|---------------------------|------------------|
|   | 2019                        | 2018             | 2019                      | 2018             |
| <b>MACI implants and kits</b>   |                             |                  |                           |                  |
| Implants based on contracted rate sold through a specialty pharmacy (a)             | \$ 12,989                   | \$ 7,363         | \$ 22,776                 | \$ 15,155        |
| Implants subject to third-party reimbursement sold through a specialty pharmacy (b) | 3,459                       | 2,639            | 6,202                     | 3,647            |
| Implants sold direct based on contracted rates (c)                                  | 3,450                       | 3,409            | 6,676                     | 6,083            |
| Implants sold direct subject to third-party reimbursement (d)                       | 281                         | 297              | 603                       | 580              |
| Biopsy kits - direct bill   | 557                         | 468              | 1,099                     | 904              |
| Change in estimates related to prior periods  | 87                          | (51)             | 50                        | (189)            |
| <b>Epicel</b>   |                             |                  |                           |                  |
| Direct bill (hospital)  | 5,328                       | 4,886            | 10,555                    | 10,858           |
| <b>Total revenue</b>  | <b>\$ 26,151</b>            | <b>\$ 19,011</b> | <b>\$ 47,961</b>          | <b>\$ 37,038</b> |

(a) Represents implants sold through Orsini or AllCare in which such specialty pharmacy has entered into a direct contract with the underlying insurance provider. The amount of reimbursement is known at the time of sale supported by the pharmacy's direct contract.

(b) Represents implants sold through Orsini or AllCare in which such specialty pharmacy does not have a direct contract with the underlying payer. The amount of reimbursement is established based on a payer or state fee schedule and/or payer history.

(c) Represents implants sold directly from the Company to the facility based on a contract and known price agreed upon prior to the surgery date.

(d) Represents implants sold directly from the Company to the facility based on a contract and known price agreed upon prior to the surgery date. The payment terms are subject to third-party reimbursement from an underlying insurance provider.

### Concentration of Credit Risk

On May 15, 2017, the Company entered into a distribution agreement with Orsini Pharmaceutical Services, Inc. as a specialty pharmacy distributor of MACI and has engaged a third-party services provider to provide the patient support program to manage patient cases for MACI. The Company's receivables risk and credit risk became more concentrated from June 30, 2017 through June 15, 2018 due to the shift to Orsini. Beginning June 16, 2018, the concentration of risk decreased because the Company retains the credit and collection risk from the end customer on implants after June 15, 2018. The Company sells Epicel directly to hospitals and not through a distributor.

The Company's total revenue and accounts receivable balances were comprised of the following concentrations from its largest customers of MACI and Epicel, as follows:

|        | Revenue Concentration       |      |                           |      | Accounts Receivable Concentration |              |
|--------|-----------------------------|------|---------------------------|------|-----------------------------------|--------------|
|        | Three Months Ended June 30, |      | Six Months Ended June 30, |      | June 30,                          | December 31, |
|        | 2019                        | 2018 | 2019                      | 2018 | 2019                              | 2018         |
| MACI   | 7%                          | 39%  | 7%                        | 41%  | 7%                                | 8%           |
| Epicel | 6%                          | 9%   | 8%                        | 12%  | 3%                                | 4%           |

## 5. Selected Balance Sheet Components

Inventory as of June 30, 2019 and December 31, 2018:

| (In thousands)  | June 30, 2019   | December 31, 2018 |
|-----------------|-----------------|-------------------|
| Raw materials   | \$ 4,127        | \$ 2,872          |
| Work-in-process | 596             | 638               |
| Finished goods  | 65              | 48                |
| Inventory       | <u>\$ 4,788</u> | <u>\$ 3,558</u>   |

Property and equipment, net as of June 30, 2019 and December 31, 2018:

| (In thousands)                           | June 30, 2019   | December 31, 2018 |
|--|-----------------|-------------------|
| Machinery and equipment                  | \$ 2,456        | \$ 1,536          |
| Furniture, fixtures and office equipment | 775             | 775               |
| Computer equipment and software          | 5,906           | 3,712             |
| Leasehold improvements                   | 4,631           | 4,587             |
| Construction in process                  | 1,230           | 2,801             |
| Financing right-of-use lease             | 166             | —                 |
| Total property and equipment, gross      | 15,164          | 13,411            |
| Less: Accumulated depreciation           | (8,201)         | (7,505)           |
|  | <u>\$ 6,963</u> | <u>\$ 5,906</u>   |

Depreciation expense for the three and six months ended June 30, 2019 was \$0.4 million and \$0.7 million and \$0.4 million and \$0.8 million for the same period in 2018.

Accrued expenses as of June 30, 2019 and December 31, 2018:

| (In thousands)             | June 30, 2019   | December 31, 2018 |
|----------------------------|-----------------|-------------------|
| Bonus related compensation | \$ 1,528        | \$ 5,161          |
| Employee related accruals  | 2,695           | 1,559             |
| Other accrued expenses     | 478             | 210               |
|                            | <u>\$ 4,701</u> | <u>\$ 6,930</u>   |

## 6. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings and in December 2017 the Company issued warrants in connection with a previous loan agreement. The following table describes the outstanding warrants classified in equity as of June 30, 2019:

|                                   | December 2017 Warrants |
|-----------------------------------|------------------------|
| Exercise price                    | \$4.27                 |
| Expiration date                   | December 6, 2023       |
| Total shares issuable on exercise | 26,951                 |

The fair value of the warrants described in the table above were initially measured using the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock-based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates remaining at zero.

## 7. Leases

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. The Cambridge facility includes clean rooms, laboratories for MACI and Epicel manufacturing and office space. The Company also leases offsite warehouse space, vehicles and computer equipment.

The Company adopted the new leasing standards using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods. As a result of adoption, no cumulative adjustment to retained earnings occurred. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. Certain of the Company's lease agreements include lease payments that are adjusted periodically for an index or rate. The leases are initially measured using the projected payments adjusted for the index or rate in effect at the commencement date. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants. Upon adoption all operating lease commitments with a lease term greater than 12 months that were previously assessed under previous lease guidance, were recognized as right to use assets and liabilities, on a discounted basis on the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet and for the six months ended June 30, 2019, lease expense of less than \$0.1 million was recorded related to short-term leases for both the three and six months ended June 30, 2019.

Adoption of ASU 2016-02 resulted in the recording of additional right-of-use assets and lease liabilities of approximately \$25.6 million and \$27.8 million, respectively, as of January 1, 2019. There was an immaterial impact on the Company's consolidated net earnings and cash flows upon adoption. The contribution toward the cost of tenant improvements is recorded as a reduction of the operating lease assets and reclassified from deferred rent to lease operating assets. For both the three and six months ended June 30, 2019 and for the same periods ending June 30, 2018 (as reported under the prior leasing guidance), the Company recognized \$1.3 million and \$2.6 million of operating lease expense and less than \$0.1 million of financing lease expense, respectively. The Company's leases contain non-lease components and activities that do not transfer a good or service to the Company. The Company elected not to combine lease and non-lease components and therefore non-lease costs were not included in the net lease assets or lease liabilities.

Total leased assets and liabilities as reassessed under the updated guidance and classified on the balance sheet, as of June 30, 2019 are as follows:

| (In thousands)     | Classification                                 | June 30, 2019    |
|--------------------|--|------------------|
| <b>Assets</b>      |  |                  |
| Operating          | Right-of-use assets                            | \$ 24,815        |
| Finance            | Property and equipment, net                    | 166              |
|                    |  | <u>\$ 24,981</u> |
| <b>Liabilities</b> |  |                  |
| <i>Current</i>     |  |                  |
| Operating          | Current portion of operating lease liabilities | 2,558            |
| Finance            | Other liabilities                              | 34               |
|                    |  | <u>\$ 2,592</u>  |
| <i>Non-current</i> |  |                  |
| Operating          | Operating lease liabilities                    | 24,607           |
| Finance            | Other long-term liabilities                    | 134              |
|                    |  | <u>\$ 24,741</u> |

Cash paid for amounts included in the measurement of the Company's operating lease liabilities was \$2.5 million for the six months ended June 30, 2019.

Maturity of lease liabilities as of June 30, 2019 are as follows:

| (In thousands) |                                    | Operating Leases |          | Finance Leases |      | Total     |
|----------------|------------------------------------|------------------|----------|----------------|------|-----------|
|                | 2019                               | \$               | 2,504    | \$             | 21   | \$ 2,525  |
|                | 2020                               |                  | 4,944    |                | 41   | 4,985     |
|                | 2021                               |                  | 4,864    |                | 41   | 4,905     |
|                | 2022                               |                  | 4,929    |                | 41   | 4,970     |
|                | 2023                               |                  | 4,901    |                | 41   | 4,942     |
|                | 2024                               |                  | 4,968    |                | —    | 4,968     |
|                | Thereafter                         |                  | 11,269   |                | —    | 11,269    |
|                | Total lease payments               |                  | 38,379   |                | 185  | 38,564    |
|                | Less: Interest                     |                  | (11,214) |                | (17) | (11,231)  |
|                | Present value of lease liabilities | \$               | 27,165   | \$             | 168  | \$ 27,333 |

An explicit rate is not provided for some of the Company's leases, therefore the Company uses a mix of incremental borrowing rate based on the information available at commencement date, as well as implicit and explicit rates in determining the present value of lease payments.

The Company has options to renew lease terms for facilities and other assets. The exercise of lease renewal options is generally at the Company's sole discretion. The Company evaluates renewal and termination options at the lease commencement date to determine if it is reasonably certain to exercise the option on the basis of economic factors. For certain leases, the Company's exercise of the renewal option was determined to be probable and the renewal period was accordingly included in the lease term and related calculations. Lease terms and discount rates as of June 30, 2019 are as follows:

|   | June 30, 2019 |
|---|---------------|
| Weighted average remaining lease term (years) |               |
| Operating leases                              | 7.26          |
| Finance leases                                | 4.01          |
| Weighted average discount rate                |               |
| Operating leases                              | 9.53%         |
| Finance leases                                | 5.00%         |

Future minimum payments related to operating and capital leases, as reflected under the prior guidance, for the fiscal year ended December 31, 2018, are as follows with no changes from prior disclosure:

| (In thousands)   | Total     | 2019     | 2020     | 2021     | 2022     | 2023   | More than 5<br>years |
|------------------|-----------|----------|----------|----------|----------|--------|----------------------|
| Operating leases | \$ 15,386 | \$ 4,879 | \$ 4,719 | \$ 4,754 | \$ 966   | \$ 68  | \$ —                 |
| Capital leases   | 205       | 41       | 41       | 41       | 41       | 41     | —                    |
| Total            | \$ 15,591 | \$ 4,920 | \$ 4,760 | \$ 4,795 | \$ 1,007 | \$ 109 | \$ —                 |

## 8. Stock-based Compensation

### *Stock Option, Restricted Stock Units and Equity Incentive Plans*

The Company has historically had various stock incentive plans and agreements that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants.

Options and restricted stock units granted to employees and non-employees under these plans expire no later than ten years from the date of grant and generally become exercisable over a four year period, under a graded-vesting methodology for stock options and annually on the anniversary grant date for restricted stock units, following the date of grant. The Company generally issues new shares upon the exercise of stock options or vesting of restricted stock units. For certain non-employee consultants, stock option awards continue to vest post-termination. The guidance for non-employee stock compensation accounting for equity-classified awards was updated, and these awards are now subject to fixed grant date fair value principles which eliminates the variable mark-to-market accounting. The options were valued as of the adoption date of July 1, 2018.

The 2019 Omnibus Incentive Plan (2019 Plan) was approved on May 1, 2019 and provides incentives through the grant of stock options, stock appreciation rights, restricted stock awards and restricted stock units. The exercise price of stock options

granted under the 2019 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2019 Plan replaced the 1992 Stock Option Plan, the 2001 Stock Option Plan, the Amended and Restated 2004 Equity Incentive Plan, the 2009 Second Amended and Restated Omnibus Incentive Plan and the 2017 Omnibus Incentive Plan (Prior Plans), and no new awards have been granted under the Prior Plans after approval. However, the expiration or forfeiture of options previously granted under the Prior Plans will increase the number of shares available for issuance under the 2019 Plan.

As of June 30, 2019, there were 3,517,347 shares available for future grant under the 2019 Plan.

### ***Employee Stock Purchase Plan***

Employees are able to purchase stock under the Vericel Corporation Employee Stock Purchase Plan (ESPP). The ESPP allows for the issuance of an aggregate of 1,000,000 shares of common stock of which 558,977 have been issued since the inception of the plan in 2015. Participation in this plan is available to substantially all employees. The ESPP is a compensatory plan accounted for under the expense recognition provisions of the share-based payment accounting standards. Compensation expense is recorded based on the fair market value of the purchase options at the grant date, which corresponds to the first day of each purchase period and is amortized over the purchase period. On July 1, 2019, employees purchased 18,729 shares resulting in proceeds from the sale of common stock of \$0.3 million under the ESPP.

### ***Service-Based Stock Options***

During the three and six months ended June 30, 2019, the Company granted 152,500 and 1,638,510 service-based options to purchase common stock. The options have an exercise price equal to the fair market value per share of common stock on the grant date, generally vest over four years (other than non-employee director options which vest over one year) and have a term of ten years. The Company issues new shares upon the exercise of stock options. The weighted average grant-date fair value of service-based options granted under the 2017 and 2019 Plans for the three and six month periods ended June 30, 2019 was \$11.94 and \$12.74, respectively and \$9.26 and \$6.85, respectively, for the same periods in 2018.

### ***Restricted Stock Units***

During the three and six months ended June 30, 2019, the Company granted 10,500 and 186,922 service-based restricted stock units. The restricted stock units vest annually over four years in equal installments commencing on the first anniversary of the grant date (other than non-employee director options which vest over one year from the grant date). The Company issues new shares upon the vesting of restricted stock units. Restricted stock awards are recorded at fair value at the date of grant, which is based on the closing share price on the grant date. Compensation expense is recorded for restricted stock units that are expected to vest based on their fair value at grant date, and is amortized over the expected vesting period. The weighted average grant-date fair value of restricted stock units awarded for the three and six month periods ended June 30, 2019 was \$16.62 and \$17.71. The total grant-date fair value of restricted stock units granted in the six months ended June 30, 2019 was \$3.3 million. No restricted stock units were granted in 2018.

### Stock Compensation Expense

Non-cash stock-based compensation expense (employee stock purchase plan, service-based stock options and restricted stock units) included in cost of goods sold, research and development expenses and selling, general and administrative expenses is summarized in the following table:

| (In thousands)                                  | Three Months Ended June 30, |          | Six Months Ended June 30, |          |
|---|-----------------------------|----------|---------------------------|----------|
|   | 2019                        | 2018     | 2019                      | 2018     |
| Cost of goods sold                              | \$ 716                      | \$ 394   | \$ 976                    | \$ 536   |
| Research and development                        | 886                         | 442      | 1,410                     | 917      |
| Selling, general and administrative             | 2,581                       | 1,629    | 4,424                     | 2,354    |
| Total non-cash stock-based compensation expense | \$ 4,183                    | \$ 2,465 | \$ 6,810                  | \$ 3,807 |

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes option-pricing model using the weighted average assumptions noted in the following table.

| Service-Based Stock Options     | Six Months Ended June 30, |            |
|---------------------------------|---------------------------|------------|
|                                 | 2019                      | 2018       |
| Expected dividend rate          | —%                        | —%         |
| Expected stock price volatility | 79.5-85.5%                | 82.3-88.3% |
| Risk-free interest rate         | 1.9-2.7%                  | 2.4-2.9%   |
| Expected life (years)           | 5.3-6.3                   | 5.2-6.3    |

### 9. Cash Equivalents and Investments

Marketable debt securities are classified as available-for-sale and carried at fair value in the accompanying consolidated balance sheets on a settlement date basis. The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of June 30, 2019 and December 31, 2018:

| (In thousands)               | June 30, 2019  |       |        |      | Fair Value |
|------------------------------|----------------|-------|--------|------|------------|
|                              | Amortized Cost | Gains | Losses |      |            |
| Money market funds           | \$ 4,831       | \$ —  | \$ —   | \$ — | \$ 4,831   |
| Commercial paper             | 17,149         | —     | —      | —    | 17,149     |
| Corporate notes              | 17,225         | 20    | —      | —    | 17,245     |
| U.S. government securities   | 6,955          | 11    | —      | —    | 6,966      |
| U.S. asset-backed securities | 10,680         | 7     | —      | —    | 10,687     |
|                              | \$ 56,840      | \$ 38 | \$ —   | \$ — | \$ 56,878  |
| Classified as:               |                |       |        |      |            |
| Cash equivalents             |                |       |        |      | \$ 4,831   |
| Short-term investments       |                |       |        |      | 52,047     |
|                              |                |       |        |      | \$ 56,878  |



December 31, 2018

Gross Unrealized

| (In thousands)               | Amortized Cost   | Gains       | Losses         | Fair Value       |
|------------------------------|------------------|-------------|----------------|------------------|
| Money market funds           | \$ 5,838         | \$ —        | \$ —           | \$ 5,838         |
| Repurchase agreements        | 5,000            | —           | —              | 5,000            |
| Commercial paper             | 30,710           | —           | —              | 30,710           |
| Corporate notes              | 13,168           | —           | (24)           | 13,144           |
| U.S. government securities   | 10,167           | —           | (1)            | 10,166           |
| U.S. asset-backed securities | 10,632           | —           | (14)           | 10,618           |
|                              | <u>\$ 75,515</u> | <u>\$ —</u> | <u>\$ (39)</u> | <u>\$ 75,476</u> |
| Classified as:               |                  |             |                |                  |
| Cash equivalents             |                  |             |                | \$ 10,838        |
| Short-term investments       |                  |             |                | 64,638           |
|                              |                  |             |                | <u>\$ 75,476</u> |

At December 31, 2018, the Company invested \$5.0 million in overnight repurchase agreement securities classified as cash equivalents on the balance sheet. As of June 30, 2019, no amounts were invested in overnight repurchase agreements.

There were no marketable securities that the Company considers to be other-than-temporarily impaired as of June 30, 2019. The Company's investment strategy is to buy short-duration marketable securities with a high credit rating. As of June 30, 2019, all marketable securities held by the Company had remaining contractual maturities of one year or less.

If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the Company's intention to sell and, if so, mark the investment to market through a charge to our consolidated statements of operations. There have been no impairments of the Company's assets measured and carried at fair value during the six months ended June 30, 2019.

## 10. Fair Value Measurements

The Company's fair value measurements are classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

There was no movement between Level 1 and Level 2 or between Level 2 and Level 3 from December 31, 2018 to June 30, 2019. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The commercial paper, corporate notes, government securities and asset-backed securities are classified as Level 2 as they were valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. The following table summarizes the valuation of the Company's financial instruments that are measured at fair value on a recurring basis:

| (In thousands)               | June 30, 2019    |                                 |                  |             | December 31, 2018 |                                 |                  |             |
|------------------------------|------------------|---------------------------------|------------------|-------------|-------------------|---------------------------------|------------------|-------------|
|                              | Total            | Fair value measurement category |                  |             | Total             | Fair value measurement category |                  |             |
|                              |                  | Level 1                         | Level 2          | Level 3     |                   | Level 1                         | Level 2          | Level 3     |
| <b>Assets:</b>               |                  |                                 |                  |             |                   |                                 |                  |             |
| Money market funds           | \$ 4,831         | \$ 4,831                        | \$ —             | \$ —        | \$ 5,838          | \$ 5,838                        | \$ —             | \$ —        |
| Repurchase agreements        | —                | —                               | —                | —           | 5,000             | —                               | 5,000            | —           |
| Commercial paper             | 17,149           | —                               | 17,149           | —           | 30,710            | —                               | 30,710           | —           |
| Corporate notes              | 17,245           | —                               | 17,245           | —           | 13,144            | —                               | 13,144           | —           |
| U.S. government securities   | 6,966            | —                               | 6,966            | —           | 10,166            | —                               | 10,166           | —           |
| U.S. asset-backed securities | 10,687           | —                               | 10,687           | —           | 10,618            | —                               | 10,618           | —           |
|                              | <u>\$ 56,878</u> | <u>\$ 4,831</u>                 | <u>\$ 52,047</u> | <u>\$ —</u> | <u>\$ 75,476</u>  | <u>\$ 5,838</u>                 | <u>\$ 69,638</u> | <u>\$ —</u> |

## 11. Net Loss Per Common Share

The following reflects the net loss attributable to common shareholders and share data used in the basic and diluted earnings per share computations using the two class method:

| (Amounts in thousands except per share amounts)                            | Three Months Ended June 30, |               | Six Months Ended June 30, |               |
|--|-----------------------------|---------------|---------------------------|---------------|
|  | 2019                        | 2018          | 2019                      | 2018          |
| <b>Numerator:</b>  |                             |               |                           |               |
| Net loss   | \$ (19,792)                 | \$ (4,651)    | (22,636)                  | \$ (12,310)   |
| <b>Denominator for basic and diluted EPS:</b>                              |                             |               |                           |               |
| Weighted-average common shares outstanding                                 | 43,956                      | 38,349        | 43,841                    | 37,251        |
| Net loss per share attributable to common shareholders (basic and diluted) | <u>\$ (0.45)</u>            | <u>(0.12)</u> | <u>\$ (0.52)</u>          | <u>(0.33)</u> |

Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The number of common equivalent shares of options of 5.6 million, restricted stock unit awards of 0.2 million and less than 0.1 million of warrants have been excluded from the computations of diluted net loss per common share at June 30, 2019 and 2018. The number of common equivalent shares of options of 5.4 million and 0.4 million of warrants have been excluded from the computations of diluted net loss per common share at June 30, 2018.

## 12. NexoBrid License and Supply Agreements

On May 6, 2019, the Company entered into exclusive license and supply agreements with MediWound Ltd. (MediWound) to commercialize NexoBrid® and any improvements to Nexobrid in all countries of North America. NexoBrid is a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns.

NexoBrid is currently in clinical development in North America, and pursuant to the terms of the license agreement, MediWound will continue to conduct all clinical activities described in the development plan to support the BLA filing with the United States Food and Drug Administration under the supervision of a Central Steering Committee comprised of members of each party.

In May 2019, the Company paid MediWound \$17.5 million in consideration of the license. The \$17.5 million upfront payment was recorded to research and development expense in the three months ended June 30, 2019 as the license is for registration-stage product rights and is considered in process research and development. The Company is also obligated to pay MediWound \$7.5 million upon U.S. regulatory approval of the BLA for NexoBrid and up to \$125 million contingent upon meeting certain sales milestones. The first sales milestone of \$7.5 million would be triggered when annual net sales of NexoBrid or improvements to it in North America exceed \$75 million. The Company also will pay MediWound tiered royalties on net sales ranging from high single-digit to low double-digit percentages, subject to customary reductions. The U.S. Biomedical Advanced Research and Development Authority (BARDA) has committed to procure NexoBrid, and the Company will pay a percentage of gross profits to MediWound on initial committed amounts and a royalty on any additional BARDA purchases of NexoBrid beyond the initial committed amount. The Company also entered into a supply agreement with MediWound under which MediWound will manufacture NexoBrid for the Company on a unit price basis which may be increased based on a published index. MediWound is obligated to supply the Company with NexoBrid for sale in North America on an exclusive basis for the first five years of the term of the supply agreement. After the exclusivity period or upon supply failure, the Company will be permitted to establish an alternate source of supply.

## 13. Commitments and Contingencies

The Company leases facilities in Ann Arbor, Michigan and Cambridge, Massachusetts. The Cambridge facility includes clean rooms, laboratories for MACI and Epicel manufacturing and office space. The Company also pays for use of an offsite warehouse space and leases various vehicles and computer equipment.

In March 2016, the Company amended its current lease in Cambridge to, among other provisions, extend the term until February 2022. Under the amendment, the landlord will contribute approximately \$2.0 million toward the cost of tenant improvements. The contribution toward the cost of tenant improvements is recorded as part of the operating lease assets under the new leasing guidance described below, on the Company's condensed consolidated balance sheet. As of June 30, 2019, the Company has recorded \$1.9 million of leasehold improvements funded by the tenant improvement allowance.

The Company adopted the updated leasing guidance as described in note 7, as of January 1, 2019. Upon adoption all operating lease commitments with a lease term greater than 12 months that were previously assessed under previous lease guidance, were recognized as right to use assets and liabilities, on a discounted basis on the balance sheet. Leases with an initial term of 12 months or less are not recorded on the balance sheet and lease expense is recorded on a straight-line basis over the lease term.

The Company's purchase commitments consist of minimum purchase amounts of materials used in the Company's cell manufacturing process to manufacture its marketed cell therapy products.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

Vericel Corporation is a leader in advanced cell therapies for the sports medicine and severe burn care markets, and a developer of cell therapies for use in the treatment of patients with severe diseases and conditions. We currently market two FDA approved autologous cell therapy products in the United States. MACI<sup>®</sup> (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. We also market Epicel<sup>®</sup> (cultured epidermal autografts), a permanent skin replacement Humanitarian Use Device (HUD) for the treatment of adult and pediatric patients with deep-dermal or full-thickness burns greater than or equal to 30 percent of total body surface area (TBSA).

### Manufacturing

We have a cell-manufacturing facility in Cambridge, Massachusetts which is used for U.S. manufacturing and distribution of MACI and Epicel.

### Product Portfolio

Our marketed products include two FDA-approved autologous cell therapies: MACI, a third-generation autologous implant for the repair of symptomatic, full-thickness cartilage defects of the knee in adult patients and Epicel, a permanent skin replacement for adult and pediatric patients with deep dermal or full thickness burns greater than or equal to 30% of TBSA. Both products are currently marketed in the U.S. We also own Carticel which is no longer marketed in the U.S. We also entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in all countries of North America. NexoBrid is currently in clinical development in North America. Until 2017, our active product candidate portfolio included ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to dilated cardiomyopathy, or DCM. We have no current plans to continue the development of ixmyelocel-T.

### MACI

MACI is a third-generation autologous implant for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. MACI replaced Carticel, an earlier generation ACI product for the treatment and repair of cartilage defects in the knee and was the first FDA-approved autologous cartilage repair product.

In the U.S., the physician target audience which repairs cartilage defects is concentrated and is comprised of a group of orthopedic surgeons who self-identify and/or have a formal specialty as sports medicine physicians. We believe this target audience is approximately 2,500 to 3,000 physicians. In addition to these physicians there is a population of approximately 8,000 general orthopedic surgeons who treat cartilage injuries, although typically at a much lower average volume relative to the sports medicine

physicians. As we look to more effectively engage this customer base, we expanded our field force from 40 to 48 representatives in the second quarter of 2019. Most private payers have a medical policy that covers treatment with MACI with the top 30 largest commercial payers having a formal medical policy for MACI or ACI in general. For those private payers which have not yet approved a medical policy for MACI, for medically appropriate cases we can often obtain approval on a case by case basis. For the three and six months ended June 30, 2019, net revenues for MACI were \$20.8 million and \$37.4 million, respectively and \$14.1 million and \$26.2 million, for the same periods in 2018.

### **Epicel**

Epicel is a permanent skin replacement for deep dermal or full thickness burns greater than or equal to 30% of TBSA. Epicel is regulated by the Center for Biologics Evaluation and Research, or CBER of the U.S. Food and Drug Administration, or FDA under medical device authorities, and is the only FDA-approved autologous epidermal product available for large total surface area burns. Epicel was designated as a HUD in 1998 and a Humanitarian Device Exception (HDE) application for the product was submitted in 1999. HUDs are devices that are intended for diseases or conditions that affect fewer than 8,000 individuals annually in the U.S. Under an HDE approval, a HUD cannot be sold for an amount that exceeds the cost of research and development, fabrication and distribution unless certain conditions are met.

A HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain eligibility criteria, including where the device is intended for the treatment of a disease or condition that occurs in pediatric patients and such device is labeled for use in pediatric patients. If the FDA determines that a HUD meets the eligibility criteria, the HUD is permitted to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the Annual Distribution Number (ADN). The ADN is defined as the number of devices reasonably needed to treat a population of 8,000 individuals per year in the U.S.

On February 18, 2016, the FDA approved our HDE supplement to revise the labeled indications of use to specifically include pediatric patients and to add pediatric labeling. The revised product label also now specifies that the probable benefit of Epicel, mainly related to survival, was demonstrated in two Epicel clinical experience databases and a physician-sponsored study comparing outcomes in patients with massive burns treated with Epicel relative to standard care. Due to the change in the label to specifically include use in pediatric patients, Epicel is no longer subject to the HDE profit restrictions. In conjunction with adding the pediatric labeling and meeting the pediatric eligibility criteria, the FDA has determined the ADN number for Epicel is 360,400 which is approximately 45 times larger than the volume of grafts sold in 2018. We currently have a 5-person field force. For the three and six months ended June 30, 2019, net revenues for Epicel were \$5.3 million and \$10.6 million, respectively, and \$4.9 million and \$10.9 million for the same periods in 2018.

### **NexoBrid**

Our preapproval stage portfolio includes NexoBrid, a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns. NexoBrid is currently in clinical development in North America, and pursuant to the terms of our license agreement with MediWound, MediWound will continue to conduct all clinical activities described in the development plan to support the filing of a BLA with the United States Food and Drug Administration under the supervision of a Central Steering Committee comprised of members of each party.

### **Ixmyelocel-T**

Our preapproval stage portfolio also includes ixmyelocel-T, a unique multicellular therapy derived from an adult patient's own bone marrow which utilizes our proprietary, highly automated and scalable manufacturing system. This multicellular therapy was developed for the treatment of advanced heart failure due to DCM.

Ixmyelocel-T has been granted a U.S. Orphan Drug designation by the FDA for the treatment of DCM. We completed enrolling and treating patients in our completed Phase 2b ixCELL-DCM study in February 2015. Patients were followed for 12 months for the primary efficacy endpoint of major cardiac adverse events, or MACE. On March 10, 2016, we announced the trial had met its primary endpoint of reduction in clinical cardiac events and that the incidence of adverse events, including serious adverse events, in patients treated with ixmyelocel-T was comparable to patients in the placebo group. Patients were then followed for an additional 12 months for safety. Because the trial met the primary endpoint, patients who received placebo or were randomized to ixmyelocel-T in the double-blind portion of the trial but did not receive ixmyelocel-T were offered the option to receive ixmyelocel-T. We successfully treated the last patients in February 2017, and the last follow-up visit occurred approximately one year later. In addition, we have conducted clinical studies for the treatment of critical limb ischemia, and an ixmyelocel-T investigator-initiated clinical study was conducted for the treatment of craniofacial reconstruction.

On September 29, 2017, the FDA indicated we would be required to conduct at least one additional Phase 3 clinical study to support a BLA for ixmyelocel-T. Given the expense required to conduct further development and our focus on growing our existing commercial products, at this time we have no current plans to initiate or fund a Phase 3 trial on our own.

## Results of Operations

### Net Loss

Our net loss for the three and six months ended June 30, 2019 totaled \$19.8 million and \$22.6 million, respectively and \$4.7 million and \$12.3 million for the same periods in 2018.

| (In thousands)           | Three Months Ended June 30, |            | Six Months Ended June 30, |             |
|--------------------------|-----------------------------|------------|---------------------------|-------------|
|                          | 2019                        | 2018       | 2019                      | 2018        |
| Total revenues           | \$ 26,151                   | \$ 19,011  | \$ 47,961                 | \$ 37,038   |
| Cost of product sales    | 9,022                       | 7,727      | 17,662                    | 15,393      |
| Gross profit             | 17,129                      | 11,284     | 30,299                    | 21,645      |
| Total operating expenses | 37,329                      | 15,530     | 53,857                    | 30,213      |
| Loss from operations     | (20,200)                    | (4,246)    | (23,558)                  | (8,568)     |
| Other income (expense)   | 408                         | (405)      | 922                       | (3,742)     |
| Net loss                 | \$ (19,792)                 | \$ (4,651) | \$ (22,636)               | \$ (12,310) |

### Net Revenues

Net revenues increased for the three and six months ended June 30, 2019 compared to the same periods in 2018 primarily due to significant MACI volume growth.

| Revenue by product (in thousands) | Three Months Ended June 30, |           | Six Months Ended June 30, |           |
|-----------------------------------|-----------------------------|-----------|---------------------------|-----------|
|                                   | 2019                        | 2018      | 2019                      | 2018      |
| MACI                              | \$ 20,823                   | \$ 14,125 | \$ 37,406                 | \$ 26,180 |
| Epicel                            | 5,328                       | 4,886     | 10,555                    | 10,858    |
| Total Revenue                     | \$ 26,151                   | \$ 19,011 | \$ 47,961                 | \$ 37,038 |

*Seasonality.* Over the last four years ACI (MACI and Carticel prior to its replacement) sales volumes from the first through the fourth quarter have on average represented 20%, 24%, 22% and 35% respectively, of total annual volumes. In some years individual quarters have deviated from these means by up to 4%. MACI orders are stronger in the fourth quarter due to several factors including insurance copay limits and the time of year patients prefer to start rehabilitation. Epicel revenue is also subject to seasonal fluctuations mostly associated with the use of heating elements during the colder months, with stronger sales occurring in the winter months of the first and fourth quarters, and weaker sales occurring in the hot summer months of the third quarter. However, in any single year, this trend can be absent due to the extreme variability inherent with Epicel's patient volume. Over the last four years the percentage of annual product orders for Epicel has on average been 28%, 25%, 21% and 27% from the first to the fourth quarters.

### Gross Profit and Gross Profit Ratio

| (In thousands) | Three Months Ended June 30, |           | Six Months Ended June 30, |           |
|----------------|-----------------------------|-----------|---------------------------|-----------|
|                | 2019                        | 2018      | 2019                      | 2018      |
| Gross profit   | \$ 17,129                   | \$ 11,284 | \$ 30,299                 | \$ 21,645 |
| Gross profit % | 66%                         | 59%       | 63%                       | 58%       |

Gross profit increased for the three and six months ended June 30, 2019 compared to the same period in 2018 due primarily to an increase in MACI sales combined with our highly fixed manufacturing cost structure which consists mainly of labor and facility costs that do not materially fluctuate with volume increases.

## Research and Development Costs

| (In thousands)                 | Three Months Ended June 30, |          | Six Months Ended June 30, |          |
|--------------------------------|-----------------------------|----------|---------------------------|----------|
|                                | 2019                        | 2018     | 2019                      | 2018     |
| Research and development costs | \$ 21,070                   | \$ 3,739 | \$ 24,078                 | \$ 7,468 |

The following table summarizes the approximate allocation of cost for our research and development projects:

| (In thousands)                       | Three Months Ended June 30, |          | Six Months Ended June 30, |          |
|--------------------------------------|-----------------------------|----------|---------------------------|----------|
|                                      | 2019                        | 2018     | 2019                      | 2018     |
| Dilated Cardiomyopathy               | \$ —                        | \$ 604   | \$ 3                      | \$ 1,160 |
| MACI                                 | 2,231                       | 2,423    | 4,390                     | 4,880    |
| Epicel                               | 1,091                       | 712      | 1,937                     | 1,428    |
| NexoBrid                             | 17,748                      | —        | 17,748                    | —        |
| Total research and development costs | \$ 21,070                   | \$ 3,739 | \$ 24,078                 | \$ 7,468 |

Research and development costs for the three months ended June 30, 2019 were \$21.1 million compared to \$3.7 million for the same period a year ago. The increase in research and development costs during the three months ended June 30, 2019 is due to a \$17.5 million upfront payment to MediWound for the North American rights to NexoBrid.

Research and development costs for the six months ended June 30, 2019 were \$24.1 million compared to \$7.5 million for the same period a year ago. The increase in research and development costs during the six months ended June 30, 2019 is due to the \$17.5 million upfront payment to MediWound for the North American rights to NexoBrid, partially offset by costs related to the ongoing MACI pediatric trial, which decreased, compared to the same period a year ago.

## Selling, General and Administrative Costs

| (In thousands)                            | Three Months Ended June 30, |           | Six Months Ended June 30, |           |
|---|-----------------------------|-----------|---------------------------|-----------|
|   | 2019                        | 2018      | 2019                      | 2018      |
| Selling, general and administrative costs | \$ 16,259                   | \$ 11,791 | \$ 29,779                 | \$ 22,745 |

Selling, general and administrative costs for the three months ended June 30, 2019 were \$16.3 million compared to \$11.8 million for the same period a year ago. The increase in selling, general and administrative costs for the three months ended June 30, 2019 is due primarily to a \$1.1 million increase in marketing expenses, an incremental \$0.7 million in MACI sales force expenses driven by the expansion in the second quarter of 2019, a \$1.0 million increase in stock-based compensation expenses and a \$0.9 million increase in selling expenses and patient reimbursement support services. The increase in selling expenses and patient reimbursement support services is primarily driven by higher MACI sales volume and the engagement of a third-party services provider to provide the patient support program under the current distributor model which began June 15, 2018, compared to the same period a year ago.

Selling, general and administrative costs for the six months ended June 30, 2019 were \$29.8 million compared to \$22.7 million for the same period a year ago. The increase in selling, general and administrative costs for the six months ended June 30, 2019 is due primarily to a \$2.1 million increase in stock-based compensation expenses, a \$1.5 million increase in selling expenses and patient reimbursement support services, an incremental \$1.3 million in MACI sales force expenses driven by the expansions in the second quarter of 2019 and a \$1.3 million increase in marketing expenses.

## Other Income (Expense)

| (In thousands)                     | Three Months Ended June 30, |          | Six Months Ended June 30, |            |
|------------------------------------|-----------------------------|----------|---------------------------|------------|
|                                    | 2019                        | 2018     | 2019                      | 2018       |
| Increase in fair value of warrants | \$ —                        | \$ (37)  | \$ —                      | \$ (2,944) |
| Other income (expense)             | (18)                        | (3)      | 18                        | 83         |
| Net interest income (expense)      | 426                         | (365)    | 904                       | (881)      |
| Total other income (expense)       | \$ 408                      | \$ (405) | \$ 922                    | \$ (3,742) |

The other income and expense for the three and six months ended June 30, 2019 is due primarily to interest income as a result of our investments in various marketable debt securities. The same periods in 2018 relate to the increase in our stock price in 2018 resulting in an increase in the fair value of warrants, and we did not experience a change in warrant value for the three and six months ended June 30, 2019 due to the expiration of the liability classified 2013 warrants in 2018 which contributed to the valuation change.

### Stock Compensation

Non-cash stock-based compensation expense included in cost of goods sold, research and development expenses and selling, general and administrative expenses is summarized in the following table:

| (In thousands)                                  | Three Months Ended June 30, |          | Six Months Ended June 30, |          |
|---|-----------------------------|----------|---------------------------|----------|
|   | 2019                        | 2018     | 2019                      | 2018     |
| Cost of goods sold                              | \$ 716                      | \$ 394   | \$ 976                    | \$ 536   |
| Research and development                        | 886                         | 442      | 1,410                     | 917      |
| Selling, general and administrative             | 2,581                       | 1,629    | 4,424                     | 2,354    |
| Total non-cash stock-based compensation expense | \$ 4,183                    | \$ 2,465 | \$ 6,810                  | \$ 3,807 |

The changes in stock-based compensation expense are due primarily to fluctuations in the fair value of the options granted in 2019 compared to 2018 as a result in the increase in stock price. In addition, we granted restricted stock units in 2019 and none in 2018.

### Liquidity and Capital Resources

Since the acquisition in 2014 of MACI, Epicel and Carticel from Sanofi, our primary focus has been to invest in our existing commercial business with the goal of growing revenue. We have raised significant funds in order to complete our product development programs, and complete clinical trials needed to market and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities. At present revenue levels, we do not currently anticipate the need to finance our operations through the sales of equity securities.

Our cash and cash equivalents totaled \$14.0 million, and short-term investments totaled \$52.0 million as of June 30, 2019. The cash used in operations of \$18.2 million was largely a result of our net loss of \$22.6 million which included a cash outflow of \$17.5 million for the upfront payment for the NexoBrid license. The net loss was offset by noncash charges including \$6.8 million of stock compensation expense and \$0.7 million of depreciation expense.

Our cash and cash equivalents totaled \$95.0 million as of June 30, 2018. During the six months ended June 30, 2018, the cash used for operations of \$5.0 million was largely a result of our net loss of \$12.3 million, offset by noncash charges including \$3.8 million of stock compensation expense, \$2.9 million due to the change in fair value of warrants and \$0.8 million of depreciation expense.

The change in cash provided by investing activities as of June 30, 2019 is the result of \$32.4 million in short-term investments purchases offset by \$45.5 million of short-term investment maturities and property plant and equipment purchases of \$1.2 million primarily for manufacturing upgrades and leasehold improvements through June 30, 2019. The change in cash used for investing activities as of June 30, 2018 is the result of the purchases of \$1.0 million of property plant and equipment for manufacturing upgrades.

The change in cash provided from financing activities is the result of net proceeds from the exercise of stock options of \$2.1 million during the six months ended June 30, 2019. The change in cash provided from financing activities during the six months ended June 30, 2018 is the result of net proceeds from our public equity offering of common stock of \$70.1 million, proceeds from the exercise of stock options of \$2.1 million and exercise of warrants of \$2.0 million.

We believe that, based on current revenue levels, cash on hand, cash equivalents and short-term investments we are able to operate our business without the need to finance our operations through the sales of equity securities. If revenues decline for a sustained period, we may need to access additional capital; however, we may not be able to obtain financing on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of our shareholders. Actual cash requirements may differ from projections and will depend on many factors, including the level of future research and development, the scope and results of ongoing and potential clinical trials, the costs involved in filing, prosecuting and enforcing patents, the need for additional manufacturing capacity, competing technological and market developments, costs of possible acquisition or development of complementary business activities, and the cost to market our products.

### Off-Balance Sheet Arrangements

At June 30, 2019, we were not party to any off-balance sheet arrangements.

### Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Form 10-K for the fiscal year ended December 31, 2018 are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the six months ended June 30, 2019.

### Forward-Looking Statements

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “estimates,” “plans,” “projects,” “trends,” “opportunity,” “current,” “intention,” “position,” “assume,” “potential,” “outlook,” “remain,” “continue,” “maintain,” “sustain,” “seek,” “target,” “achieve,” “continuing,” “ongoing,”

“expects,” “management believes,” “we believe,” “we intend” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “could,” “may,” or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. The factors described in our Annual Report, among others, could have a material adverse effect upon our business, results of operations and financial conditions.

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor 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. These forward-looking statements include statements regarding:

- manufacturing and facility capabilities;
- potential strategic collaborations with others;
- future capital needs and financing sources;
- adequacy of existing capital to support operations for a specified time;
- reimbursement for our products;
- submission of a BLA for NexoBrid to the FDA;
- product development and marketing plans;
- features and successes of our therapies;
- clinical trial plans, including publication thereof;
- anticipation of future losses;
- replacement of manufacturing sources;
- commercialization plans; or
- revenue expectations and operating results.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As of June 30, 2019, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. For additional information regarding our market risk, refer to Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2018.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

The Company has established disclosure controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported



within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer (its "Certifying Officers"), as appropriate, to allow timely decisions regarding required disclosure.

Management of the Company, with the participation of its Certifying Officers, evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation as of June 30, 2019, our Certifying Officers concluded that the Company's disclosure controls and procedures were effective.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time we receive threats or may be subject to litigation matters incidental to our business. However, we are not currently a party to any material pending legal proceedings.

### Item 1A. Risk Factors

Certain risks described below update the risk factors discussed in Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which could materially affect our business, financial condition, results of operations, or cash flows. The risks described below and in the Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known or currently deemed to be immaterial also may materially and adversely affect our business, financial condition, results of operations or cash flows.

***We rely on complex information technology (IT) systems for various critical purposes, including timely delivery of product and maintaining patient confidentiality.***

We have developed a comprehensive, integrated information technology (IT) system for the intake of physician orders for our products, to track product delivery, and to store patient-related data we obtain for purposes of manufacturing MACI and Epicel. We rely on this system to maintain the chain of identity for each autologous product, and to ensure timely delivery of product prior to expiration. Each product has a limited usable life measured in days from the completion of the manufacturing process to patient implant or grafting. Accordingly maintaining accurate scheduling logistics is critical. In addition, this IT system stores and protects the privacy of the required patient information for the manufacture of our products. If our systems were to fail or be disrupted for an extended period of time, we could lose product sales and our revenue and reputation would suffer. In the event our systems were to be breached by an unauthorized third party, they could potentially access confidential patient information we obtain in manufacturing our products, which could cause us to suffer reputational damage and loss of customer confidence. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

***If we fail to fulfill our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are a party to intellectual property license agreements with third parties, including our license agreement with MediWound Ltd. for NexoBrid, and may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. In addition, if these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours after the expiry of data exclusivity. The occurrence of such events could materially harm our business.

***If our licensing arrangement with MediWound is unsuccessful, our revenues and product development may be limited.***

We have entered into a licensing arrangement with MediWound Ltd. for the development of NexoBrid in North America. However, there can be no assurance that this agreement and our and MediWound's efforts pursuant to it will result in FDA approval of NexoBrid, or that we will be able to market NexoBrid at a profit. Under the terms of the License Agreement, MediWound will continue to conduct all development activities under the supervision of a Central Steering Committee comprised of members of each party until the BLA is approved and subsequently transferred to Vericel. Collaboration and licensing arrangements pose the following risks:

- collaborations and licensing arrangements may be terminated;
- collaborators and licensors may delay clinical trials and prolong clinical development, or under-fund or stop a clinical trial;
- expected revenue might not be generated because product candidates may not be approved;

- collaborators and licensors could independently develop, or develop with third parties, products that could compete with our future products despite non-competition provisions;
- the terms of our contracts with current or future collaborators and license parties may not be favorable to us in the future;
- disputes may arise delaying or terminating the research, development, or commercialization of our product candidates, or result in significant and costly litigation or arbitration; and
- one or more third-party developers could obtain approval for a similar product prior to the product candidate resulting in unforeseen price competition in connection with the product candidate.

***Product development is a lengthy and expensive process, with an uncertain outcome.***

We intend to commercialize NexoBrid in the U.S. and potentially other North American countries. However, before we can commercialize NexoBrid, we must first obtain regulatory approval for the sale of NexoBrid in any jurisdiction, which includes the submission of an application utilizing completed and ongoing clinical studies to demonstrate that the product is safe and effective. We depend on MediWound for its efforts in completing clinical trials and other clinical activities pursuant to the development plan, obtaining regulatory approval and manufacturing and supplying NexoBrid.

Certain events could delay or prevent our ability to successfully gain regulatory approval, including:

- patients may not participate in necessary follow-up visits to obtain required data, which would result in significant delays in the clinical testing process;
- third-party contractors, such as a research institute, may fail to comply with regulatory requirements or meet their contractual obligations to MediWound;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent; and
- an audit of preclinical or clinical studies by regulatory authorities may reveal noncompliance with applicable protocols or regulations, which could lead to disqualification of the results and the need to perform additional studies.

***We may be unable to successfully obtain approval of NexoBrid for treatment of severe burns in the United States and other North American markets.***

Our continued growth partially depends on our and MediWound's ability to develop and obtain regulatory approval from the FDA for NexoBrid for treatment of severe burns in the United States. MediWound recently announced top-line results from the Phase 3 pivotal study to support a BLA submission to the FDA, according to which the study has met its primary and all secondary endpoints. Planned twelve-month and twenty-four month safety follow-ups are ongoing for cosmesis, function, quality of life and other safety measurements. While this and previous studies have met their primary endpoints, we cannot predict the outcome of the planned safety follow-ups, whether the FDA will accept a BLA submission based on the available preclinical and clinical data, how long the FDA may take to review and approve NexoBrid following the BLA submission or whether any such approval in the United States will ultimately be granted. Similarly, we cannot predict how long regulatory authorities in Mexico or Canada will take to provide NexoBrid with marketing authorization in their jurisdictions or whether such authorizations will be granted at all. The failure to receive regulatory approval in the United States would have a materially adverse impact on our business prospects.

***There is no guarantee that NexoBrid will be accepted in the market even if regulatory approval is received.***

The success of NexoBrid, if and when approved, depends upon the acceptance of NexoBrid by patients, the medical community and third-party payors, effectively competing with other products, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending related intellectual property rights and claims. Even if we and MediWound successfully obtain regulatory approvals to market NexoBrid, our revenues will be dependent, in part, upon the size of the markets for which we gain regulatory approval. If the markets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

***Our licensor MediWound is dependent on a contract with the U.S. Biomedical Advanced Research and Development Authority to fund the Phase 3 pivotal studies and other development activities of NexoBrid in the United States.***

MediWound has a contract with BARDA valued at up to \$132 million for the advancement of the development and manufacturing, as well as the procurement, of NexoBrid in the United States. Under the contract, BARDA has agreed to fund up to \$56 million of the development costs of NexoBrid required to obtain marketing approval in the United States, including its ongoing pediatric Phase 3 study and its expansion to include U.S. pediatric burn care sites, and has an option to further fund \$10 million in development activities for other potential NexoBrid indications. BARDA has also made a \$16.5 million commitment for procurement of NexoBrid, which is contingent upon the U.S. FDA Emergency Use Authorization and/or FDA regulatory approval for NexoBrid, and has a \$50 million option for additional procurement of NexoBrid. In addition, MediWound was recently awarded a new contract to develop NexoBrid for the treatment of Sulfur Mustard injuries as part of BARDA preparedness for mass casualty events. The contract provides approximately \$12 million of funding to support research and development activities up to pivotal studies in animals under the U.S. FDA Animal Efficacy Rule and contains options for additional funding of up to \$31 million for additional development activities, animal pivotal studies, and the BLA submission for licensure of NexoBrid for the treatment of Sulfur Mustard injuries. MediWound also was recently awarded funding for the NexoBrid expanded access treatment (NEXT) protocol being conducted under the FDA's expanded access program. However, the contracts provide that BARDA may terminate the contract at any time, at its convenience, without any further funding obligations. There can be no assurances that BARDA will not terminate the contract. Changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the development of products for the treatment of severe burns such as NexoBrid. Any reduction or delay in BARDA funding may result in a decrease in planned development activities, including the development of NexoBrid for the treatment of Sulfur Mustard injuries and the NEXT study. In addition, the loss of funding may adversely affect MediWound's ability to complete the required activities to file the BLA without access to alternative sources of funding. This could lead to a modification to the financial provisions of our agreement or a significant delay in the development of NexoBrid. Further, we cannot provide any assurances as to when or whether BARDA's commitment for procurement of NexoBrid will occur nor when or whether BARDA's option to fund additional development activities for NexoBrid will be exercised.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

The Company did not have any repurchases or unregistered issuances of its equity securities during the quarter ended June 30, 2019.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

The Exhibits listed in the Exhibit Index are filed as a part of this Quarterly Report on Form 10-Q.

## EXHIBIT INDEX

| Exhibit No. | Description   |
|-------------|---|
| 10.1†**     | <a href="#">Sixth Amendment to Distribution Agreement between Orsini Pharmaceutical Services, Inc. and the Company, dated April 18, 2019.</a>   |
| 10.2†**     | <a href="#">First Amendment to Dispensing Agreement by and between AllCare Plus Pharmacy and the Company, dated May 1, 2019.</a>  |
| 10.3#       | <a href="#">Vericel Corporation 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a>  |
| 10.4#       | <a href="#">Form of Incentive Stock Option Agreement for Employees under the 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a>                   |
| 10.5#       | <a href="#">Form of Incentive Stock Option Agreement for New Hires under the 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a>                   |
| 10.6#       | <a href="#">Form of Non-Qualified Stock Option Agreement under the 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a>                             |
| 10.7#       | <a href="#">Form of Restricted Stock Unit Award Agreement for Employees under the 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a>              |
| 10.8#       | <a href="#">Form of Restricted Stock Unit Award Agreement for non-employee directors under the 2019 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed on May 1, 2019).</a> |
| 10.9†**     | <a href="#">License Agreement between MediWound, Ltd. and the Company, dated May 6, 2019.</a>   |
| 10.10†**    | <a href="#">Supply Agreement between MediWound, Ltd. and the Company, dated May 6, 2019.</a>  |
| 10.11**     | <a href="#">Amended and Restated Employment Agreement by and between Michael Halpin and the Company, dated September 14, 2017.</a>  |
| 10.12**     | <a href="#">First Amendment to Employment Agreement by and between Michael Halpin and the Company, dated June 3, 2019.</a>  |
| 31.1**      | <a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>   |
| 31.2**      | <a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>   |
| 32.1**      | <a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>   |
| 32.2**      | <a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>   |
| 101.INS**   | <a href="#">XBRL Instance Document</a>  |
| 101.SCH**   | <a href="#">XBRL Taxonomy Extension Schema Document</a>   |
| 101.CAL**   | <a href="#">XBRL Taxonomy Extension Calculation Linkbase Document</a>   |
| 101.LAB**   | <a href="#">XBRL Taxonomy Extension Label Linkbase Document</a>   |
| 101.PRE**   | <a href="#">XBRL Taxonomy Extension Presentation Linkbase Document</a>  |
| 101.DEF**   | <a href="#">XBRL Taxonomy Extension Definition Linkbase Document</a>  |

# Management contract or compensatory plan or arrangement covering executive officers or directors of Vericel.

† Portions of this Exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

\*\* Filed herewith.

**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.

Date: August 6, 2019

VERICEL CORPORATION

/s/ DOMINICK C. COLANGELO

---

Dominick C. Colangelo  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ GERARD MICHEL

---

Gerard Michel  
*Chief Financial Officer and Vice President, Corporate Development*  
*(Principal Financial Officer)*

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[\*\*\*]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

## SIXTH AMENDMENT TO DISTRIBUTION AGREEMENT

---

This Sixth Amendment to the Distribution Agreement ("Sixth Amendment") is between Vericel Corporation ("Vericel") and Orsini Pharmaceutical Services, Inc. ("Orsini"). This Sixth Amendment is effective as of April 18, 2019 ("Effective Date").

**Whereas**, Vericel and Orsini are parties to a Distribution Agreement dated May 15, 2017 (as amended, the "Agreement"), under which Vericel appointed Orsini as a specialty pharmacy distributor for MACI®;

**Whereas**, the Parties entered into the First Amendment to the Agreement effective August 10, 2017;

**Whereas**, the Parties entered into the Second Amendment to the Agreement effective October 13, 2017;

**Whereas**, the Parties entered into the Third Amendment to the Agreement effective November 14, 2017;

**Whereas**, the Parties entered into the Fourth Amendment to the Agreement effective July 25, 2018;

**Whereas**, the Parties entered into the Fifth Amendment to the Agreement effective August 10, 2018; and

**Whereas**, the Parties desire to modify certain terms of the Agreement, including the revision and restatement of Exhibits A and B;

**Now therefore**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to amend the Agreement as follows:

1. **Section 7.1 Term.** Section 7.1 shall be deleted and replaced with the following:

The Term of this Agreement shall continue until **May 15, 2022** ("Term"). The Parties may renew the Agreement for two (2) additional two year terms, upon mutual agreement.

During the Term, Orsini shall be one in a limited network of pharmacies, not to exceed [\*\*\*], supplying the Product for the cases covered by Section 1.1. Orsini shall not enter into any agreement with a Payor covering the Product unless Vericel [\*\*\*]. Unless otherwise agreed to in writing by Vericel, the minimum reimbursement amount for the Product shall be the Product's [\*\*\*]. Vericel shall review and approve any proposed material modifications to the conditions for reimbursement for the Product relating to Payors on Exhibit B and/or for the proposed addition of Payors to Exhibit B - Contracted Payors, which approval shall not be unreasonably withheld or delayed. Orsini shall provide to Vericel the [\*\*\*]. Should a Payor request extended payment terms in excess of [\*\*\*], Orsini will secure advance approval from Vericel. Exhibit B. will be modified from time to time in writing by the Parties as additional Payors are contracted with Orsini and approved by Vericel.

2. **Section 7.2(a).** The Parties agree to delete in its entirety Section 7.2(a).



3. **Exhibits A and B.** The Parties agree that Exhibits A and B to the Agreement shall be deleted and replaced with the attached revised and restated Exhibits A and B.
4. **No Other Changes.** To the extent terms in the Sixth Amendment conflict with the Agreement and/or any of the amendments to the Agreement, the terms of this Sixth Amendment shall prevail. Except as provided in this Sixth Amendment, the terms and conditions of the Agreement will continue in full force.
5. **Counterparts/Signatures.** This Sixth Amendment may be executed in multiple counterparts, each of which constitutes an original, and all of which, collectively, constitute only one agreement. The signatures of the parties need not appear on the same counterpart, and delivery of an executed counterpart signature page by facsimile or other form of electronic transmission shall be as effective as executing and delivering this Sixth Amendment in the presence of the other parties to this Sixth Amendment.

**IN WITNESS WHEREOF**, the parties executed this Sixth Amendment as of its Effective Date.

**Vericel Corporation**

By: /s/ Daniel Orlando

Name: Daniel Orlando  
Title: Chief Operating Officer

Date: 04/18/2019

**Orsini Pharmaceutical Services, Inc.**

By: /s/ Michael Fieri

Name: Michael Fieri  
Title: President and CEO

Date: 04/18/2019

**EXHIBIT A -- PAYMENT TERMS AND PRICING**

**1. Product.**

Product, under this Agreement is defined as:

| <b><u>Product</u></b> | <b><u>NDC Number</u></b> |
|-----------------------|--------------------------|
| MACI                  | 69866-1030-01            |
| MACI                  | 69866-1030-02            |

**2. Orsini Counseling and Dispensing.**

- A. Orsini, when acting as the dispensing specialty pharmacy for Product, shall [\*\*\*]. Vericel shall provide Orsini, through its vendors or its web-based data-sharing platform (“Vericel Central”), with daily data feeds regarding cases, [\*\*\*].
- B. Vericel shall, [\*\*\*], arrange for Product to be shipped to Orsini so that Orsini may label and dispense the Product [\*\*\*] by the surgery date. Vericel shall also be responsible [\*\*\*].
- C. In order to perform its specialty pharmacy services, Orsini shall take title to the Product upon receipt of the Product at its facility. [\*\*\*].

**3. Claim Submittal, Contracting and Payment Coordination between Parties.**

- A. To the extent permitted by Orsini’s Payor agreements, the Parties agree that they will work together to manage reimbursement issues regarding the Product. Orsini, working with Vericel’s contractor, shall submit claims for Products [\*\*\*] of Product implantation. [\*\*\*]. Orsini shall appeal or resubmit for payment all denied and otherwise rejected claims for which a good faith basis exists to do so, [\*\*\*] from Orsini’s receipt of such notice of denial or rejection. [\*\*\*]. Orsini shall notify Vericel daily of denials or claims otherwise rejected and the reason for the denial or rejection.
- B. When reasonably determined by Vericel representatives and Orsini, Orsini will consult with Vericel and its designated representatives with [\*\*\*].
- C. [\*\*\*]. Orsini agrees to provide to Vericel representatives the payment history for the Product. If required for Vericel’s financial reporting purposes under generally accepted accounting principles, Orsini agrees to provide redacted portions of the relevant agreements or other payment arrangements between a Payor and Orsini to the extent allowed by the confidentiality provisions of such agreements.

**4. Payment Terms.**

- A. Vericel shall pay Orsini for each Product dispensed by Orsini, regardless of the Product NDC, [\*\*\*] (“Dispensing Fee”). Orsini shall invoice Vericel for the Dispensing Fee weekly for claims submitted during the week, and such payment is due to Orsini [\*\*\*] of Vericel’s receipt of the invoice. Vericel’s obligation to pay this fee shall survive the termination of the Agreement.

- B. Within [\*\*\*] of receipt of payment from a Payor related to the Product, Orsini shall remit to Vericel all reimbursements related to Products dispensed by Orsini except as provided above. The payments shall be deposited into a bank account maintained by and in the name and sole control of Vericel (the "Vericel Account"). In conjunction with each deposit, Orsini shall remit to Vericel a schedule detailing the cases for which a payment was deposited into the account including the case number and the amount deposited for each case.
- C. On a [\*\*\*] basis, Orsini shall remit to Vericel a schedule which includes the gross reimbursements received [\*\*\*] related to Products dispensed by Orsini, including whether the payments were deposited into the Vericel Account and the date of payment into the Vericel Account. Such schedule of payments shall include the case number and other identifiers agreed to by the Parties. In addition, Orsini shall provide to Vericel and its agent [\*\*\*] for each reimbursed case.
- D. In addition to the remitting of payment to Vericel as set forth above, Orsini shall update, [\*\*\*], the payment status of submitted cases to Vericel and its contractors through Vericel Central or other mutually agreed upon method.
- E. Subject to the terms of the Agreement, as amended, Vericel acknowledges that it retains the risk of [\*\*\*].
- F. Except as provided herein, all payments (including interest payments, if any) for the Product received by Orsini during the Term and after the expiration or termination of the Agreement shall be the sole property of Vericel and shall be remitted to Vericel in accordance with the Agreement. In the event of a termination or expiration of the Agreement, Orsini shall continue to collect on claims covered by the Agreement, consistent with the terms of the Agreement, for a period [\*\*\*] following the expiration or termination of the Agreement.
- G. Orsini represents and warrants that each of Orsini's Payor agreements set forth on Exhibit B are in full force and effect and apply to the Product.
- H. If a Payor recoups any payment on a case for which Orsini has made payment to Vericel, Orsini shall notify Vericel and shall be entitled to deduct from Vericel funds a sum equal to the amount of the recoupment. If there are insufficient Vericel Funds, Orsini shall invoice Vericel for the amount of the recoupment and Vericel shall pay Orsini within [\*\*\*] of receipt of the invoice. Vericel's obligation under this Paragraph K shall survive the termination of the Agreement. The Parties shall discuss appealing and/or disputing the proposed recoupment with the Payor. If an appeal is successful, Orsini shall treat the payment in accordance with the terms of this Sixth Amendment.
- I. The Parties agree that fees paid hereunder are not designed nor constitute inducements for Orsini to utilize or recommend the utilization of Vericel Products under federal and/or similar state laws. Orsini shall properly disclose and otherwise comply with applicable law.

**EXHIBIT B –Contracted Payors**

Consistent with Section 1.1 and Section 7.1 of the Agreement, the Payors listed on this Exhibit shall only apply to [\*\*\*].

[\*\*\*]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[\*\*\*]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

### **First Amendment to Dispensing Agreement**

This First Amendment to the July 26, 2018 Dispensing Agreement (“Agreement”) between Vericel Corporation and AllCare Plus Pharmacy (“AllCare”) shall be effective as of May 1, 2019 (“Effective Date”).

#### **RECITALS**

WHEREAS, Vericel and AllCare are Parties to the Agreement;

WHEREAS, the Parties desire to amend the Agreement;

NOW, THEREFORE, in consideration of good and valuable consideration, the Parties hereby agree to modify the Agreement as follows

1. The Parties agree to modify Section 7.1, Term, by replacing the first sentence to the following: “The term of this Agreement shall continue until May 15, 2022 (“Term”), unless otherwise terminated pursuant to this Agreement.”
2. The Parties agree to replace Section 2(A) of Exhibit A to the Agreement with “Vericel shall pay AllCare \$[\*\*\*] for each Patient to whom Product is dispensed. If a customer receives more than one Product within the same order, AllCare shall receive \$[\*\*\*].”
3. The Parties agree that all other conditions of the Agreement shall remain in force and that such terms shall prevail in the event of a conflict with this First Amendment.

**IN WITNESS WHEREOF**, the Parties have executed this Amendment, by their duly authorized representatives, as of the Effective Date.

**VERICEL CORPORATION**

**ALLCARE PLUS PHARMACY**

/s/ Daniel Orlando  
Dan Orlando, Chief Operating Officer

/s/ Daniel Apelian  
President & CEO

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[\*\*\*]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

**LICENSE AGREEMENT**

by and between

**VERICEL CORPORATION**

and

**MEDIWOUND LTD.**

**May 6, 2019**

8976368/35

## TABLE OF CONTENTS

### Page

|  |    |
|--|----|
| 1. Definitions   | 1  |
| 2. Governance  | 14 |
| 2.1 Governance   | 14 |
| 3. Product Development and Commercialization             | 15 |
| 3.1 General  | 15 |
| 3.2 Development Plan                                     | 15 |
| 3.3 Transition Obligations of MediWound                  | 16 |
| 3.4 Diligence  | 16 |
| 3.5 Regulatory Approvals                                 | 18 |
| 3.6 Pharmacovigilance Agreement; Adverse Event Reporting | 18 |
| 3.7 Commercialization Activities                         | 19 |
| 3.8 Extra-Territorial Sales                              | 20 |
| 3.9 Manufacturing and Supply                             | 21 |
| 4. License Grants  | 21 |
| 4.1 Exclusive License from MediWound to Vericel          | 21 |
| 4.2 Vericel Sublicense Rights                            | 22 |
| 4.3 Rights of Reference                                  | 22 |
| 4.4 No Implied Rights                                    | 23 |
| 4.5 Initial Data Transfer                                | 23 |
| 4.6 Non-Competition Obligations                          | 23 |
| 4.7 Assignment of Contracts                              | 23 |
| 4.8 Bankruptcy   | 23 |
| 5. Payments  | 24 |
| 5.1 Upfront Payment                                      | 24 |
| 5.2 Development Milestone Payments                       | 24 |

|     |  |    |
|-----|--|----|
| 5.3 | Sales Milestone Payments                             | 24 |
| 5.4 | Royalty Payments; BARDA Purchases                    | 25 |
| 5.5 | Sublicense Income                                    | 28 |
| 5.6 | Reports and Payments                                 | 28 |
| 5.7 | ***]   | 31 |
| 5.8 | No Guarantee of Success                              | 32 |
| 6.  | Intellectual Property                                | 32 |
| 6.1 | Ownership of Intellectual Property                   | 32 |
| 6.2 | Patent Rights  | 33 |
| 6.3 | Enforcement and Defense of Joint Know-How            | 37 |
| 6.4 | Recording  | 37 |
| 7.  | Confidentiality                                      | 38 |
| 7.1 | Confidentiality                                      | 38 |
| 7.2 | Authorized Disclosure                                | 38 |
| 7.3 | SEC Filings and Other Disclosures                    | 39 |
| 7.4 | Public Announcements; Publications                   | 39 |
| 8.  | Representations and Warranties; Covenants            | 40 |
| 8.1 | Mutual Representations and Warranties                | 40 |
| 8.2 | Representations and Warranties of MediWound          | 40 |
| 8.3 | Representations, Warranties and Covenants of Vericel | 44 |
| 8.4 | MediWound Covenants                                  | 44 |
| 8.5 | Additional Covenants of the Parties                  | 46 |
| 8.6 | Disclaimer   | 47 |
| 9.  | Term and Termination                                 | 48 |
| 9.1 | Term   | 48 |
| 9.2 | Termination by MediWound                             | 48 |
| 9.3 | Termination by Vericel                               | 49 |
| 9.4 | Termination for Insolvency                           | 49 |



|       |  |    |
|-------|--|----|
| 9.5   | Effects of Termination; Survival                       | 50 |
| 10.   | Limitation on Liability, Indemnification and Insurance | 53 |
| 10.1  | Limitation of Liability                                | 53 |
| 10.2  | Indemnification by Vericel                             | 53 |
| 10.3  | Indemnification by MediWound                           | 53 |
| 10.4  | Procedure  | 54 |
| 10.5  | Insurance  | 55 |
| 11.   | Miscellaneous  | 56 |
| 11.1  | Assignment   | 56 |
| 11.2  | Further Actions  | 56 |
| 11.3  | Force Majeure  | 56 |
| 11.4  | Notices  | 57 |
| 11.5  | Amendment  | 57 |
| 11.6  | Waiver   | 57 |
| 11.7  | Severability   | 57 |
| 11.8  | Descriptive Headings                                   | 58 |
| 11.9  | Interpretation   | 58 |
| 11.10 | Governing Law  | 58 |
| 11.11 | Dispute Resolution                                     | 58 |
| 11.12 | Consent to Jurisdiction                                | 59 |
| 11.13 | Entire Agreement                                       | 59 |
| 11.14 | Representation by Legal Counsel                        | 59 |
| 11.15 | Independent Contractors                                | 59 |
| 11.16 | Counterparts   | 59 |
| 11.17 | No Third Party Rights or Obligations                   | 60 |

## **SCHEDULES**

Schedule 1.58 Licensed Trademarks

Schedule 3.2 Development Plan

Schedule 3.7.2(c) Websites

Schedule 4.7 Assigned Contracts

Schedule 5.6.6 Payment Information

Schedule 7.4 Public Announcement

Schedule 8.2.3 MediWound Patent Rights

Schedule 8.2.4 MediWound In-Licenses

Schedule 8.2.11 Disclosed Third Party Agreements

Schedule 8.2.12 Government Grants and Funding

Schedule 10.2(d) BARDA Agreement Provisions

## LICENSE AGREEMENT

This License Agreement (the “**Agreement**”) is entered into as of May 6, 2019 (the “**Effective Date**”), by and between Vericel Corporation, a corporation organized and existing under the laws of Michigan and having a principal place of business at 64 Sidney Street, Cambridge, MA (“**Vericel**”) and MediWound Ltd., a corporation organized and existing under the laws of Israel and having a principal place of business at 42 Hayarkon Street, Yavne, Israel 8122745 (“**MediWound**”). Vericel and MediWound may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

**WHEREAS**, MediWound owns or otherwise controls certain patents, patent applications, technology, know-how, and other proprietary rights and information relating to the Licensed Products (as defined below);

**WHEREAS**, Vericel has experience and expertise in the development and commercialization of pharmaceutical products, and desires to acquire an exclusive license in the Territory (as defined below) under MediWound’s patents, patent applications, technology, know-how, and other proprietary rights and information relating to the Licensed Products; and

**WHEREAS**, subject to the terms of this Agreement, MediWound wishes to grant to Vericel, and Vericel wishes to receive from MediWound, an exclusive license in the Territory to use, research, develop and commercialize Licensed Products.

**NOW THEREFORE**, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

**1. DEFINITIONS.**

1.1 “**Additional Third Party License**” has the meaning set forth in Section 5.4.5(a).

1.2 “**Affiliate**” means, with respect to a particular Person, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Person. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of an entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 “**Agreement**” has the meaning set forth in the Preamble.

1.4 “**Assigned Contracts**” has the meaning set forth in Section 4.7.

1.5 “**Bankruptcy Code**” has the meaning set forth in Section 9.4.

1.6 “**BARDA**” means Biomedical Advanced Research and Development Authority or any successor agency thereto.

1.7 “**BARDA Agreements**” means (a) BARDA Contract HHSO100201500035C and (b) BARDA Contract HHSO100201800023C.

1.8 “**BARDA Purchases**” has the meaning set forth in Section 5.4.2.

1.9 “**Big Four**” means PriceWaterhouseCoopers, Ernst & Young, Deloitte and KPMG, and any similarly situated accounting firms or successors thereto.

1.10 “**Binding Obligation**” means, with respect to a Party (a) any oral or written agreement, arrangement or settlement that binds or affects such Party’s operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party’s charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party’s operations or property are bound.

1.11 “**Biosimilar Product**” means, with respect to a Licensed Product and on a country-by-country basis, a product that (a) is marketed for sale in such country by a Third Party (not licensed, supplied or otherwise permitted by a Party or its Affiliate or Sublicensee), (b) contains the corresponding Licensed Product or substantial equivalent as an active pharmaceutical ingredient in such country, and (c) such product, as and to the extent required, is approved through an abbreviated process similar, with respect to the United States, to an Abbreviated New Drug Application under Section 505(j) of the FD&C Act (21 USC 355(j)) or is approved as a “Biosimilar Biologic Product” under Title VII, Subtitle A Biologics Price Competition and Innovation Act of 2009, Section 42 U.S.C. 262, Section 351 of the PHSA, or, outside the United States, in accordance with European Directive 2001/83/EC on the Community Code for medicinal products (Article 10(4) and Section 4, Part II of Annex I) and European Regulation EEC/2309/93 establishing the Community procedures for the authorization and evaluation of medicinal products, each as amended, and together with all associated guidance, and any counterparts thereof or equivalent process inside or outside of the United States or European Union to the foregoing.

1.12 “**BLA**” means (a) a Biologics License Application as defined in the FD&C Act and the regulations promulgated thereunder, (b) a Marketing Authorization Application (“**MAA**”) in the European Union or (c) any equivalent or comparable application, registration or certification in any other country or region.

1.13 “**Burn Indications**” means eschar removal of wounds caused by burn, whether such burns are caused by chemical, electrical, mechanical, thermal or other agents or conditions, including wounds caused by sulphur mustard and mustard gas.

1.14 “**Business Day**” means a day other than a Friday, Saturday, Sunday or bank or other public holiday in New York, New York or Tel Aviv, Israel.

1.15 “**Calendar Quarter**” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.16 “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; *provided* that the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term.

1.17 “**Clinical Trial**” means a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing, (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

1.18 “**Combination Product**” has the meaning set forth in Section 1.68.

1.19 “**Commercialize**” or “**Commercializing**” means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize or exploit a compound or product, including without limitation market access, reimbursement and medical affairs activities. When used as a noun, “Commercialization” means any and all activities involved in Commercializing.

1.20 “**Commercially Reasonable Efforts**” means, with respect to the efforts to be expended by a Party with respect to any [\*\*\*]. With respect to any efforts relating to the Development, Regulatory Approval or Commercialization of a Licensed Product by a Party, generally or with respect to any particular country in the Territory, a Party will be deemed to have exercised Commercially Reasonable Efforts if such Party [\*\*\*], in each case, taking into account all Relevant Factors in effect at the time such efforts are to be expended. Further, to the extent that the performance of a Party’s obligations hereunder is adversely affected by the other Party’s failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.21 “**Confidential Information**” means, with respect to each Party, all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party’s technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the Effective Date, but only to the extent that such Know-How or other information in written form is marked or otherwise designated in writing as “confidential” at the time of disclosure or within [\*\*\*] thereafter, and such Know-How or other information disclosed orally or in non-tangible form is (a) identified by the Disclosing Party as “confidential” at the time of disclosure and (b) within [\*\*\*] thereafter, the Disclosing Party provides a written summary of such Know-How or other information marked or otherwise designated in writing as “confidential”; or (c) reasonably should be considered

confidential due to the nature of the information and circumstances of disclosure. Confidential Information does not include any Know-How or other information that (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, as evidenced by written records in the possession of the Receiving Party, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement, (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party, as evidenced by written records in the possession of the Receiving Party, or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party, as evidenced by written records in the possession of the Receiving Party. The terms and conditions of this Agreement shall be considered Confidential Information of both Parties.

1.22 “**Control**” or “**Controlled**” means with respect to any intellectual property right or material (including any Patent Right, Know-How or other data, information or material), the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to this Agreement) to, without violating the terms of any agreement with a Third Party, grant a license or sublicense or provide or provide access or other right in, to or under such intellectual property right or material.

1.23 “**Cover**,” “**Covering**” or “**Covers**” means, as to a Licensed Product and Patent Rights, that, in the absence of a license granted under, or ownership of, such Patent Rights, the Development, manufacture, use, offer for sale, sale or importation of such Licensed Product would infringe such Patent Rights assuming the validity and enforceability thereof.

1.24 “**CSC**” has the meaning set forth in Section 2.1.1.

1.25 “**Data**” means any and all scientific, technical, test, pharmacoeconomic, marketing, sales, pricing, reimbursement or other data pertaining to a Licensed Product that is generated by or on behalf of Vericel or its Affiliates or Sublicensees or by or on behalf of MediWound or its Affiliates or sublicensees, including research data, clinical pharmacology data, CMC data (including analytical and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with any regulatory filings (including any IND or BLA) with respect to any Licensed Product.

1.26 “**Develop**” or “**Developing**” means conducting non-clinical and clinical research *provided* that such development is made solely for the purpose of supporting the Commercialization, Manufacturing, safety profile or marketing activities and efforts of the Licensed Products in the Territory, including but not limited to, post marketing trials, manufacturing optimization and publications. When used as a noun, “Development” means any and all activities involved in Developing.

1.27 “**Development Milestone Event**” means each Development event listed in the table that appears in Section 5.2.

1.28 “**Development Milestone Payment**” has the meaning set forth in Section 5.2.

1.29 “**Development Plan**” has the meaning set forth in Section 3.2.

1.30 “**Diligence Issue**” has the meaning set forth in Section 3.4.3.

1.31 “**Disclosed Third Party Agreements**” has the meaning set forth in Section 8.2.11.

1.32 “**Disclosing Party**” has the meaning set forth in Section 7.1.

1.33 “**Distributor**” means any Third Party that (a) with respect to a country, is used by pharmaceutical manufacturers generally in such country on a non-exclusive basis, and without any intellectual property or Development right or license grant from the pharmaceutical manufacturers, to distribute (but not to market or promote) finished, packaged pharmaceutical products to pharmacies, managed care organizations, governmental agencies (e.g., federal, state and local), and other group purchasing organizations (e.g., pharmaceutical benefits managers) and the like in such country, (b) purchases any Licensed Product in finished form from or at the direction of Vericel or any of its Affiliates or Sublicensees, but does not otherwise make any royalty, milestone or similar payments to Vericel with respect to its intellectual property rights with respect to such Licensed Product, or (c) has the right to distribute, market and sell such Licensed Product (with or without packaging rights) in one or more countries in the Territory and that does not make any royalty, milestone or similar payments to Vericel in connection with its resale of such Licensed Product.

1.34 “**Effective Date**” has the meaning set forth in the Preamble.

1.35 “**Existing Distribution Agreements**” means the agreements listed as such on Schedule 8.2.11.

1.36 “**FCPA**” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.37 “**FD&C Act**” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

1.38 “**FDA**” means the United States Food and Drug Administration or any successor agency thereto.

1.39 “**Field**” means the field of Burn Indications.

1.40 “**First Commercial Sale**” means, with respect to any Licensed Product and with respect to any country of the Territory, the first sale of such Licensed Product by

Vericel or an Affiliate or Sublicensee of Vericel to a Third Party in such country after such Licensed Product has been granted Regulatory Approval by the appropriate Regulatory Authority(ies) for such country.

1.41 “**GAAP**” means United States generally accepted accounting principles, consistently applied.

1.42 “**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any supranational, national, provincial, state, regional, county, city or other political subdivision.

1.43 “**Grant**” has the meaning set forth in Section 8.2.12.

1.44 “**Gross Profit**” means Sale Price minus Supply Price.

1.45 “**Gross Receipts**” has the meaning set forth in Section 5.4.5(c).

1.46 “**ICH**” means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.47 “**IIA**” means the Israeli Innovation Authority (formerly known as the Office of the Chief Scientist in the Israeli Ministry of Industry and Commerce).

1.48 “**IND**” means an Investigational New Drug Application submitted under the FD&C Act, or an analogous application or submission with any analogous agency or Regulatory Authority outside of the United States for the purposes of obtaining permission to conduct Clinical Trials.

1.49 “**Indemnified Party**” has the meaning set forth in Section 10.4.1.

1.50 “**Infringement Claim**” has the meaning set forth in Section 6.2.4.

1.51 “**Joint Know-How**” has the meaning set forth in Section 6.1.3.

1.52 “**Joint Patent Rights**” has the meaning set forth in Section 6.1.3.

1.53 “**Joint Technology**” has the meaning set forth in Section 6.1.3.

1.54 “**Know-How**” means any invention, discovery, development, Data, information, process, method, technique, material (including any chemical or biological material), technology, result, cell line, protocol, compounds, probe, sequence, regulatory correspondence or other know-how, whether or not patentable, and any physical embodiments of any of the foregoing.

1.55 “**Law**” means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.

1.56 “**Liability**” has the meaning set forth in Section 10.2.



1.57 “**Licensed Product**” means (a) NexoBrid in its current configuration or formulation and (b) any improvements of NexoBrid developed by either Party during the Term.

1.58 “**Licensed Trademarks**” means all Trademarks owned or Controlled by MediWound or its Subsidiaries in the Territory and intended for use in connection with the Commercialization of any Licensed Product in the Territory, including the Trademarks and associated registrations and applications listed in Schedule 1.58.

1.59 “**Litigation Conditions**” has the meaning set forth in Section 10.4.2.

1.60 “**Manufacture**” or “**Manufacturing**” means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release a compound or product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing a compound or product or any component thereof.

1.61 “**MediWound Indemnified Party**” has the meaning set forth in Section 10.2.

1.62 “**MediWound In-Licenses**” means any agreements entered into by MediWound or any of its Subsidiaries with a Third Party prior to the Effective Date, including any amendments or restatements thereto during the Term, pursuant to which MediWound or any of its Subsidiaries Controls any MediWound Technology.

1.63 “**MediWound Know-How**” means any and all Know-How, other than Joint Know-How, that (a) is Controlled by MediWound or any of its Subsidiaries as of the Effective Date or that comes into the Control of MediWound or any of its Subsidiaries during the Term (other than through the grant of a license by Vericel) and (b) is reasonably necessary or useful for the research, development and commercialization of the Licensed Products in the Field in the Territory. For clarity, MediWound Know-How includes Sponsored Know-How.

1.64 “**MediWound Patent Right**” means any Patent Right, other than a Joint Patent Right, that (a) is Controlled by MediWound or any of its Subsidiaries as of the Effective Date or comes into the Control of MediWound or any of its Subsidiaries during the Term (other than through the grant of a license by Vericel) and (b) is reasonably necessary or useful for the research, development and commercialization of the Licensed Products in the Field in the Territory. For the avoidance of doubt, and without limiting the foregoing, MediWound Patent Rights include the Patent Rights set forth on Schedule 8.2.3. For clarity, MediWound Patent Right includes Sponsored Patent Right.

1.65 “**MediWound Technology**” means any and all MediWound Patent Rights and MediWound Know-How.

1.66 “**MediWound Third Party Agreement**” means any agreement between MediWound (or any of its Affiliates) and any Third Party that relates to the Licensed Products, excluding any MediWound In-Licenses.

1.67 “**MediWound Transition Activities**” has the meaning set forth in Section 3.3.

1.68 “**Net Sales**” means, with respect to a Licensed Product, the aggregate gross invoiced sales prices from sales of a Licensed Product sold by Vericel and its Affiliates or Sublicensees to independent Third Parties (including Distributors) less the following deductions as determined in accordance with GAAP, and if not previously deducted from the amount invoiced or received (to the extent stated on the applicable invoice, actually paid or credited by Vericel and its Affiliates and Sublicensees in effecting such sale and not reimbursed by any Third Party):

- (a) trade, quantity and cash discounts, credits or allowances actually paid, granted or accrued;
- (b) credits or allowances actually granted for returns, rejections, recalls or wastage replacement (due to spoilage, damage, expiration of useful life or otherwise), and for bad debts or uncollectible amounts;
- (c) rebates, chargebacks, hospital buying group/group purchasing organization administration fees or managed care organization rebates actually given or made;
- (d) rebates and similar payments actually given or made with respect to sales paid for by any Governmental Authority or Regulatory Authority;
- (e) credits or allowances actually given or made for retroactive price reductions or billing corrections (subject to true-up);
- (f) value added, sales and use, excise and other similar taxes and surcharges, duties, and other governmental charges;
- (g) charges for freight, customs and insurance with respect to the distribution and wholesaler; and
- (h) other future similar deductions, taken in the ordinary course of business in accordance with GAAP or the corresponding accounting standard in each country in the Territory.

Such amounts shall be determined from the books and records of Vericel or its Affiliates and Sublicensees, maintained in accordance with GAAP.

In the case of any sale or other disposal for value, such as barter or counter-trade, of the Licensed Products, or part thereof, other than in an arm’s length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Licensed Products in the country of sale or disposal, as determined in accordance with GAAP. For clarity, any payment to MediWound under this Agreement shall be made in cash or other payment of immediately available funds.

Notwithstanding the foregoing, the following will not be included in Net Sales for a Party: (1) sales between or among Vericel and its Affiliates or Sublicensees (but Net Sales shall include sales to the first Third Party (other than a Sublicensee) by Vericel or its Affiliates or Sublicensees), (2) samples of Licensed Products used to promote additional Net Sales, in amounts consistent with normal business practices of Vericel or its Affiliates or Sublicensees where the Licensed Products is supplied without charge or at or below the actual manufacturing cost thereof (without allocation of indirect costs or any mark-up), and (3) disposal or use of Licensed Products in Clinical Trials or under compassionate use, patient assistance, named patient use, or test marketing programs or other similar programs or studies where the Licensed Products are supplied without charge or at the actual manufacturing cost thereof (without allocation of indirect costs or any mark-up).

For avoidance of doubt, Net Sales shall also include any amounts that are paid by a Distributor to Vericel or any of its Affiliates or Sublicensees in connection with the grant or exercise of distribution rights to the extent such amounts are used as a deposit or similar payment to be credited against subsequent purchases by such Distributor from Vericel or such Affiliate or Sublicensee. Any purported Distributor that makes any payments to Vericel or any of its Affiliates or Sublicensees that are not either (i) Net Sales, as determined in accordance with the above paragraphs in this definition, or (ii) directly attributed to the fair market value of other services or products provided by Vericel or such Affiliate or Sublicensee to such Distributor, shall, in either case (clauses (i) or (ii)), be, and hereby are deemed to be, part of Net Sales for purposes of this Agreement.

With respect to sales of any Combination Product in any country, the Net Sales of the applicable Licensed Product, for purposes of the Agreement, shall be calculated by multiplying the actual Net Sales of the Combination Product by the fraction  $A/(A+B)$ , where A is the gross selling price on a country-by-country basis, during the royalty period in question, of such Licensed Product when sold separately (i.e., without the other components of the Combination Product) and B is the gross selling price on a country-by-country basis, during the royalty period in question, of the other components when sold separately. In the event that the gross selling price of such Licensed Product in a country can be determined but the gross selling price of the other components cannot be determined, Net Sales for purposes of the Agreement shall be calculated by multiplying the actual Net Sales of the Combination Product by the fraction  $A/C$ , where A is the gross selling price of such Licensed Product in such country when sold separately in finished form and C is the gross selling price of the Combination Product in such country. In the event that such separate sales are not made of such Licensed Product, Net Sales shall be calculated for purposes of the Agreement by multiplying the actual Net Sales of the Combination Product by a fraction fairly and reasonably reflecting the relative value contributed by such Licensed Product to the total value of the Combination Product as determined by mutual agreement of the Parties in good faith. For purposes of this Section 1.68, “**Combination Product**” includes a product made up of a Licensed Product and at least one active ingredient other than a Licensed Product. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be “active ingredients”, except in the case where such delivery vehicle, adjuvant, or excipient is recognized by the FDA as an active ingredient in accordance with 21 CFR 210.3(b)(7).

1.69 “**NexoBrid**” means a powder and gel for gel, for topical cutaneous use having an active pharmaceutical ingredient of concentrate of proteolytic enzymes enriched in bromelain, corresponding to 0.09 g/g concentrated of proteolytic enzymes enriched in bromelain after mixing, indicated for the removal of eschar.

1.70 “**Notice Date**” has the meaning set forth in Section 11.11.

1.71 “**Party**” and “**Parties**” have the meaning set forth in the Preamble.

1.72 “**Patent Rights**” means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.

1.73 “**Payment Discount**” has the meaning set forth in Section 9.5.1(d)(iii).

1.74 “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.75 “**PHSA**” means the United States Public Health Service Act, as amended.

1.76 “**Price Approval**” means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.77 “**Program Know-How**” has the meaning set forth in Section 6.3.

1.78 “**Program Patent Rights**” has the meaning set forth in Section 6.2.1.

1.79 [\*\*\*] has the meaning set forth in Section 5.7.

1.80 “**Receiving Party**” has the meaning set forth in Section 7.1.

1.81 “**Regulatory Approval**” means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of BLAs, supplements and amendments, pre- and post- approvals, Price Approvals, and labeling

approvals) of any Regulatory Authority, necessary for the use, Development, Manufacture, and Commercialization of a pharmaceutical product in a regulatory jurisdiction.

1.82 “**Regulatory Authority**” means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or, to the extent required in such country, Price Approval, for pharmaceutical products in such country.

1.83 “**Regulatory Exclusivity Period**” means with respect to any particular Licensed Product in any particular country in the Territory, the period of time during which (a) the data and information submitted by MediWound, Vericel or any of their respective Affiliates or Sublicensees to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval may not be disclosed, referenced or relied upon in any way by such Regulatory Authority (including by relying upon the Regulatory Authority’s previous findings regarding the safety or effectiveness of such Licensed Product) to support the Regulatory Approval or Commercialization of any product by a Third Party in such country; or (b) Vericel or any of its Affiliates or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Law) in such country to market and sell such Licensed Product in such country, including but not limited to, exclusivity under the Orphan Drug Act, Biologics Price Competition and Innovation Act and Pediatric Research Equity Act and analogous laws in other countries in the Territory.

1.84 “**Relevant Factors**” means the factors typically considered by [\*\*\*]. For purposes of clarity, Relevant Factors shall be determined on [\*\*\*].

1.85 “**Representatives**” means (a) with respect to Vericel, Vericel, its Subsidiaries, its Sublicensees and each of their respective officers, directors, employees, consultants, contractors and agents and (b) with respect to MediWound, MediWound, its Subsidiaries and each of their respective officers, directors, employees, consultants, contractors and agents.

1.86 “**Royalty Term**” means, with respect to any particular Licensed Product in any particular country in the Territory, the period commencing with the First Commercial Sale of such Licensed Product in such country and continuing until the latest of (a) the twelfth (12<sup>th</sup>) anniversary of the First Commercial Sale of such Licensed Product in such country, (b) the earliest date on which there are no Valid Claims of MediWound Patent Rights Covering such Licensed Product in such country [\*\*\*] and (c) the last day of the Regulatory Exclusivity Period for such Licensed Product in such country. For the avoidance of doubt, the Royalty Term for a given Licensed Product in a given country in the Territory (i) will not begin until the First Commercial Sale of such Licensed Product in such country, and (ii) if not previously expired, will expire immediately upon expiration or termination of this Agreement (except with respect to any existing inventory of such Licensed Product at such time as set forth in Section 9.5.1(a)).

1.87 “**Safety Data**” means Data related solely to any adverse experiences and serious adverse experience related to a drug or medical product as such information is reportable to Regulatory Authorities in the Territory. Safety Data also includes “adverse events”, “adverse drug reactions” and “unexpected adverse drug reactions” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.88 “**Sales Milestone Payment**” has the meaning set forth in Section 5.3.

1.89 “**Sale Price**” has the meaning set forth in [\*\*\*].

1.90 “**SEC**” has the meaning set forth in Section 7.3.

1.91 “**Similar Product**” means a topical agent for cutaneous use containing as the active pharmaceutical ingredient [\*\*\*]±[\*\*\*]concentrated of proteolytic enzymes enriched in bromelain after mixing or any product containing bromelain for topical use in Burn Indications.

1.92 “**Sponsored Know-How**” has the meaning set forth in Section 6.1.2.

1.93 “**Sponsored Patent Rights**” has the meaning set forth in Section 6.1.2.

1.94 “**Sponsored Technology**” has the meaning set forth in Section 6.1.2.

1.95 “**Sublicense Income**” means income received by Vericel or its Affiliates in consideration for a sublicense or other agreement providing the right to negotiate for or obtain a sublicense. Sublicense Income includes income received from a Sublicensee in the form of license issue fees, milestone payments and similar fixed payments whether by cash or by shares or other valuable consideration but specifically excludes [\*\*\*].

1.96 “**Sublicensee**” means any Person to whom Vericel grants or has granted, directly or indirectly, a sublicense of rights licensed by MediWound to Vericel under this Agreement. “Sublicensee” excludes any Distributor of a Licensed Product.

1.97 “**Subsidiaries**” means, with respect to a particular Person, a person, corporation, partnership, or other entity that is controlled by such Person. For the purposes of this definition, the word “control” (including, with correlative meaning, the term “controlled by”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of an entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.98 “**Supply Agreement**” has the meaning set forth in Section 3.9.

1.99 “**Supply Price**” has the meaning as defined in the Supply Agreement.

1.100 “**Term**” has the meaning set forth in Section 9.1.

1.101 “**Territory**” means the United States, Canada and Mexico.

1.102 “**Third Party**” means any Person other than Vericel, MediWound or their respective Affiliates.

1.103 “**Third Party Claim**” has the meaning set forth in Section 10.4.1.

1.104 “**Total Annual Net Sales**” has the meaning set forth in Section 5.3.

1.105 “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.106 “**United States**” or “**U.S.**” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.107 “**Valid Claim**” means, with respect to a particular country, a claim of an issued and unexpired MediWound Patent Right or Joint Patent Right that (a) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and (b) has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.108 “**Vericel Diligence Obligations**” means Vericel’s diligence obligations under Section 3.4.1.

1.109 “**Vericel Indemnified Party**” has the meaning set forth in Section 10.3.

1.110 “**Websites**” has the meaning set forth in Section 3.7.2(c).

## 2. GOVERNANCE.

### 2.1 Governance.

2.1.1 Central Steering Committee. The Parties hereby establish a central steering committee (the “**CSC**”) as of the Effective Date to prepare and review the Development Plan and track the progress of the Development Plan.

2.1.2 Composition of the Central Steering Committee. The CSC shall be comprised of up to three (3) representatives of each Party. Each Party shall appoint its respective representatives to the CSC and may substitute any of its representatives, in its sole discretion, effective upon notice to the other Party of such change. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend CSC meetings, subject to such representatives and consultants undertaking confidentiality obligations, whether in a written agreement or by operation of law, no less stringent than the confidentiality provisions of this Agreement.

2.1.3 Meetings. During the Term, the CSC shall meet no less frequently than once a calendar quarter, at a location mutually agreed by the Parties. Alternatively, the CSC may meet by means of teleconference, videoconference or other similar means of communication. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives. At meetings of the CSC or more frequently at the reasonable request of Vericel during the Term, MediWound shall disclose to Vericel any MediWound Know-How developed by MediWound regarding the Licensed Products since MediWound's most recent disclosure.

2.1.4 CSC Responsibilities. The CSC shall have the following responsibilities:

- (a) reviewing, commenting on and monitoring the Development Plan and all MediWound Transition Activities and any and all Development activities;
- (b) reviewing and monitoring the requirements under the BARDA Agreements; and
- (c) performing such other activities as the Parties agree in writing shall be the responsibility of the CSC.

2.1.5 Action by Consensus; Final Decision Making Authority. Regardless of the number of Vericel CSC representatives or MediWound CSC representatives attending a meeting, each Party shall have one vote, and the CSC shall endeavor to make decisions by consensus. If the CSC is unable to reach consensus with respect to a given matter, then the CSC representatives of either Party may submit such matter to the Chief Executive Officers of the Parties, or their designees (any such designee to be a senior member of the designating Chief Executive Officer's management team) for resolution. If such matter is not resolved within [\*\*\*] days following such escalation, then [\*\*\*] shall have final decision-making authority with respect to such matter, *provided* that (a) there are [\*\*\*] with respect to the matter; [\*\*\*]. Notwithstanding the foregoing, the Parties acknowledge that changes to the Statement of Work or Integrated Master Project Plan established under the BARDA Agreements, at a minimum, will require BARDA approval.

2.1.6 Limits on CSC Authority. Notwithstanding any provision of this Agreement to the contrary, (a) each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the CSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing and (b) the CSC shall not have the power to amend this Agreement or otherwise modify or waive compliance with this Agreement in any manner.

### **3. PRODUCT DEVELOPMENT AND COMMERCIALIZATION.**



3.1 General. Except as expressly set forth otherwise herein, Vericel shall have authority over and control of the Development, Regulatory Approval and Commercialization of Licensed Products in the Territory.

3.2 Development Plan. All Development of the Licensed Products in the Territory shall be conducted pursuant to the development plan (the “**Development Plan**”) attached hereto as Schedule 3.2, which will govern all research and development activities for the Licensed Products, including, but not limited to, the planning of clinical and regulatory Development, publications, presentations, and BARDA-related requirements. Until such time as MediWound’s obligations regarding Development of Licensed Products under the BARDA Agreements are transferred to and assumed by Vericel, MediWound shall be responsible at its cost for such Development activities in relation to BARDA and otherwise as further described in the Development Plan. Either Party may propose any amendments to the Development Plan, and any such amendments will be reviewed by the CSC and shall be subject to BARDA’s consent and the BARDA Agreements.

3.3 Transition Obligations of MediWound. MediWound shall cooperate with and provide timely assistance to Vericel to ensure the transition of Development, Regulatory Approval and Commercialization of Licensed Products to Vericel, including by (a) using diligent efforts to effect the transition and/or subcontract BARDA Agreements promptly after Regulatory Approval of Licensed Product has been obtained by MediWound in the United States, and (b) performing other transition activities as set forth herein, in the Development Plan or in the Supply Agreement at Vericel’s cost (clauses (a) and (b), collectively the “**MediWound Transition Activities**”). During the Term, MediWound shall, at Vericel’s expense, make appropriate personnel available to Vericel at reasonable times and places and upon reasonable prior notice for the purpose of training and the use of MediWound Technology in connection with Vericel’s research, Development, Commercialization and use of Licensed Products. Unless otherwise agreed to by the Parties, MediWound shall submit a budget to Vericel and obtain Vericel’s pre-approval of such budget for any MediWound Transition Activities or other activities to be performed by MediWound at Vericel’s cost or expense pursuant to this Section 3.

#### 3.4 Diligence.

3.4.1 Vericel Diligence Obligations. Vericel will use Commercially Reasonable Efforts to seek Regulatory Approval for the Licensed Products with respect to the Burn Indication in each country in the Territory; *provided* that in the event [\*\*\*], Vericel shall not be obligated to conduct such Clinical Trial(s). Prior to and following the receipt or assignment of the Regulatory Approval in each country in the Territory with respect to the Burn Indication as described in Section 3.5, Vericel will use Commercially Reasonable Efforts to Commercialize the Licensed Products in such country with respect to the Burn Indication, which will include, but not be limited to, the following: marketing, sale, market access/reimbursement, medical affairs and distribution of the Licensed Products in compliance with relevant legal requirements (as may be amended or updated from time to time) relating to the storage, distribution, advertising, promotion and sale of the Licensed Products in such country. For the sake of clarity, the Parties agree and acknowledge that “Commercially Reasonable Efforts” of

Vericel under this Section 3.4.1 do not obligate Vericel to obtain Regulatory Approval or Commercialize the Licensed Products in each country in the Territory.

3.4.2 Exceptions to Diligence Obligations. Notwithstanding any provision of this Agreement to the contrary, Vericel will be relieved of all Vericel Diligence Obligations to the extent that:

(a) Vericel or MediWound receives or generates any safety, tolerability or other data indicating or signaling that a Licensed Product has or would have an unacceptable risk-benefit profile or is otherwise not suitable for initiation or continuation of Clinical Trials or marketing of Licensed Product;

(b) Vericel or MediWound receives any notice, information or correspondence from an applicable Regulatory Authority, or an applicable Regulatory Authority takes any action, that indicates that a Licensed Product will not receive Regulatory Approval with respect to the Burn Indication; or

(c) MediWound fails to satisfactorily perform the MediWound Transition Activities or other obligations under this Agreement not as a result of act or omission of Vericel and such failure impairs Vericel's ability to fulfill the Vericel Diligence Obligations.

3.4.3 Assertion of Vericel Diligence Obligation Claims. If MediWound is, becomes or reasonably should be aware of facts that might form a reasonable basis to allege that Vericel has failed to meet any of its obligations under Section 3.4.1, then MediWound will promptly notify Vericel in writing of such potential alleged performance failure (each such potential alleged performance failure, a "**Diligence Issue**"). Promptly upon Vericel's receipt of any notice of a Diligence Issue pursuant to this Section 3.4.2, Vericel will contact MediWound to discuss the specific nature of such Diligence Issue and seek to identify an appropriate corrective course of action. If, no later than [\*\*\*] after Vericel's receipt of such a notice, (a) the Parties have not reached consensus regarding whether Vericel has failed to satisfy its obligations pursuant to Section 3.4.1 or (b) the Parties have not agreed upon an appropriate corrective course of action for such Diligence Issue, then such Diligence Issue will be escalated and resolved pursuant to the dispute resolution provisions set forth in Sections 11.11 and 11.12.

3.4.4 Remedies for Breach of Vericel Diligence Obligations.

(a) If Vericel materially breaches any Vericel Diligence Obligation and fails to remedy such breach within [\*\*\*] of Vericel's receipt of notice of such breach from MediWound, then MediWound may, in its sole discretion, on a Licensed Product-by-Licensed Product and country-by-country basis, elect to either: (i) terminate this Agreement with respect to a given Licensed Product in a given country in the Territory, or (ii) convert any exclusive license granted to Vericel under this Agreement with respect to a given Licensed Product in a given country into a non-exclusive license for such Licensed Product in such country.

(b) Notwithstanding the foregoing, in the event that Vericel materially breaches any Vericel Diligence Obligation with respect to the United States and fails to remedy such breach within [\*\*\*] of Vericel's receipt of notice of such breach from MediWound, then MediWound may, in its sole discretion, elect to either: (i) terminate this Agreement in its entirety, or (ii) convert any exclusive license granted to Vericel under this Agreement with respect to a given Licensed Product into a non-exclusive license. For the sake of clarity, the Parties agree and acknowledge that Vericel's failure to Develop, obtain Regulatory Approval for, or Commercialize a Licensed Product in a given country in the Territory other than the United States as specified in Section 3.4.1 will in no event constitute a basis for termination of the entire Agreement pursuant to this Section 3.4.4(b) but rather termination of the Agreement with respect to such specific country pursuant to Section 3.4.4(a).

(c) Notwithstanding the foregoing, in the event that the dispute resolution procedures set forth in Sections 11.11 and 11.12 have been invoked, the above time periods shall be tolled until such time as the final decision of a court from which no appeal is or can be taken determines that Vericel materially breached the Vericel Diligence Obligation and failed to cure such breach within [\*\*\*] of Vericel's receipt of notice of such breach from MediWound. The Parties acknowledge and agree that the elections set forth in this Section 3.4.4: (i) have been negotiated by the Parties to fully address any harm that MediWound may incur as a result of Vericel's material breach of the Vericel Diligence Obligations, and (ii) constitute MediWound's sole and exclusive remedies with respect to any breach by Vericel of any Vericel Diligence Obligation.

3.4.5 Reports. Vericel shall provide MediWound quarterly with a summary of Development and Commercialization activities relating to the Licensed Products that were performed by Vericel in the previous quarter in order to enable MediWound to monitor Vericel's compliance with the diligence efforts as described under this Agreement. In addition, Vericel shall provide MediWound by the end of the fourth (4<sup>th</sup>) quarter of each Calendar Year following the Effective Date, marketing and promotional plans for the Licensed Products for the next Calendar Year, which shall include without limitation pre-launch and launch of the Licensed Products, plans related to the main planned marketing activities and planned price of the Licensed Products.

3.4.6 No Other Covenants. Except as expressly set forth in this Section 3.4, Vericel makes no representation, warranty or covenant, either express or implied, that (a) it will successfully Develop, Commercialize or continue to Develop or Commercialize any Licensed Product in any country, (b) if Commercialized, that any Licensed Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (c) Vericel will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Licensed Product in any country, or in the Territory in general.

3.5 Regulatory Approvals. MediWound will use best efforts to file a Biologics License Application and to secure Regulatory Approval in the United States for the

initial Licensed Product with respect to the Burn Indication. MediWound shall promptly make the required submissions to FDA in order to assign such Regulatory Approval to Vericel promptly after obtaining it, but in no event later than [\*\*\*] after obtaining such Regulatory Approval, as well as all other filings with Regulatory Authorities or Governmental Authorities in the United States (including INDs) owned or Controlled by MediWound. MediWound shall use diligent efforts in order to secure FDA approval for such assignment. After such assignment, Vericel will assume responsibility for regulatory matters for Licensed Products in the United States. Outside of the United States, Vericel (itself or through its designated Affiliates, Sublicensees, Distributors or other designees) shall have the sole authority, at its sole expense except as otherwise set forth in this Agreement, to file applications for Regulatory Approval of Licensed Products in the Field in the Territory, including communicating with any Regulatory Authority both prior to and following Regulatory Approval, *provided* that any such application will be provided to MediWound for its review and comments, at least [\*\*\*] (and if not possible, at the earliest possible time) prior to the filing of any application and provide any communication to MediWound for its review and comments prior to the submission thereof to the Regulatory Authority.

3.6 Pharmacovigilance Agreement; Adverse Event Reporting. Vericel shall be solely responsible for maintaining the safety database for Licensed Products in the Territory. Within [\*\*\*] after the Effective Date, the Parties shall discuss the timing of entry into a pharmacovigilance agreement on terms that comply with ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of Safety Data relating to all Licensed Product worldwide within appropriate timeframes and in an appropriate format to enable each Party to meet both expedited and periodic regulatory reporting requirements, and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities on a worldwide basis for the reporting of Safety Data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of Safety Data. As between the Parties: (a) after the effective date of the pharmacovigilance agreement, Vericel shall become responsible for the pharmacovigilance surveillance and timely reporting of all relevant adverse drug reactions/experiences, Licensed Product quality, Licensed Product complaints and Safety Data relating to any Licensed Product to the appropriate Regulatory Authorities in the Territory; and (b) MediWound or its licensee(s) shall be responsible for the pharmacovigilance surveillance and timely reporting of all relevant adverse drug reactions/experiences, Licensed Product quality, Licensed Product complaints and Safety Data relating to any Licensed Product to the appropriate Regulatory Authorities worldwide prior to the effective date of the pharmacovigilance agreement and following the effective date of the pharmacovigilance agreement solely outside the Territory in accordance with the terms of the pharmacovigilance agreement, in each case in accordance with applicable Laws. The Parties shall cooperate with each other with respect to their respective pharmacovigilance responsibilities, and each Party shall be solely responsible for costs relating to its respective pharmacovigilance responsibilities, unless agreed otherwise by the Parties in writing.

3.7 Commercialization Activities.

3.7.1 General. As between the Parties, Vericel shall have sole and exclusive control, at its sole expense, over all matters relating to the Commercialization of Licensed Products in the Field in the Territory, including sole and exclusive control over pricing of Licensed Products.

3.7.2 Branding.

(a) General. Vericel and its designated Affiliates or Sublicensees shall have the right to brand all Licensed Products in the Territory using any one or more Trademarks, including any Licensed Trademark, that it determines appropriate for a Licensed Product, which may vary by country or within a country. Vericel or its designated Affiliates or Sublicensees shall own all rights, title and interests in and to such Trademarks (excluding the Licensed Trademarks, names, logos and other marks owned by or on behalf of MediWound or its Affiliates) and Vericel or such Affiliates or Sublicensees may file, seek registration of and maintain such Trademarks in the countries and regions they determine reasonably necessary.

(b) License Grant; Use of Licensed Trademarks. Effective as of the Effective Date, MediWound hereby grants to Vericel an exclusive (even as to MediWound), sublicensable, royalty-free, fully paid-up, license in the Territory to use the Licensed Trademarks and a non-exclusive, sublicensable, royalty-free, fully paid-up, license to use the MediWound name and trademark, in each case, in connection with the Development and Commercialization of Licensed Products in or for the Territory. All uses of the Licensed Trademarks by Vericel (and its Affiliates, Sublicensees and Distributors) in connection with the Development and Commercialization of Licensed Products in or for the Territory shall be in accordance with Regulatory Approvals and all applicable Laws and MediWound's quality control guidelines for the Licensed Trademarks, as may be amended from time to time. Vericel (and its Affiliates) shall only use the Licensed Trademarks pursuant to the terms of this Agreement in connection with the research, Development and Commercialization of Licensed Products in the Territory. Vericel shall not (and shall cause its Affiliates, Sublicensee and Distributors not to) use such Licensed Trademark to identify, or in connection with the marketing of, any other products. MediWound shall own and retain all rights to the Licensed Trademarks (in each case, together with all goodwill associated therewith throughout the Territory), and Vericel shall assign (and shall cause its Affiliates, Sublicensees, subcontractors, and Distributors to assign), and hereby does assign, to MediWound, all of its and their right, title and interest in and to such Licensed Trademarks.

(c) Websites. Schedule 3.7.2(c) contains a description of all websites of MediWound relating to Licensed Products (the "**Websites**"), including information on the IP addresses. MediWound has all rights required to operate and maintain the Websites. The Websites are not linked to any websites containing unlawful or illicit content. All links to Third Party pages are lawful, and consents required for such links have been obtained. Vericel shall establish one or more websites relating to Licensed Products for the Territory which MediWound hereby consents to be linked to

nexobrid.com, *provided* that such websites are not linked to any third party websites containing unlawful or illicit content and all links to third party pages are lawful, and consents required for such links have been obtained.

3.7.3 International and Regional Meetings. In the event that there is an international meeting being held in a country in the Territory, Vericel will have control of the presence at the meeting for Licensed Products, and MediWound may request to be included in such meeting with the right to have representation (use or shared space). In the event that there is a regional meeting for or in the Territory, Vericel will have control of the presence at the meeting for Licensed Products. In the event that there is an international meeting being held outside the Territory, MediWound or any party identified to Vericel by MediWound to act on its behalf will have control of the presence at the meeting for Licensed Products, and Vericel may request to be included in such meetings with the right to have representation (use or shared space) for Licensed Products. Notwithstanding the foregoing, each Party acknowledges that the other Party may be present at any international meeting in the other Party's territory regarding products that are not Licensed Products.

### 3.8 Extra-Territorial Sales.

3.8.1 Subject to applicable Law, Vericel agrees not to engage in any advertising or promotional activities relating to the Licensed Products directed primarily to customers or other buyers or users of the Licensed Products located outside the Territory or to accept orders for the Licensed Products from or to sell the Licensed Products outside of the Territory, and if Vericel receives any order for the Licensed Products from outside of the Territory, it shall refer such orders to MediWound. Subject to applicable Law and with the exception of sales to BARDA or another office of the U.S. Department of Health and Human Services under the BARDA Agreements, MediWound agrees not to engage in any advertising or promotional activities relating to the Licensed Products directed primarily to customers or other buyers or users of the Licensed Products located in the Territory or to accept orders for the Licensed Products from or to sell the Licensed Products inside the Territory, and if MediWound receives any order for the Licensed Products from inside the Territory, it shall refer such orders to Vericel.

3.8.2 Vericel will and shall ensure that its Affiliates, Sublicensees and Distributors will use reasonable efforts to monitor and prevent exports of the Licensed Products outside of the Territory (other than for the benefit of or as directed by MediWound) using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and shall promptly inform MediWound of any such exports of the Licensed Products and any actions taken to prevent such exports. Vericel agrees to take reasonable actions requested in writing by MediWound that are consistent with applicable Law to prevent exports of the Licensed Products from the Territory (other than for the benefit of or as directed by MediWound). MediWound will and shall ensure that its Affiliates and sublicensees will use reasonable efforts to monitor and prevent exports of the Licensed Products into the Territory (other than for the benefit of or as directed by Vericel) using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and shall promptly inform

Vericel of any such exports of the Licensed Products and any actions taken to prevent such exports. MediWound agrees to take reasonable actions requested in writing by Vericel that are consistent with applicable Law to prevent exports of the Licensed Products into the Territory (other than for the benefit of or as directed by Vericel).

3.9 Manufacturing and Supply. MediWound will supply Licensed Products pursuant to the terms of a supply agreement to be executed concurrently herewith (the “**Supply Agreement**”).

#### 4. LICENSE GRANTS.

4.1 Exclusive License from MediWound to Vericel. As of the Effective Date, MediWound hereby grants to Vericel an exclusive license (exclusive even as to MediWound) under the MediWound Technology and MediWound’s interest in the Joint Technology to Develop, have Developed, Commercialize, have Commercialized (but not to Manufacture or have Manufactured) Licensed Products in the Field and in the Territory. Notwithstanding the rights granted to Vericel in this Section 4.1, and without limiting the generality of Section 4.4, the Parties acknowledge that MediWound retains the right (non-sublicensable) to practice the MediWound Technology in the Territory to fulfill its obligations under this Agreement and the Supply Agreement, including Manufacturing the Licensed Products for Vericel, and under the BARDA Agreements until such time as MediWound’s obligations regarding Development and Commercialization of Licensed Products under the BARDA Agreements are transferred to and assumed by Vericel. For clarification purposes, this Section 4.1 shall not limit MediWound in any way from practicing the MediWound Technology for any product other than the Licensed Product.

#### 4.2 Vericel Sublicense Rights.

4.2.1 Vericel Sublicensees. Vericel shall have the right to grant sublicenses, directly or indirectly, to its Affiliates and Third Parties of any and all rights granted to Vericel under this Agreement by MediWound, including any and all rights licensed to Vericel pursuant to Section 4.1. Each sublicense agreement shall be in writing and provide that the applicable Sublicensee is bound by all applicable terms and conditions of this Agreement, including with respect to record keeping obligations and audit rights. Vericel shall remain responsible for the payment to MediWound of all milestone payments and royalties payable with respect to Net Sales of Licensed Products made by such Sublicensees. Vericel shall be responsible for the acts and omissions of its Sublicensees. Vericel shall deliver to MediWound a true, accurate and complete copy of each sublicense agreement and any material amendment or addendum thereto entered into by Vericel promptly after the execution of such sublicense agreement, amendment or addendum (which may include redaction of certain non-financial terms). It is agreed by the Parties that the right to further sublicense under any such sublicense agreement shall be subject to the prior written consent of MediWound, such consent not to be unreasonably withheld, and that if such consent is obtained Vericel shall remain liable towards MediWound with respect to such further sublicense as it is liable for its Sublicensees according to this Agreement.

4.2.2 Vericel Distributors. Subject to the terms and conditions of this Agreement, Vericel, its Affiliates and Sublicensees will have the right to appoint one or more Distributors to resell Licensed Products in finished form purchased from or at the direction of Vericel, its Affiliates or Sublicensees. The commercial rights under the license granted in Section 4.1 may be sublicensed, in full or in part, by Vericel or any of its Affiliates or Sublicensees to permit any such Distributor to resell Licensed Products pursuant to a written distribution agreement entered into with such Distributor. The terms and conditions of Section 4.2.1 will not apply with respect to the grant of such sublicense to a Distributor and such Distributor will not be deemed a “Sublicensee” hereunder as a result of any such sublicense. Vericel shall be responsible for the acts and omissions of any such Distributor. Vericel shall deliver to MediWound a true, accurate and complete copy of each distribution agreement entered into by Vericel, its Affiliates and Sublicensees and any material amendment or addendum thereto promptly after the execution of such distribution agreement, amendment or addendum (which may include redaction of certain non-financial terms).

4.2.3 Confidential Information. Notwithstanding any provision of this Agreement to the contrary, all information of the Parties, their Affiliates or their licensees or sublicensees that is disclosed to the other Party under this Section 4.2 shall be deemed to be the Confidential Information of the disclosing Party and subject to the provisions of Section 7.

#### 4.3 Rights of Reference.

4.3.1 MediWound to Vericel. MediWound hereby grants to Vericel a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b), 21 C.F.R. § 312.23(b) (or any analogous Law recognized outside of the United States), to all Data Controlled by MediWound or its Affiliates that relate to any Licensed Product, and MediWound shall provide a signed statement to this effect, if requested by Vericel, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Law outside of the United States).

4.3.2 Vericel to MediWound. Vericel hereby grants to MediWound a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b), 21 C.F.R. § 312.23(b) (or any analogous Law recognized outside of the United States), to the BLA for any Licensed Product for the Burn Indication and other filings with Regulatory Authorities Controlled by Vericel or its Affiliates that relate to any Licensed Product in the Burn Indication for use in connection with any product of MediWound, and Vericel shall provide a signed statement to this effect, if requested by MediWound, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Law outside of the United States).

4.4 No Implied Rights. Except as expressly provided in this Agreement, neither Party shall be deemed to have granted the other Party (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any intellectual property, Know-How or information Controlled by such Party.

4.5 Initial Data Transfer. Promptly following the Effective Date, MediWound shall disclose to Vericel all MediWound Know-How necessary or useful in connection with securing Regulatory Approval and Commercializing Licensed Products in the Territory,



including without limitation editable copies of (a) customer lists, marketing materials, training materials, market research and any other marketing materials, (b) material minutes, videos, and related materials of any meetings with advisors, consultants and physicians related to commercialization, and (c) and other Data Controlled by MediWound, together with such additional MediWound Know-How as Vericel may reasonably request, in each case to the extent developed by MediWound on or prior to the Effective Date, in either the format in which such MediWound Know-How then exists or in such other format as Vericel may reasonably request (including by download of digital files to a secure website or e-room designated and controlled by Vericel).

4.6 Non-Competition Obligations. During the Term, (a) Vericel shall not, directly or indirectly, itself or through any Subsidiary, Sublicensee or Third Party, Develop or Commercialize in the Territory any product containing bromelain for use in any indications other than Burn Indications and (b) MediWound shall not, directly or indirectly, itself or through any Subsidiary, Sublicensee or Third Party, Develop or Commercialize any Similar Product in the Territory. Each Party will use commercially reasonable efforts to actively monitor customer usage of pharmaceutical products containing bromelain in the Territory and limit sales to permitted indications for such Party.

4.7 Assignment of Contracts. On the Effective Date, MediWound will assign, and will cause its Subsidiaries to assign, to Vericel all contracts listed on Schedule 4.7 (the “**Assigned Contracts**”). Promptly following the written request by Vericel, MediWound will, at Vericel’s option, assign or terminate the Existing Distribution Agreements.

4.8 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the Bankruptcy Code. The Parties agree that the Parties and their respective Sublicensees, as Sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto.

## 5. PAYMENTS.

5.1 Upfront Payment. In consideration for the exclusive license granted to Vericel in Section 4.1, Vericel shall pay to MediWound a one-time non-refundable payment of seventeen million five hundred thousand dollars (\$17,500,000), within ten (10) days following the Effective Date.

5.2 Development Milestone Payments. Vericel shall pay MediWound the amounts set forth below within [\*\*\*] days following the first occurrence of the event described below for the first Licensed Product to achieve such event (the “**Development Milestone Payment**”).

| <b>Development Milestone Event</b>   | <b>Development Milestone Payment</b> |
|--------------------------------------|--------------------------------------|
| Approval of BLA in the United States | \$7,500,000                          |

The Development Milestone Payment set forth above shall be non-refundable (except for amounts paid in error) and shall be payable one time only (regardless of the number of Licensed Products with respect to which, or the number of times with respect to any Licensed Product, the specified Development Milestone Event occurs). No Development Milestone Payments shall be payable for any subsequent Licensed Product regardless of the number of Licensed Products Developed.

5.3 Sales Milestone Payments. Vericel shall pay MediWound the following non-refundable (except for amounts paid in error) one-time payments (each, a “**Sales Milestone Payment**”) when aggregate Net Sales of all Licensed Products in the Territory in a Calendar Year (the “**Total Annual Net Sales**”) first reach the respective thresholds indicated below:

| <b>Total Annual Net Sales</b>                 | <b>Sales Milestone Payment</b> |
|---|--------------------------------|
| Total Annual Net Sales exceeding \$75 million | \$7,500,000                    |
| Total Annual Net Sales exceeding [***]        | [***]                          |
| Total Annual Net Sales exceeding [***]        | [***]                          |
| Total Annual Net Sales exceeding [***]        | [***]                          |
| Total Annual Net Sales exceeding [***]        | [***]                          |

Vericel shall make any Sales Milestone Payment payable with respect to a Calendar Year within [\*\*\*] after the end of the applicable Calendar Year. For the avoidance of doubt, each of the Sales Milestone Payments set forth above shall be payable one time only, regardless of the number of times the corresponding Total Annual Net Sales levels are achieved. It is agreed that in case the Total Annual Net Sales achieved is the second, third, fourth or fifth stage and the previous step was not yet achieved, then the Sales Milestone Payment related to the previous step (or steps) shall be payable in addition to the relevant Sales Milestone Payment (for illustration purposes, if at a certain year the [\*\*\*]).

5.4 Royalty Payments; BARDA Purchases.

5.4.1 Royalties for the United States. Subject to the provisions of Section 5.4.5, Vericel shall pay MediWound non-refundable (except for amounts paid in error) royalties in the amount of the royalty rates set forth below of the aggregate Net Sales resulting from the sale of all Licensed Products, in the United States during each Calendar Year of the applicable Royalty Term for each Licensed Product:

| <b>Annual U.S. Net Sales of Licensed Products</b> | <b>Royalty Rate</b> |
|---|---------------------|
| Amount above [***]                                | [***]               |
| Amount above [***]                                | [***]               |
| Amount above [***]                                | [***]               |
| Amount above [***]                                | [***]               |

Each royalty rate set forth in the table above shall apply only to that portion of the Net Sales of the Licensed Products in the United States during a given Calendar Year that falls within the indicated range.

5.4.2 Payments for Purchases under the BARDA Agreements. The Party in receipt of the revenue from sales to BARDA or another office of the U.S. Department of Health and Human Services (“**BARDA Purchases**”) shall make the following payments to the other Party for BARDA Purchases of Licensed Products in the amounts set forth below:

(a) BARDA Purchases from MediWound.

| <b>Description</b>   | <b>Payment to Vericel</b> |
|--|---------------------------|
| BARDA Purchases of Licensed Product from MediWound on committed (CLIN 0002) procurement under BARDA Contract HHSO100201500035C     | [***]                     |
| BARDA Purchases of Licensed Product from MediWound beyond committed (CLIN 0002) procurement under BARDA Contract HHSO100201500035C | [***]                     |

(b) BARDA Purchases from Vericel.

| <b>Description</b>   | <b>Payment to MediWound</b> |
|--|-----------------------------|
| BARDA Purchases of Licensed Product from Vericel on committed (CLIN 0002) procurement under BARDA Contract HHSO100201500035C     | [***]                       |
| BARDA Purchases of Licensed Product from Vericel beyond committed (CLIN 0002) procurement under BARDA Contract HHSO100201500035C | [***]                       |

\*In the event that an amendment to the Development Plan involves an agreement by the Parties to execute an expanded access study relating to a Licensed Product and BARDA or another office of the U.S. Department of Health and Human Services agrees to fund such study under the BARDA Agreements, the payment to Vericel (if purchased from MediWound) or MediWound (if purchased from Vericel), will be changed to [\*\*\*].

(c) Responsibility for Sales to BARDA. Until such time as MediWound's obligations regarding the sale of Licensed Products under the BARDA Agreements are transferred to and assumed by Vericel, MediWound shall be responsible for selling activities in relation to BARDA Purchases.

(d) Other BARDA Fees. In the event that BARDA or another office of the U.S. Department of Health and Human Services pays other fees in connection with BARDA Purchases or the BARDA Agreements (beyond committed (CLIN 0002) procurement under BARDA Contract HHSO100201500035C), including without limitation fees for vendor managed inventory, the Parties will discuss and mutually agree to an allocation of such fees that will [\*\*\*].

5.4.3 Royalties Outside the United States. Subject to the provisions of Section 5.4.5, Vericel shall pay MediWound royalties of [\*\*\*] percent [\*\*\*] of the aggregate Net Sales resulting from the sale of Licensed Products in Canada and/or Mexico during each Calendar Year of the applicable Royalty Term for each Licensed Product. For the sake of clarity, the foregoing [\*\*\*] percent [\*\*\*] royalty will also apply to income received by Vericel under the Existing Distribution Agreements in the event any such agreements are assigned to Vericel.

5.4.4 Fully Paid-Up, Royalty Free License. Following expiration of the Royalty Term for any Licensed Product in a given country, no further royalties shall be payable in respect of sales of such Licensed Product in such country and, thereafter the licenses granted to Vericel under Sections 4.1 and 3.7.2(b) with respect to such Licensed Product in such country shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.

5.4.5 Royalty Adjustments. The following adjustments shall be made, on a Licensed Product-by-Licensed Product and country-by-country basis, to the royalties payable pursuant to Section 5.4.1, in each case, subject to the limitations set forth in Section 5.4.6:

(a) Third Party Patents. If, Vericel, in its reasonable judgment, determines that it is required to obtain a license from any Third Party in order to avoid infringement of such Third Party's patent rights as a result of the practice of its Development and/or Commercialization of any Licensed Product, whether directly or through any Vericel Affiliate or Sublicensee, then Vericel may, in its sole discretion, negotiate and obtain a license under such Patent Right(s) (each such Third Party license referred to herein as an "**Additional Third Party License**"). To the extent arising after the Effective Date and not known to MediWound as of the Effective Date, any royalty otherwise payable to MediWound under this Agreement with respect to Net Sales of any Licensed Product by Vericel, its Affiliates or Sublicensees shall be reduced by [\*\*\*]. It is further clarified that in case [\*\*\*].

(b) No Adjustment for MediWound Third Party Agreements or MediWound In-Licenses. MediWound shall be solely responsible for (i) all obligations (including any royalty or other obligations that relate to the MediWound Technology) under its agreements with Third Parties that are in effect as of the Effective Date or that

MediWound enters into during the Term, in each case, other than the Assigned Contracts, and (ii) all payments to inventors (other than inventors that are Representatives of Vericel) of MediWound Technology or Joint Technology, including payments under inventorship compensation Laws.

(c) Biosimilar Competition. As used in this Section 5.4.5(c), “**Biosimilar Competition**” means, with respect to a given Licensed Product in a given country in the Territory, that (a) one or more Biosimilar Products to such Licensed Product are available in such country and (b) [\*\*\*]. Notwithstanding any provision of this Agreement to the contrary, upon the occurrence of Biosimilar Competition with respect to a Licensed Product in a given country in the Territory, any royalty payments owed with respect to such Licensed Product in such country pursuant to this Section 5.4 shall be [\*\*\*].

5.4.6 Limitations on Adjustments. Notwithstanding anything herein to the contrary, in no event shall the royalties payable to MediWound for any Licensed Product under this Agreement be [\*\*\*].

5.5 Sublicense Income. In addition to any and all the payments to be made under Sections 5.2, 5.3 and 5.4 above, Vericel shall pay to MediWound a percentage of any Sublicense Income received by Vericel as indicated in the table below:

| Type of Sublicense Income   | % of Sublicense Income Payable to MediWound |
|---|---|
| Sublicense Income received by Vericel for grants of rights within the United States | [***]                                       |
| Sublicense Income received by Vericel for grants of rights outside the U.S.         | [***]                                       |

5.6 Reports and Payments.

5.6.1 Cumulative Royalties. The obligation to pay royalties under this Agreement shall be imposed only once with respect to any sale of any given unit of a Licensed Product.

5.6.2 Royalty and Sublicense Income Reports. Within [\*\*\*] after the end of each Calendar Quarter and [\*\*\*] after the end of each Calendar Year, Vericel shall deliver to MediWound a report setting out all details necessary to calculate the royalties and Sublicense Income due under this Section 5 for such Calendar Quarter, including with respect to each country:

(a) Number of each Licensed Product sold by Vericel, its Affiliates and Sublicensees in each country, and the corresponding name of each such Licensed Product;

- (b) Gross sales, Net Sales of each Licensed Product made by Vericel, its Affiliates and Sublicensees;
- (c) Royalties;
- (d) Sublicense Income;
- (e) The method and currency exchange rates (if any) used to calculate the royalties and Sublicense Income; and
- (f) Date of First Commercial Sale.

5.6.3 Royalty and Sublicense Payment Terms. Within [\*\*\*] after the end of each Calendar Quarter and [\*\*\*] after the end of each Calendar Year, Vericel shall pay MediWound the royalties and Sublicense Income with respect to the applicable quarter and in accordance with the report submitted in accordance with Section 5.6.2 above.

5.6.4 Taxes and Withholding. It is understood and agreed between the Parties that any payments made by Vericel under this Agreement are exclusive of any value added or similar tax imposed upon such payments. In addition, in the event any payments made by Vericel pursuant to this Agreement become subject to withholding taxes under the Laws or regulations of any jurisdiction or Governmental Authority, Vericel shall deduct and withhold the amount of such taxes for the account of MediWound to the extent required by applicable Laws or regulations; such amounts payable to MediWound shall be reduced by the amount of taxes deducted and withheld; and Vericel shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and transmit to MediWound an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable MediWound to claim such payment of taxes. Any such withholding taxes required under applicable Laws or regulations to be paid or withheld shall be an expense of, and borne solely by, MediWound. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable Laws. Vericel will provide MediWound with reasonable assistance to enable MediWound to recover such taxes as permitted by applicable Laws or regulations.

5.6.5 Currency. All amounts payable and calculations under this Agreement shall be in United States dollars. As applicable, Net Sales and any adjustments to payments under this Agreement shall be translated into United States dollars at the exchange rate used by Vericel for public financial accounting purposes. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Section 5, the Parties shall consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then Vericel may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

5.6.6 Method of Payment. Except as permitted pursuant to Section 5.6.5, each payment hereunder shall be made by electronic transfer in immediately available funds via a bank wire transfer as set forth in the attached Schedule 5.6.6 as may be amended in writing and executed by the CFO or the CEO of MediWound at least [\*\*\*] before the payment is due.

5.6.7 Record Keeping. Vericel shall keep and shall cause its Affiliates and Sublicensees to keep books and accounts of record in connection with the sale of Licensed Products in sufficient detail to permit accurate determination of all figures necessary for verification of royalties and Sales Milestone Payments to be paid hereunder and in accordance with the guidelines and standard of books of the Big Four. Vericel and its Affiliates and Sublicensees shall maintain such records for a period of at least [\*\*\*] after the end of the Calendar Quarter in which they were generated. The annual financial statements of Vericel shall be audited as required by Law [\*\*\*].

5.6.8 Audits. Upon [\*\*\*] prior notice from MediWound, Vericel shall permit an independent certified public accounting firm from the Big Four or from other accounting firm of nationally recognized standing selected by MediWound and reasonably acceptable to Vericel, to examine, at MediWound's sole expense, the relevant books and records of Vericel and its Affiliates and Sublicensees as may be reasonably necessary to verify the amounts reported by Vericel in accordance with Section 5.6.2 and the payment of royalties and Sales Milestone Payments hereunder. An examination by MediWound under this Section 5.6.8 shall occur not more than once in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than five (5) years before the date of the request. The accounting firm shall be provided access to such books and records at Vericel's or its Affiliates' or Sublicensees' facility(ies) where such books and records are normally kept and such examination shall be conducted during Vericel's normal business hours. Vericel may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to Vericel's or its Affiliates' or Sublicensees' facilities or records. Upon completion of the audit, the accounting firm shall provide both Vericel and MediWound a written report disclosing any discrepancies in the reports submitted by Vericel or the royalties or Sales Milestone Payments paid by Vericel, and, in each case, the specific details concerning any discrepancies.

5.6.9 Underpayments/Overpayments. If any audit conducted pursuant to Section 5.6.8 concludes that additional royalties, Sublicense Income or milestone payments were due to MediWound, then Vericel will pay to MediWound the additional royalties, Sublicense Income or milestone payments, plus interest on the deficient amount, as calculated pursuant to Section 5.6.10, within [\*\*\*] of the date Vericel receives such accountant's written report. Further, if the amount of such underpayments [\*\*\*]. If any audit conducted pursuant to Section 5.6.8 concludes that Vericel overpaid royalties or Sales Milestone Payments to MediWound, then such overcharges or overpayments shall be credited against future royalty payments.

5.6.10 Late Payments. Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. In the event that any payment due under this Agreement is not made when due, the amount due shall accrue interest beginning on the [\*\*\*] following the date on which such payment was due, calculated at the [\*\*\*] for the due date, or, if lower, the maximum rate permitted by law, calculated from the due date until paid in full. Each payment made after the due date shall be accompanied by all interest so accrued. Notwithstanding the foregoing, a Party shall have recourse to any other remedy available at law or in equity with respect to any delinquent payment, subject to the terms of this Agreement.

5.6.11 Other Reports. Vericel will provide MediWound any reports and information and any related documentations in a timely manner, which shall be required for MediWound to comply with any applicable Law (including, but not limited to, any securities law and regulations), terms of the BARDA Agreements and any MediWound In-License agreements.

5.6.12 Confidentiality. Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of the Parties, their Affiliates or their Sublicensees which are provided to or subject to review by the other Party under this Section 5 shall be deemed to be the Confidential Information of the reporting or audited Party, as applicable, and subject to the provisions of Section 7.

5.6.13 MediWound Payments. In the event that MediWound is required to make any payments under Section 5.4.2 or Section 5.7, the provisions of Section 5.6 shall apply *mutatis mutandis*.

5.7 [\*\*\*]

5.1 No Guarantee of Success. Vericel and MediWound acknowledge and agree that payments to MediWound pursuant to Section 5.2, Section 5.3 and Section 5.4: (a) have been included in this Agreement on the basis that they are only payable or otherwise relevant if a Licensed Product is successfully Developed or Commercialized, as applicable, and (b) are not intended to be used and will not be used as a measure of damages if this Agreement is terminated for any reason, including pursuant to Vericel's right to terminate for convenience in compliance with the terms of this Agreement, before any such success is achieved and such amounts become due.

## **6. INTELLECTUAL PROPERTY**

### 6.1 Ownership of Intellectual Property.

6.1.1 Ownership of Inventions. Subject to the grant of licenses to Vericel under Section 4.1 and the Parties' other rights and obligations under this Agreement, including Sections 6.1.2 and 6.1.3, each Party shall own all rights, title and interests in and to: (a) any and all Know-How and Licensed Products (i) owned by such Party prior to the Effective Date or (ii) made solely by or on behalf of such Party or its Representatives in connection with their activities under this Agreement and (b) any and all Patent Rights claiming any such Know-



How, or Licensed Products described in clause (a) of this Section 6.1.1. Inventorship shall be determined in accordance with United States patent laws.

6.1.2 Ownership of Sponsored Technology. Notwithstanding any provision of Section 6.1.1 to the contrary, MediWound shall own all rights, title and interests in and to: (a) any and all Know-How, whether or not patentable and including all pharmacological, toxicological, pre-clinical, clinical, analytical, manufacturing related, quality control and other data, discovered, developed or made solely by or on behalf of MediWound or its Representatives related to the Licensed Products or MediWound Technology or made either by MediWound or jointly by or on behalf of (i) MediWound or its Representatives and (ii) Vericel or its Representatives directly related to the Licensed Products or MediWound Technology (“**Sponsored Know-How**”) and (b) any and all Patent Rights claiming any invention included in Sponsored Know-How (“**Sponsored Patent Rights**,” and, together with Sponsored Know-How, “**Sponsored Technology**”). Vericel agrees to assign and hereby assigns, and shall cause its Representatives to assign, to MediWound all rights, title and interests throughout the world in and to any and all Sponsored Technology. Further, Vericel shall, and shall cause its Representatives to (a) disclose to MediWound any Sponsored Technology created or conceived during the Term, (b) deliver all physical embodiments of Sponsored Technology to MediWound and (c) execute any and all assignments, applications for domestic and foreign patents and other documents and to do such other acts (including the execution and delivery of instruments of further assurance or confirmation) reasonably requested by MediWound to assign the Sponsored Technology to MediWound and to permit MediWound or its designees to practice and enforce the Sponsored Technology.

6.1.3 Ownership of Joint Technology. Notwithstanding any provision of Section 6.1.1 to the contrary, the Parties shall jointly own all rights, title and interests in and to: (a) any and all Know-How, whether or not patentable and including all pharmacological, toxicological, pre-clinical, clinical, analytical, manufacturing related, quality control and other data, discovered, developed or made solely by or on behalf of Vericel or its Representatives (excluding MediWound) directly related to the Licensed Products for use in the Burn Indication or MediWound Technology (“**Joint Know-How**”) and (b) any and all Patent Rights claiming any invention included in Program Know-How (“**Joint Patent Rights**,” and, together with Joint Know-How, “**Joint Technology**”). Subject to the grant of licenses to Vericel under Section 3.1 and the Parties’ other rights and obligations under this Agreement, each Party shall be free to exploit, either itself or through the grant of licenses to Third Parties (which Third Party licenses may be further sublicensed), Joint Patent Rights and Joint Know-How throughout the world without restriction, without the need to obtain further consent from or provide notice to the other Party, and without any duty to account or otherwise make any payment of any compensation to the other Party.

## 6.2 Patent Rights.

6.2.1 Filing, Prosecution and Maintenance of MediWound Patent Rights and Joint Patent Rights. To the extent certain MediWound Patent Rights or Joint Patent Rights include claims directed to the use of the Licensed Products in the Field and in the Territory,

Vericel shall have the first right with respect to such MediWound Patent Rights and the Joint Patent Rights in the Territory (collectively, the “**Program Patent Rights**”), but not the obligation, to prepare, file, prosecute and maintain the Program Patent Rights at Vericel’s sole cost and expense. Vericel shall consult and reasonably cooperate with MediWound with respect to the preparation, filing, prosecution and maintenance of the Program Patent Rights, including: (i) allowing MediWound a reasonable opportunity and reasonable time to review and comment regarding relevant communications to Vericel and drafts of any responses or other proposed filings by Vericel before any applicable filings are submitted to any relevant patent office or Governmental Authority and (ii) considering in good faith any reasonable comments offered by MediWound with respect to any final filings submitted by Vericel to any relevant patent office or Governmental Authority. MediWound shall promptly execute such documents and perform such acts as may be reasonably necessary for Vericel to prepare, file, prosecute and maintain the Program Patent Rights, including making available to Vericel its authorized attorneys, agents or representatives, or such of its employees, in each case, as are reasonably necessary to assist Vericel in obtaining and maintaining the patent protection described in this Section 6.2.1. If Vericel elects not to file a patent application for an invention or application included in the Program Patent Rights in a given country or elects to cease the prosecution or maintenance of any Program Patent Right in a given country, then Vericel shall provide MediWound with written notice promptly, but not less than [\*\*\*] before any action is required, upon the decision to not file or continue the prosecution of such patent application or maintenance of such patent, *provided* that Vericel shall be obligated to file or maintain a patent application in the United States. In such event, MediWound shall have the right, but not the obligation, to file or continue prosecution or maintenance of any such Program Patent Right in such country and at MediWound’s expense. Further, in such event Vericel shall promptly execute such documents and perform such acts as may be reasonably necessary for MediWound to prepare, file, prosecute and maintain the Program Patent Rights, including making available to MediWound its authorized attorneys, agents or representatives, or such of its employees, in each case, as are reasonably necessary to assist MediWound in obtaining and maintaining the patent protection described in this Section 6.2.1. For clarity and notwithstanding the above, with respect to MediWound Patent Rights in the patent family known as MWD/006 and with respect to any of the MediWound Patent Rights or Joint Patent Rights that relate to a MediWound product other than Licensed Products in the Field, MediWound shall have the first right with respect to such MediWound Patent Rights and to such Joint Patent Rights in the Territory and the above terms shall apply *mutatis mutandis*.

#### 6.2.2 Enforcement and Defense of Patent Rights.

(a) Enforcement of MediWound Patent Rights and Joint Patent Rights. Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of a patent under the Program Patent Rights in the Territory by any Third Party. As between Vericel and MediWound, Vericel shall have the first right, except as otherwise provided in this Section 6.2.2, but not the obligation, to institute litigation or take other steps to remedy infringement in connection therewith, and any such litigation or steps shall be at Vericel’s expense, subject to MediWound’s obligations to indemnify Vericel for such expenses pursuant to Section 10 (to the extent applicable);

*provided* that any recoveries resulting from such litigation or steps relating to a claim of Third Party infringement, after deducting Vericel's out of pocket expenses (including counsel fees and expenses and any amounts paid to MediWound for its cooperation with such litigation) in pursuing such claim, will be awarded to Vericel and treated as Sublicense Income for purposes of payments to MediWound. Vericel shall not, without the prior written consent of MediWound, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Program Patent Rights in the Territory or (ii) requires Vericel or MediWound to abandon or relinquish any Program Patent Rights in the Territory; or (iii) may affect any of MediWound's rights with respect to MediWound Patent Rights or Joint Patent Rights relate(s) to the Licensed Products outside the Territory. If necessary in order to establish standing for Vericel, MediWound, upon request of Vericel, agrees to timely commence or to join in any such litigation, and in any event to cooperate with Vericel in such litigation or steps, all at Vericel's expense. MediWound will have the right to consult with Vericel about such litigation and to participate in and be represented by independent counsel in such litigation at MediWound's own expense. If Vericel fails to institute such litigation or otherwise take steps to remedy the actual, potential or suspected infringement of a Program Patent Right in the Territory (A) within [\*\*\*] of its receipt of notice thereof in the case of a MediWound Patent Right, or (B) within [\*\*\*] of its receipt of notice thereof in the case of a Joint Patent Right, then MediWound shall have the right, but not the obligation, upon [\*\*\*] prior notice to Vericel, at MediWound's expense, to institute any such litigation and MediWound will solely retain any recoveries resulting from such litigation or steps. If necessary in order to establish standing for MediWound, Vericel, upon request of MediWound, agrees to timely commence or to join in any such litigation, and in any event to cooperate with MediWound in such litigation or steps at MediWound's expense. Vericel will have the right to consult with MediWound about such litigation and to participate in and be represented by independent counsel in such litigation at Vericel's own expense. MediWound shall not, without the prior written consent of Vericel, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Program Patent Rights in the Territory or (ii) requires Vericel or MediWound to abandon or relinquish any Program Patent Rights in the Territory. Except in the case of a breach of a term of this Agreement, neither Party shall incur any liability to the other Party as a consequent of any litigation initiated or pursued pursuant to this Section 6.2.2(a) or any unfavorable decision resulting therefrom, including any decision holding any MediWound Patent Right or Joint Patent Right invalid or unenforceable.

### 6.2.3 Allegations of Infringement and Right to Seek Third Party Licenses.

(a) Notice. If the Development, Manufacture, Commercialization or use of any Licensed Product, the practice of any MediWound Technology or Joint Technology, or the exercise of any other right granted by MediWound to Vericel hereunder by Vericel or any of its Affiliates or Sublicensees is alleged by a Third Party to infringe, misappropriate or otherwise violate such Third

Party's Patent Rights or other intellectual property rights, then the Party discovering the same shall, promptly upon becoming aware of such allegation, notify the other Party in writing. Additionally, if either Party determines that, based upon the review of any Third Party Patent Right or other Third Party intellectual property rights, it may be desirable to obtain a license from such Third Party with respect thereto so as to avoid any potential claim of infringement by such Third Party against either Party or their respective Affiliates or Sublicensees, then such Party shall promptly notify the other Party of such determination.

6.2.4 Third Party Infringement Suits. Each of the Parties shall promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Vericel or MediWound or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture, Commercialization or use of any Licensed Product or the practice of any Joint Technology (any such suit or other action referred to herein as an "**Infringement Claim**"). In the case of any Infringement Claim against Vericel (including its Affiliates or Sublicensees) alone or against both Vericel and MediWound (including its Affiliates) solely with respect to the Development or Commercialization of Licensed Products, Vericel shall have the right, but not the obligation, at Vericel's sole cost and expense subject to the provisions of this Section 6.2.4, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. MediWound, upon request of Vericel, agrees to join in any litigation associated with any Infringement Claim at Vericel's expense and in any event to reasonably cooperate with Vericel at Vericel's expense (in all cases subject to MediWound's indemnification obligations under Section 10.3). MediWound will have the right to consult with Vericel concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which MediWound is a party at MediWound's own expense. Vericel shall not, without the prior written consent of MediWound, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Program Patent Rights in the Territory or (ii) requires Vericel or MediWound to abandon or relinquish any Program Patent Rights in the Territory; or (iii) may affect any of MediWound's rights with respect to MediWound Patent Rights or Joint Patent Rights relate(s) to the Licensed Products outside the Territory. In the case of any Infringement Claim against MediWound (including MediWound's Subsidiaries) alone, MediWound shall have the right, but not the obligation, at MediWound's sole cost and expense, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith; *provided* that MediWound shall not, without the prior written consent of Vericel, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Program Patent Rights in the Territory or (ii) requires Vericel or MediWound to abandon or relinquish any Program Patent Rights in the United States or Canada. Vericel shall have the right to consult with MediWound concerning such Infringement Claim and Vericel, upon request of MediWound, will reasonably cooperate with MediWound at MediWound's expense (but Vericel shall have no obligation to join any Infringement Claim or associated litigation).

6.2.5 Other Actions by Third Parties. Each Party shall promptly notify the other Party in the event of any legal or administrative action by any Third Party involving any Program Patent Rights in the Territory of which it becomes aware, including any nullity, revocation, interference, reexamination or compulsory license proceeding. Vericel shall have the first right, but not the obligation, to defend against any such action involving any Program Patent Rights in the Territory, in its own name (to the extent permitted by applicable Law), and any such defense shall be at Vericel's reasonable expense, subject to MediWound's obligations to indemnify Vericel for such expenses pursuant to Section 10 (to the extent applicable). MediWound, upon Vericel's request, agrees to join in any such action at Vericel's expense and in any event to cooperate with Vericel at Vericel's expense. If Vericel fails to defend against any such action involving a MediWound Patent Right or Joint Patent Right, then MediWound shall have the right to defend such action, in its own name, and any such defense shall be at MediWound's expense. In such event, Vericel, upon MediWound's request, shall reasonably cooperate with MediWound in any such action at MediWound's expense.

6.2.6 Patent Term Restoration and Extension. Vericel shall be obligated to seek in the United States and Canada, in MediWound's name if so required, patent term extensions, and supplemental protection certificates and the like available under Law, including 35 U.S.C. § 156 and applicable foreign counterparts in relation to the Program Patent Rights at Vericel's sole cost and expense. MediWound and Vericel shall coordinate and cooperate in connection with all such activities. Vericel, its agents and attorneys will give due consideration to all suggestions and comments of MediWound regarding any such activities, but in the event of a disagreement between the Parties, Vericel will have the final decision-making authority; *provided, however*, that Vericel shall seek (or allow MediWound to seek) to extend any MediWound Patent Right at MediWound's request, including through the use of supplemental protection certificates and the like, unless in Vericel's reasonable legal determination such MediWound Patent Right may not be extended under Law without limiting Vericel's right to extend any other Patent Right.

6.3 Enforcement and Defense of Joint Know-How. Each Party will promptly notify the other in the event of any actual, potential or suspected misappropriation of any MediWound Know-How or Joint Know-How ("**Program Know-How**") by any Third Party. As between Vericel and MediWound, with respect to such misappropriation that relates solely to the Licensed Products, Vericel shall have the first right, except as otherwise provided in this Section 6.3, but not the obligation, to institute litigation or take other steps to remedy misappropriation of the MediWound Know-How in the Territory or of the Joint Know-How in connection therewith, and any such litigation or steps shall be at Vericel's expense, subject to MediWound's obligations to indemnify Vericel for such expenses pursuant to Section 10 (to the extent applicable); *provided* that any recoveries resulting from such litigation or steps after deducting Vericel's out of pocket expenses (including counsel fees and expenses and any amounts paid to MediWound for its cooperation with such litigation) in pursuing such claim, will be shared equally by MediWound and Vericel. Vericel shall not, without the prior written consent of MediWound, enter into any compromise or settlement relating to such litigation that (a) admits that all or any portion of the MediWound Know-How or Joint Know-How is not protectable under relevant trade secret Laws or (b) requires Vericel or MediWound to abandon or

relinquish trade secret protection for any MediWound Know-How or Joint Know-How. If necessary in order to establish standing for Vericel, MediWound, upon request of Vericel, agrees to timely commence or to join in any such litigation, at Vericel's expense, and in any event to cooperate with Vericel in such litigation or steps at Vericel's expense. MediWound will have the right to consult with Vericel about such litigation and to participate in and be represented by independent counsel in such litigation at MediWound's own expense. If Vericel fails to institute such litigation or otherwise take steps to remedy the actual, potential or suspected misappropriation of any MediWound Know-How or Joint Know-How in the Territory (i) within [\*\*\*] of its receipt of notice thereof in the case of any MediWound Know-How, or (ii) within [\*\*\*] of its receipt or notice thereof in the case of any Joint Know-How, then MediWound shall have the right, but not the obligation, upon [\*\*\*] prior notice to Vericel, at MediWound's expense, to institute any such litigation. If necessary in order to establish standing for MediWound, Vericel, upon request of MediWound, agrees to timely commence or to join in any such litigation, and in any event to cooperate with MediWound in such litigation or steps at MediWound's expense. Vericel will have the right to consult with MediWound about such litigation and to participate in and be represented by independent counsel in such litigation at Vericel's own expense. MediWound shall not, without the prior written consent of Vericel, enter into any compromise or settlement relating to such litigation that (a) admits that all or any portion of the MediWound Know-How or Joint Know-How is not protectable under relevant trade secret Laws or (b) requires Vericel or MediWound to abandon or relinquish trade secret protection for any MediWound Know-How or Joint Know-How.

6.4 Recording. If Vericel deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority(ies) solely with respect to the Program Patent Rights in one or more jurisdictions in the Territory, MediWound shall reasonably cooperate to execute and deliver to Vericel any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Vericel's reasonable judgment, to complete such registration or recordation. Vericel shall reimburse MediWound for all reasonable out-of-pocket expenses, including attorneys' fees, incurred by MediWound in complying with the provisions of this Section 6.4.

## 7. CONFIDENTIALITY.

7.1 Confidentiality. Except to the extent expressly authorized by this Agreement, the Parties agree that each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder shall: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement.

### 7.2 Authorized Disclosure.

7.2.1 Disclosure to Party Representatives. Notwithstanding the foregoing provisions of Section 7.1, the Receiving Party may disclose Confidential Information

belonging to the Disclosing Party to the Receiving Party's Representatives who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Section 7. In any event, the Receiving Party shall remain liable for any breach of the terms of this Agreement by such Representative.

7.2.2 Disclosure to Third Parties. Notwithstanding the foregoing provisions of Section 7.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:

- (a) to Governmental Authorities (i) to the extent desirable to obtain or maintain INDs or Regulatory Approvals for any Licensed Product within the Territory, and (ii) in order to respond to inquiries, requests or investigations relating to Licensed Products in the Territory or this Agreement;
- (b) in connection with filing or prosecuting Program Patent Rights as permitted by this Agreement;
- (c) in connection with prosecuting or defending litigation as permitted by this Agreement; or
- (d) to the extent necessary or desirable in order to enforce its rights under this Agreement.

If the Receiving Party deems it reasonably necessary to disclose Confidential Information belonging to the Disclosing Party pursuant to this Section 7.2.2, then the Receiving Party shall to the extent possible give reasonable advance written notice of such disclosure to the Disclosing Party and take such measures to ensure confidential treatment of such information as is reasonably requested by the Disclosing Party, at the Disclosing Party's expense.

7.3 SEC Filings and Other Disclosures. Either Party may disclose the terms of this Agreement to the extent required (including any requirement of either Party's shareholders), to comply with applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission ("**SEC**") or any equivalent governmental agency and stock market regulations in any country in the Territory. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 7.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the disclosing Party providing as much advance notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 7.3, such Party shall, at its own expense, seek such confidential treatment of confidential portions of this Agreement, as may be reasonably requested by the other Party.

7.4 Public Announcements; Publications. Except as may be expressly permitted under Section 7.2, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. MediWound shall submit to Vericel for review and approval any proposed public announcement relating to any Licensed Product in the Territory. MediWound will not make any publication or presentation relating to any Licensed Product in the Territory without Vericel's prior written approval, such approval not to be unreasonably withheld except that no such approval shall be required in connection with any presentation or overview made for shareholders or potential shareholders of MediWound. MediWound shall submit any such intended publication or presentation to Vericel at least [\*\*\*] prior to submission for publication or presentation in order to enable Vericel to provide any comments and to protect its intellectual property rights and its Confidential Information and to further ensure that such publication or presentation will not adversely affect the Development, Manufacture or the Commercialization of the Licensed Product in the Territory and upon Vericel's request, will delay publication or presentation of same for an additional [\*\*\*] in order to enable Vericel to file patent applications to protect its intellectual property rights. For the sake of clarity, nothing in this Agreement shall prevent Vericel from making any scientific publication or public announcement with respect to any product under this Agreement; *provided, however*, that, except as permitted under Section 7.2, Vericel shall not disclose any of MediWound's Confidential Information in any such publication or announcement without obtaining MediWound's prior written consent to do so and shall submit such intended publication to MediWound at least [\*\*\*] prior to submission of such publication or presentation in order to enable MediWound to provide any comments and to protect its intellectual property rights and its Confidential Information and to further ensure that such publication or presentation will not adversely affect the Development, Manufacture or the Commercialization of the Licensed Product outside the Territory and upon MediWound's request, will delay publication or presentation of same for an additional [\*\*\*] in order to enable MediWound to file patent applications to protect its intellectual property rights. With respect to any proposed publications or announcements by investigators or academic or non-profit collaborators, such materials will be subject to review under this Section 7.4 to the extent that Vericel or MediWound, as the case may be, has the right and ability to do so within such time periods. Notwithstanding the foregoing, without prior consent of the other Party, each Party may disseminate material substantially similar to material included in a press release or other document previously approved for external distribution by the other Party. The Parties agree that each Party may release the announcement attached hereto as Schedule 7.4 regarding the signing of this Agreement on or following the Effective Date. The Parties' rights and obligations in this Section 7.4 shall not derogate from the Parties' obligations (if any) towards BARDA under the BARDA Agreements.

## **8. REPRESENTATIONS AND WARRANTIES; COVENANTS.**

8.1 Mutual Representations and Warranties. Each of MediWound and Vericel hereby represents and warrants to the other Party that:

8.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;



8.1.2 the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

8.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

8.1.4 this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms; and

8.1.5 the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Effective Date.

8.2 Representations and Warranties of MediWound. MediWound hereby represents and warrants to Vericel that:

8.2.1 subject to the terms of the BARDA Agreements, MediWound is the sole and exclusive owner of, or otherwise Controls pursuant to a MediWound In-License, the MediWound Technology, all of which is free and clear of any claims, liens, charges or encumbrances;

8.2.2 MediWound has and will have the full right, power and authority to grant all of the rights, title and interests in and to the licenses and other rights granted or to be granted to Vericel, Vericel's Affiliates or Vericel's Sublicensees under this Agreement;

8.2.3 as of the Effective Date, (a) Schedule 8.2.3 sets forth a true and complete list of all Patent Rights owned or otherwise Controlled by MediWound or its Subsidiaries that relate to the Licensed Products, (b) each such Patent Right remains in full force and effect and (c) MediWound or its Subsidiaries have timely paid all filing and renewal fees payable with respect to such Patent Rights. For each such Patent Right that is owned, but not owned exclusively, by MediWound, or that is licensed to MediWound, Schedule 8.2.3 identifies the Third Party owner(s) and, if applicable, the MediWound In-License pursuant to which MediWound Controls such MediWound Patent Right;

8.2.4 as of the Effective Date, Schedule 8.2.4 sets forth a [\*\*\*] related to the Licensed Products. MediWound has provided Vericel with true and correct copies of each of the MediWound In-Licenses. MediWound and its Subsidiaries are in compliance in all material respects with all MediWound In-Licenses;

8.2.5 as of the Effective Date, MediWound has made available to Vericel all material scientific and technical information relating to safety and efficacy known to it or its Subsidiaries with respect to the Licensed Products;

8.2.6 to its best knowledge, the MediWound Patent Rights, are, or, upon issuance, will be, valid and enforceable patents and, as of the Effective Date, no Third Party (a) is infringing any MediWound Patent Right or (b) has challenged or threatened to challenge the scope, validity or enforceability of any MediWound Patent Right (including, by way of example, through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);

8.2.7 it has complied in all material respects with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the MediWound Patent Rights;

8.2.8 MediWound has independently developed all MediWound Know-How or otherwise has a valid right to use, and to permit Vericel, Vericel's Affiliates and Vericel's Sublicensees to use the MediWound Know-How for all permitted purposes under this Agreement;

8.2.9 it has obtained from all inventors of MediWound Technology existing as of the Effective Date, valid and enforceable agreements assigning to MediWound each such inventor's entire right, title and interest in and to all such MediWound Technology;

8.2.10 neither MediWound nor any of its Subsidiaries are party to or otherwise subject to any agreement, arrangement or settlement which limits the ownership or licensed rights of Vericel or its Affiliates with respect to, or limits the ability of Vericel or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any intellectual property right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement, arrangement or settlement, be included in the rights licensed or assigned to Vericel or its Affiliates pursuant to this Agreement;

8.2.11 (a) there are no [\*\*\*] under this Agreement, except for (i) agreements with employees or consultants, (ii) contract research agreements entered into in the ordinary course of business that do not assign or grant to any Third Party any right, title or interest in or to, or any license to the Licensed Products except for the BARDA Agreements and the Existing Distribution Agreements, and (iii) the MediWound Third Party Agreements expressly disclosed in Schedule 8.2.11 (each, a "**Disclosed Third Party Agreement**"), true and complete copies of which have been provided to Vericel, (b) except as provided in the [\*\*\*] and the BARDA Agreements, no Third Party has any right, title or interest in or to, or any license under, the Licensed Products in the Territory, (c) no rights granted by or to MediWound or its Subsidiaries under [\*\*\*] conflict with any right or license granted to Vericel or its Affiliates hereunder and (d) MediWound and its Subsidiaries are in compliance in all material respects with all Disclosed Third Party Agreements;

8.2.12 Schedule 8.2.12 sets forth a complete and accurate list of all pending, previously issued and outstanding loans, grants, awards, material direct incentives, material direct subsidies and agreements for funding (each, a "**Grant**" and collectively,

“Grants”) from any Governmental Authority related to the Licensed Products granted to MediWound or any of its Subsidiaries, the amount of such Grant and, if applicable, a description of the period for which such Grant applies or applied. MediWound has made available to Vericel true and complete copies of all documents evidencing Grants submitted by MediWound or any of its Subsidiaries and of all letters of approval, and supplements thereto, granted to MediWound or any of its Subsidiaries related to the Licensed Products, except documents that do not contain any information materially different than the information contained in the documents provided to Vericel;

8.2.13 MediWound and its Subsidiaries (a) have complied in all material respects (and any past non-compliance by MediWound or its Subsidiaries has not placed any Grant by the IIA or BARDA related to the Licensed Products at risk of revocation or termination), and are in compliance with the terms and conditions of all Grants related to the Licensed Products, including without limitation the Grants by the IIA and BARDA set forth on Schedule 8.2.12, and (b) have duly fulfilled, in all material respects, all the undertakings and requirements of applicable Laws relating to such Grants;

8.2.14 except as required from IIA or from BARDA in connection with the BARDA Agreements, no consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by MediWound in connection with the authorization, execution and delivery by MediWound of this Agreement;

8.2.15 other than IIA review and approval of this Agreement and the Supply Agreement between the parties and except for the rights of BARDA set forth under the BARDA Agreements, the authorization, execution and delivery of this Agreement by MediWound will not contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Authority the right to revoke, withdraw, suspend, cancel, terminate, modify or exercise any right or remedy or require any refund or recapture with respect to, any Grant or other permit, license, consent, authorization, grant, benefit, or right held by MediWound related to the MediWound Technology or Licensed Products in the Territory.

8.2.16 to its best knowledge, the use, research, Development, Manufacture or Commercialization by MediWound or Vericel (or their respective Affiliates or Sublicensees) of any Licensed Product (a) does not and will not infringe any issued patent of any Third Party or (b) will not infringe the claims of any published Third Party patent application when and if such claims issue;

8.2.17 there is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the best knowledge of MediWound, threatened against MediWound or any of its Subsidiaries or (b) judgment or settlement against or owed by MediWound or any of its Subsidiaries, in each case in connection with the Licensed Products or relating to the transactions contemplated by this Agreement;

8.2.18 neither MediWound nor any of its Subsidiaries, nor any of their respective employees, officers, directors, or agents, has been debarred or disqualified by any Regulatory Authority, is the subject of a conviction described in 21 U.S.C. § 335a, or is subject to any similar sanction or comparable laws in any country or jurisdiction outside the U.S.;

8.2.19 MediWound, and each of its Subsidiaries that are or will be involved in the conduct of activities under this Agreement, is in compliance with all applicable Laws with respect to the conduct of such activities;

8.2.20 MediWound and its Subsidiaries have conducted, and to MediWound's knowledge, their respective contractors, consultants and Distributors have conducted prior to the Effective Date, all Development and Commercialization of the Licensed Products in all material aspects in accordance with applicable Law, including, without limitation, that MediWound's pivotal U.S. Phase III clinical study (DETECT) was performed in accordance with the FD&C Act and the Guidelines for Good Clinical Practice;

8.2.21 all regulatory filings generated, prepared, maintained, and retained by or on behalf of MediWound or its Subsidiaries with respect to the Licensed Products have been maintained or retained pursuant to and in accordance with good laboratory and clinical (if applicable) practice and applicable Law, and all such information is true, complete and correct in all material respects and any material updates, changes, corrections or modification to such regulatory filings required under applicable Law have been submitted to the necessary Regulatory Authorities; and

8.2.22 MediWound (a) is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any supranational, national, state or federal healthcare program for the provision of items or services for which payment may be made by such healthcare program, (b) to its best knowledge has not contracted with any Person to conduct activities under this Agreement who is excluded from participation in any such healthcare program and (c) is not subject to a final adverse action, as defined in 42 U.S.C. § 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g) or comparable laws in any country or jurisdiction other than the U.S., and has no adverse action pending or threatened against it.

8.3 Representations, Warranties and Covenants of Vericel. Vericel hereby represents, warrants and covenants to MediWound that:

8.3.1 Vericel has reviewed the complete BARDA Agreements provided by MediWound and understood the terms and conditions stated therein;

8.3.2 neither Vericel nor any of its Affiliates, nor any of their respective employees, officers, directors, or agents, has been debarred or disqualified by any Regulatory Authority, is the subject of a conviction described in 21 U.S.C. § 335a, or is subject to any similar sanction or comparable laws in any country or jurisdiction outside the U.S.;

8.3.3 it has sufficient resources, including without limitation, qualified personnel and contractors with the requisite skill and expertise, to Develop and Commercialize the Licensed Products in accordance with the terms of this Agreement;

8.3.4 Vericel (a) is not excluded from, and has not been convicted of any crime or engaged in any conduct that could result in exclusion from, participation in any supranational, national, state or federal healthcare program for the provision of items or services for which payment may be made by such healthcare program, (b) to its best knowledge has not contracted with any Person to conduct activities under this Agreement who is excluded from participation in any such healthcare program and (c) is not subject to a final adverse action, as defined in 42 U.S.C. § 1320a-7a(e) and 42 U.S.C. § 1320a-7a(g) or comparable laws in any country or jurisdiction other than the U.S., and has no adverse action pending or threatened against it;

8.3.5 Vericel shall not, and shall cause its Affiliates not to (a) sell, assign, license or otherwise transfer to any Person (other than MediWound or its Subsidiaries) any Joint Technology for Licensed Products outside the Territory (or agree to do any of the foregoing); or (b) incur, with respect to any MediWound Technology or Joint Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding Obligation, in each case that is or would be inconsistent with the rights of MediWound or its Subsidiaries under this Agreement; *provided* that, for clarity, this Section 8.3.5 shall not prohibit or restrict existing or future liens or security interests that are standardly granted by Vericel or its Affiliates to commercial lenders in connection with secured financing transactions so long as such lien or security interest shall not affect any of MediWound's rights following termination of the Agreement for any reason whatsoever.

8.4 MediWound Covenants. In addition to the covenants made by MediWound elsewhere in this Agreement, MediWound hereby covenants to Vericel that, from the Effective Date until expiration or termination of this Agreement, as set forth in this Section 8.4:

8.4.1 MediWound shall not, and shall cause its Affiliates not to (a) sell, assign, license or otherwise transfer to any Person (other than Vericel or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any MediWound Technology or Joint Technology for Licensed Products in the Territory (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any MediWound Technology or Joint Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding Obligation, in each case that is or would be inconsistent with the licenses and other rights granted (or to be granted) to Vericel or its Affiliates or Sublicensees under this Agreement.

8.4.2 MediWound will not take any action that diminishes the rights to the Licensed Products granted (or to be granted) to Vericel or Vericel's Affiliates under this Agreement.

8.4.3 MediWound will use its best efforts to maintain Control of all Patent Rights and Know-How licensed to MediWound under the MediWound In-Licenses and which relate to the Licensed Products. MediWound will not materially and intentionally breach or be in material default under any of its obligations under any MediWound In-License that relate to the Licensed Products. MediWound will not terminate any MediWound In-License in a manner that would terminate rights that are sublicensed to Vericel or Vericel's Affiliates or Sublicensees. MediWound will remain, and cause its Affiliates to remain, in compliance in all material respects with all MediWound In-Licenses. In the event that MediWound receives notice of an alleged breach or default under a MediWound In-License which may affect the rights granted to Vericel under this Agreement, then MediWound will promptly provide written notice thereof to Vericel if such breach may affect Vericel's rights under this Agreement and grant Vericel the right (but not the obligation) to cure such alleged breach or such default. In the event that MediWound amends or otherwise modifies a MediWound In-License in any way that may adversely affect the rights granted to Vericel under this Agreement, then MediWound will promptly, but in no event less than [\*\*\*] before, provide written notice thereof to Vericel and grant Vericel the right (but not the obligation), acting reasonably, to reject any amendment or modification that would either increase Vericel's obligations under this Agreement, including any financial obligations or decrease Vericel's rights under this Agreement.

8.4.4 MediWound will remain, and cause its Affiliates to remain, in compliance in all material respects with the terms and conditions of Grants related to the Licensed Products including without limitation the terms and conditions of the BARDA Agreements regarding costs, reimbursements or other funding limitations or restrictions, and will furnish Vericel with copies of all notices received by MediWound or its Affiliates relating to any alleged breach or default by MediWound or its Affiliates of such terms or conditions within [\*\*\*] after receipt thereof.

8.4.5 MediWound will (a) not enter into any MediWound Third Party Agreement that adversely affects (i) the rights granted (or to be granted) to Vericel, Vericel's Affiliates or Sublicensees hereunder or (ii) MediWound's ability to perform its obligations hereunder, (b) not amend or otherwise modify any MediWound Third Party Agreement (including any Disclosed Third Party Agreement) or consent or waive rights with respect thereto in any manner that (i) adversely affects the rights granted (or to be granted) to Vericel or Vericel's Affiliates or Sublicensees hereunder or (ii) MediWound's ability to perform its obligations hereunder, (c) promptly furnish Vericel with true and complete copies of all (i) amendments to the Disclosed Third Party Agreements and (ii) MediWound Third Party Agreements and related amendments executed following the Effective Date, *provided* that financial terms may be redacted, (d) remain, and cause its Affiliates to remain, in compliance in all material respects with all MediWound Third Party Agreements (including Disclosed Third Party Agreements), and (e) furnish Vericel with copies of all notices received by MediWound or its Affiliates relating to any alleged breach or default by MediWound or its Affiliates under any MediWound Third Party Agreement (including any Disclosed Third Party Agreement) within [\*\*\*] after receipt thereof.

8.4.6 MediWound will not enter into or otherwise allow itself or its Affiliates to be subject to any agreement, arrangement or settlement which limits the ownership or licensed rights of Vericel or its Affiliates with respect to, or limits the ability of Vericel or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any intellectual property right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement, arrangement or settlement, be included in the rights licensed or assigned to Vericel or its Affiliates pursuant to this Agreement.

8.4.7 MediWound will maintain valid and enforceable agreements with all Persons acting by or on behalf of MediWound or its Affiliates under this Agreement which require such Persons to assign to MediWound their entire rights, title and interests in and to the Licensed Products and Joint Technology.

#### 8.5 Additional Covenants of the Parties.

8.5.1 Each of MediWound and Vericel hereby covenants to the other Party that, from the Effective Date until expiration or termination of this Agreement, it will perform its obligations under this Agreement in compliance with applicable Laws.

8.5.2 Each Party and its Subsidiaries, and their respective employees and contractors shall not, in connection with the exercise of their rights (including rights retained) and performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, and each Party represents and warrants that as of the Effective Date, it, its Subsidiaries, and their respective employees and contractors, have not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other person in connection with the performance of its obligations under this Agreement, and each Party covenants that it and its Subsidiaries and their respective employees and contractors shall not, directly or indirectly, engage in any of the foregoing.

8.5.3 Each Party and its Subsidiaries, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause the other Party to be in violation of the FCPA or any other applicable Laws, rules, or regulations or otherwise cause any reputational harm to the other Party. In connection with the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Subsidiaries' employees and contractors to comply with its own then-existing anti-corruption and anti-bribery policy.

8.5.4 Each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA or any other applicable Laws, rules, or regulations in connection with the performance of this Agreement or the Development, Manufacture or Commercialization of any Licensed Product.

8.5.5 Vericel may, upon reasonable prior written notice, not more than once a year, and during MediWound's regular business hours, have an independent Third Party reasonably acceptable to MediWound, audit, subject to the execution of a confidentiality agreement, the portion of MediWound's books and records relating to the Licensed Products in the Territory or the BARDA Agreements if a suspected violation of any of the representations, warranties or covenants in this Section 8 needs to be investigated. MediWound shall, at the Vericel's request, [\*\*\*], in connection with the performance of MediWound's obligations under this Agreement, with the representations, warranties or covenants in this Section 8.

8.5.6 MediWound may, upon reasonable prior written notice, not more than once a year, and during Vericel's regular business hours, have an independent Third Party reasonably acceptable to Vericel, audit, subject to the execution of a confidentiality agreement, the portion of Vericel's books and records relating to the Licensed Products if a suspected violation of any of the representations, warranties or covenants in this Section 8 needs to be investigated. Vericel shall, at the MediWound's request, [\*\*\*], in connection with the performance of Vericel's obligations under this Agreement, with the representations, warranties or covenants in this Section 8.

8.5.7 To the extent MediWound is obligated to provide under the BARDA Agreements or receives a request from BARDA in writing for information and/or documents in Vericel's possession or that Vericel can reasonably obtain and provides such request to Vericel, Vericel shall provide MediWound with such information and documents in as timely a manner as practicable. Furthermore, Vericel shall fully cooperate with MediWound for MediWound to be in compliance with all the terms and conditions set forth in [\*\*\*].

8.5.8 All of a Party's activities related to the research, Development and Commercialization of the Licensed Products in the Territory, pursuant to this Agreement shall comply in all material aspects with applicable Law, and any such non-compliance shall not constitute a breach hereunder unless it affects the rights of the other Party under this Agreement and is not timely cured.

8.6 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, (A) NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY LICENSED PRODUCTS, PATENT RIGHTS OR KNOW-HOW OR ANY RIGHT OR LICENSE GRANTED BY MEDIWOUND HEREUNDER, AND (B) NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY MEDIWOUND THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE PATENT RIGHTS ARE VALID OR ENFORCEABLE OR THAT USE OF THE PATENT RIGHTS AND KNOW-HOW CONTEMPLATED HEREUNDER DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY.

## **9. TERM AND TERMINATION**



9.1 Term. The term of this Agreement (the “**Term**”) will commence on the Effective Date and extend on a country-by-country basis (in the Territory), unless this Agreement is terminated earlier in accordance with this Section 9, until the last to expire of any Royalty Term for any Licensed Product in such country in the Territory.

9.2 Termination by MediWound.

9.2.1 Termination for Cause. Subject to Section 9.2.2, MediWound may terminate this Agreement for cause at any time during the Term, by giving written notice to Vericel in the event that Vericel commits a material breach of its obligations under this Agreement and such material breach remains uncured for [\*\*\*], measured from the date written notice of such material breach is given to Vericel; *provided, however*, that if any breach is not reasonably curable within [\*\*\*] and if Vericel is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties in order to permit Vericel a reasonable period of time to cure such breach. If the alleged material breach relates to non-payment of any amount due under this Agreement, the cure period shall be tolled pending resolution of any bona fide dispute between the Parties as to whether such payment is due.

9.2.2 Termination for Breach of Vericel Diligence Obligations. In the event of a breach of Vericel Diligence Obligations, MediWound may (but is not required to) terminate the Agreement on a Licensed Product-by-Licensed Product, country-by-country basis, or in its entirety, solely in accordance with the terms of Section 3.4.4.

9.2.3 Termination for Patent Challenge.

(a) MediWound shall have the right to terminate this Agreement in its entirety in accordance with the terms of Section 9.2.1 in the event Vericel (or any of its Affiliates) challenges or knowingly supports (other than as may be necessary or reasonably required to assert a cross-claim or a counter-claim, or in response to a subpoena or court or administrative law request or order), including by providing information, documents, and/or funding, a challenge to the validity, scope, enforceability or patentability of any of the Patent Rights. MediWound’s right to terminate this Agreement under this Section may be exercised at any time after Vericel (or any of its Affiliates) may have challenged or knowingly supports (other than in response to a subpoena or court order) a challenge to the validity, scope, enforceability or patentability of any of the Patent Rights.

(b) Vericel shall (i) include within each agreement with each Sublicensee a right on the part of Vericel to terminate such agreement in the event such Sublicensee challenges or knowingly supports a Third Party in challenging (other than in response to a subpoena or court order), in a judicial or administrative proceeding, including without limitation by providing information, documents, or funding, the validity, scope or enforceability of any of the Patent Rights after grant of the patent and (ii) Vericel shall exercise such right to terminate the agreement with a Sublicensee should such Sublicensee challenge or knowingly support a Third Party in challenging (other than in response to a subpoena or court order) in a judicial or administrative proceeding the

validity or enforceability of any of the Patent Rights after grant of the patent. If Vericel fails to exercise such termination right against such Sublicensee or is unable to do so because it did not include such a provision in its sublicense, MediWound may terminate this Agreement in accordance with the terms of Section 9.2.1.

### 9.3 Termination by Vericel.

9.3.1 Termination for Convenience. Upon at least one hundred fifty (150) days' written notice to MediWound, Vericel may terminate this Agreement on a Licensed Product-by-Licensed Product and country-by-country basis, or in its entirety, without cause, for any or no reason; *provided* that in the event Vericel wishes to terminate the Agreement with respect to a Licensed Product in the United States under this Section 9.3.1, Vericel may only terminate the Agreement in its entirety and not solely with respect to the United States.

9.3.2 Termination for Cause. Vericel may terminate this Agreement for cause with respect to one or more Licensed Products in one or more countries in the Territory or may terminate this Agreement in its entirety, at any time during the Term, by giving written notice to MediWound in the event that MediWound commits a material breach of its obligations under this Agreement and such material breach remains uncured for [\*\*\*], measured from the date written notice of such material breach is given to MediWound; *provided, however*, that if any breach is not reasonably curable within [\*\*\*] and if MediWound is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties in order to permit MediWound a reasonable period of time to cure such breach. If the alleged material breach relates to non-payment of any amount due under this Agreement, the cure period shall be tolled pending resolution of any bona fide dispute between the Parties as to whether such payment is due.

9.4 Termination for Insolvency. If, at any time during the Term (a) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of applicable Law outside the United States (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within [\*\*\*] after the commencement thereof, (b) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for either Party's business, or (e) a substantial portion of either Party's business is subject to attachment or similar process; then, in any such case ((a), (b), (c), (d) or (e)), the other Party may terminate this Agreement upon written notice to the extent permitted under applicable Law.

### 9.5 Effects of Termination; Survival.

#### 9.5.1 Effect of Termination.

(a) Inventory. In the event this Agreement is terminated other than pursuant to Section 9.2.1, should Vericel have any inventory of any Licensed Product on hand prior to termination, Vericel shall be entitled to sell such inventory of

Licensed Product affected by such termination that remains on hand as of the effective date of the termination within [\*\*\*], *provided however*, that such Licensed Product shall not be sold by Vericel at a discount to a purchaser that is greater than the average discount provided to such purchaser for such Licensed Product in the applicable country during the [\*\*\*] period preceding such termination. In the event this Agreement is terminated pursuant to Section 9.2.1, at MediWound's discretion, MediWound shall have the option to purchase any inventory of Licensed Product affected by such termination at cost.

(b) Wind-Down. Unless the Parties otherwise agree, Vericel will, if consistent with applicable Law, responsibly wind-down any ongoing Clinical Trials for the applicable Licensed Product being conducted by Vericel. [\*\*\*]. In the event that MediWound requests that Vericel continue conducting any ongoing Clinical Trials, the Parties will discuss such request in good faith.

(c) Termination for Cause by MediWound or for Convenience by Vericel. In the event that MediWound terminates this Agreement for cause pursuant to Section 9.2.1 or 9.2.2, or Vericel terminates this Agreement for convenience pursuant to Section 9.3.1, the following will apply (with respect to the terminated countries in the Territory, in the event of partial termination, and with respect to the entire Territory, in the event of termination of the Agreement in its entirety):

(i) Except as otherwise expressly provided herein, all rights and obligations of each Party hereunder shall cease (including all rights and licenses granted by either Party to the other Party hereunder) in the relevant country or Territory, as applicable;

(ii) With respect to all regulatory filings (including all INDs and NDAs) and Regulatory Approvals and all other regulatory documents necessary to further Develop and Commercialize the Licensed Products, as they exist as of the date of such termination (and all of Vericel's right, title and interest therein and thereto), MediWound shall determine in its sole discretion subject to applicable Laws which of these shall be (i) assigned to MediWound, and Vericel shall provide to MediWound one (1) copy of the applicable documents and filings, all documents and filings contained in or referenced in any such filings, together with the raw and summarized data for any preclinical studies and Clinical Trials of the Licensed Products as well as any final documentation to inactivate any open INDs as MediWound may elect to inactivate, or (ii) withdrawn or inactivated. In the event of failure to obtain such assignment referenced in this Section 9.5.1, Vericel hereby consents and grants to MediWound the right to access and reference (without any further action required on the part of Vericel, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings relating to the Licensed Products to the extent necessary to further Develop and Commercialize the Licensed Products in the Territory. In addition, Vericel hereby consents and grants MediWound the right to continue marketing and sale of the Licensed Products following termination under Vericel's labeling until it obtains a new labeling with respect thereto.

(iii) All amounts due or payable to MediWound that were accrued prior to the effective date of termination shall remain due and payable. MediWound shall have the right to retain all amounts previously paid to MediWound by Vericel (except for amounts paid in error).

(iv) Vericel will assign all applications and registrations for the Trademarks used in connection with the Licensed Products or Patent Rights issued or pending that relate to the Licensed Products (including Vericel's interests in the Joint Patent Rights and the Joint Know-How) that are Controlled by Vericel or its Affiliates in the relevant country (or the Territory in the event of termination of this Agreement in its entirety) to MediWound.

(v) Vericel will disclose to MediWound all of its Agreements with Affiliates, Sublicensees and Distributors as well as suppliers' agreements, customers' agreements, clinical trials and other agreements which relate to the Licensed Products or to the Development or Commercialization thereof, as they exist as of the date of such termination. MediWound shall determine in its sole discretion which of these shall be either assigned to MediWound or terminated.

(vi) Vericel will disclose and provide to MediWound copies of any marketing materials it may have upon termination with respect to the Licensed Product.

(vii) Vericel will use Commercially Reasonable Efforts to assign the BARDA Agreements to MediWound, *provided* that Vericel shall remain liable for any and all acts or omissions made by Vericel prior to such assignment.

(d) Termination for Cause by Vericel.

(i) Partial Termination. In the event that Vericel terminates this Agreement pursuant to Section 9.3.2 with respect to any Licensed Product in any country in the Territory, except as otherwise expressly provided herein, all rights and obligations of each Party hereunder with respect to such Licensed Product in such country shall cease (including all relevant rights and licenses granted by either Party to the other Party hereunder).

(ii) Complete Termination. In the event that Vericel terminates this Agreement in its entirety pursuant to Section 9.3.2, except as otherwise expressly provided herein, all rights and obligations of each Party hereunder shall cease (including all rights and licenses granted by either Party to the other Party hereunder).

(iii) Alternative Remedy for Breach by MediWound. If MediWound commits a material breach of its obligations under this Agreement that would entitle Vericel to terminate this Agreement (in whole or in part) pursuant to Section 9.3.2 and Vericel elects, in its sole discretion, not to terminate this Agreement (in whole or in part) as a result of such breach, then, notwithstanding any provision of this

Agreement to the contrary, all payments due to MediWound under Section 5.2, Section 5.3 and Section 5.4 following the date of such material breach (but with respect to partial termination, solely with respect to the terminated part) will [\*\*\*]. Notwithstanding the foregoing, Vericel shall have recourse to any other remedy available at law or in equity with respect to such material breach, including an action for specific performance of this Agreement, subject to the terms of this Agreement. [\*\*\*].

9.5.2 Cross-Termination of Ancillary Agreements. In the event of the expiration or termination of this Agreement, the Supply Agreement and the Quality Agreement (as defined in the Supply Agreement) shall automatically immediately terminate.

9.5.3 Accrued Rights. Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement shall not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination.

9.5.4 Survival Period. The following sections, together with any sections that expressly survive (including any perpetual licenses granted hereunder), shall survive expiration or termination of this Agreement for any reason: Sections 1, 4.8, 5.4.4 (with respect to any licenses that accrue thereunder prior to the end of the Term), 5.6, 5.7, 6.1, 7, 8.6, 9, 10, and 11.

9.5.5 Restrictions Following Termination. In the event of termination (but not expiration) of this Agreement for any reason and by either Party, [\*\*\*].

## **10. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE.**

10.1 Limitation of Liability. [\*\*\*], (I) IN NO EVENT WILL EITHER PARTY OR ITS REPRESENTATIVES BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE SUFFERED BY EITHER PARTY OR ANY OF ITS REPRESENTATIVES, AND [\*\*\*].

10.2 Indemnification by Vericel. Vericel will indemnify, defend and hold harmless MediWound, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "**MediWound Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the MediWound Indemnified Party may be required to pay to one or more Third Parties (other than shareholders of MediWound or its Affiliates) resulting from or arising out of:

(a) Development, Commercialization or use of any Licensed Product by, on behalf of, or under the authority of, Vericel (other than by any MediWound Indemnified Party);

- (b) the material breach by Vericel of any of its representations and warranties set forth in Section 8;
- (c) the breach of any applicable Law or regulation by any Vericel Indemnified Party; or
- (d) the breach of [\*\*\*] due to the breach by Vericel of its obligations under this Agreement.

except, in each case, to the extent (y) caused by the negligence, recklessness or intentional acts of MediWound or any MediWound Indemnified Party or (z) MediWound is required to indemnify Vericel pursuant to Section 10.3.

10.3 Indemnification by MediWound. MediWound will indemnify, defend and hold harmless Vericel, its Affiliates, Sublicensees, contractors, Distributors and each of its and their respective employees, officers, directors and agents (each, a “**Vericel Indemnified Party**”) from and against any and all Liabilities that the Vericel Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

- (a) Development, Manufacture, Commercialization or use of any Licensed Product by, on behalf of, or under the authority of, MediWound;
- (b) the breach of any applicable Law or regulation by any MediWound Indemnified Party;
- (c) the material breach by MediWound of any of its representations, warranties or covenants set forth in Section 8; or
- (d) any claim that the practice of the MediWound Technology to Develop, Manufacture, Commercialize or use any Licensed Product infringes or misappropriates any issued patent or other proprietary right owned or possessed by any Third Party;

except, in each case, to the extent (y) caused by the negligence, recklessness or intentional acts of Vericel or any Vericel Indemnified Party or (z) Vericel is required to indemnify MediWound pursuant to Section 10.2.

#### 10.4 Procedure.

10.4.1 Notice. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the “**Indemnified Party**”) is entitled to indemnification hereunder (a “**Third Party Claim**”), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the “**Indemnifying Party**”) thereof; *provided, however*, that no delay on the part of the Indemnified Party in

notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

10.4.2 Control. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within ten Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; *provided that* (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the “**Litigation Conditions**”). Within ten (10) Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party shall give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party shall continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party shall be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall cooperate, and shall cause its Subsidiaries and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party’s intent to defend any Third Party Claim within ten Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party’s expense (including reasonable, out-of-pocket attorneys’ fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

10.4.3 Settlement. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other

non-monetary relief, but shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party shall not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other party, and the Indemnified Party shall use reasonable efforts to mitigate liabilities arising from such Third Party Claim.

10.5 Insurance. Each Party shall maintain at all times during the term of this Agreement, and until the later of (i) [\*\*\*] after termination or expiration of this Agreement, or (ii) the date that all statutes of limitation covering claims or suits that may be brought for personal injury based on the sale or use of a Licensed Product have expired in all the applicable countries, insurance relating to the Licensed Products from a recognized, creditworthy insurance company, on a claims-made basis, with endorsements for contractual liability and for clinical trial, product liability, and other insurance policies that is comparable in type and amount to the insurance customarily maintained by such Party with respect to similar prescription pharmaceutical products that are marketed, distributed and sold in the Territory; *provided* that if such Party does not market, distribute and sell any such similar pharmaceutical products, such insurance shall be comparable in type and amount to the insurance customarily maintained by a company within the bio-pharmaceutical industry and in any event with limits of not less than [\*\*\*] per occurrence and in the aggregate. Insurance shall be procured with carriers having an A.M. Best Rating of A-VII or better. Each Party shall name the other Party as an additional insured on all related insurance policies. Within [\*\*\*] following the Effective Date, and within [\*\*\*] following any material change or cancellation in coverage, each Party shall furnish to the other Party a certificate of insurance evidencing such coverage as of such date, and in the case of cancellation, provide a certificate evidencing that such replacement coverage meets the requirements in the first sentence of this Section. The foregoing insurance requirement shall not be construed to create a limit on either Party's liability hereunder.

## 11. MISCELLANEOUS.

11.1 Assignment. Neither this Agreement nor any interest hereunder shall be assignable by a Party without the prior written consent of the other Party, except that a Party may assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets or sale of stock or ownership interest, *provided* that the assignee shall expressly agree to be bound by such Party's obligations under this Agreement and that such sale is not primarily for the benefit of its creditors. Each Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 11.1. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.1 shall be void. Each Party will take reasonable steps to create a "firewall" between such Party and any Affiliate of such Party who becomes such Party's Affiliate through any change of control or acquisition by such Party to prevent the use of the other Party's Confidential Information, materials and intellectual property in a manner that is in breach of this Agreement.



11.2 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

11.3 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (as defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes Commercially Reasonable Efforts to remove the condition. For purposes of this Agreement, “force majeure” shall include conditions beyond the control of the Parties, including an act of God, acts, omissions or delays in acting by any Governmental Authority, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

11.4 Notices. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) shall be in writing and shall be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), five days after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next Business Day if sent by overnight delivery using a nationally recognized express courier service and specifying next Business Day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as shall be specified by like notice, *provided, however*, that notices of a change of address shall be effective only upon receipt thereof):

All correspondence to Vericel shall be addressed as follows:

Vericel Corporation  
64 Sidney Street  
Cambridge, Massachusetts 02139  
Attention: Chief Financial Officer

with a copy to:

General Counsel

All correspondence to MediWound shall be addressed as follows:

MediWound Ltd.  
42 Hayarkon Street  
Yavne, Israel 8122745  
Attention: Chief Financial Officer

with a copy to:

General Counsel

11.5 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

11.6 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.7 Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

11.8 Descriptive Headings. The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

11.9 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules shall be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and

instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

11.10 Governing Law. This Agreement, and all claims arising under or in connection therewith, shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof.

11.11 Dispute Resolution. In the event of any dispute arising out of or relating to this Agreement, the affected Party shall notify the other Party, and the Parties shall first attempt in good faith to resolve the matter within [\*\*\*] after the date of such notice (the “**Notice Date**”). Any disputes not resolved by good faith discussions shall be referred to senior executives of each Party, who shall meet at a mutually acceptable time and location within [\*\*\*] after the Notice Date and attempt to negotiate a settlement. If the matter remains unresolved within [\*\*\*] after the Notice Date, or if the senior executives fail to meet within [\*\*\*] after the Notice Date, then Section 11.12 will govern the adjudication of such dispute.

11.12 Consent to Jurisdiction. Each Party to this Agreement hereby (a) irrevocably submits to the exclusive jurisdiction of the state courts of the State of New York or the United States District Court for the Southern District of New York for the purpose of any and all actions, suits or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof, (b) waives to the extent not prohibited by applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts should be dismissed on grounds of *forum non conveniens*, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) agrees not to commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise. Notwithstanding the foregoing, MediWound agrees that a final judgement in an action, suit or proceeding brought in one of the above-named courts may be enforced by Vericel in the competent courts of the State of Israel by suit on such judgment or in any other manner provided by applicable Law.

11.13 Entire Agreement. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

11.14 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

11.15 Independent Contractors. Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

11.16 Counterparts. This Agreement may be executed in two counterparts, each of which shall be an original and both of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile or PDF file, each of which shall be binding when received by the applicable Party.

11.17 No Third Party Rights or Obligations. No provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement.

*(Signature page follows.)*

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Effective Date.

**VERICEL CORPORATION**

**MEDIWOUND LTD.**

By /s/ Dominick Colangelo  
Name: Dominick Colangelo  
Title: President & CEO

By /s/ Stephen T. Wills  
Name: Stephen T. Wills  
Title: Chairman

8976368/35

**SCHEDULE 1.58**

**LICENSED TRADEMARKS**

NexoBrid  
Debrase

**SCHEDULE 3.2**  
**DEVELOPMENT PLAN**

[\*\*\*]

**SCHEDULE 3.7.2(c)**

**WEBSITES**

[www.nexobrid.com](http://www.nexobrid.com)

[www.mediwound.com](http://www.mediwound.com)

[www.nexobrid.co.il](http://www.nexobrid.co.il)

[www.mediwound.co.il](http://www.mediwound.co.il)



**SCHEDULE 4.7**  
**ASSIGNED CONTRACTS**

None.

**SCHEDULE 5.6.6**  
**PAYMENT INFORMATION**

[\*\*\*]

[\*\*\*]

**SCHEDULE 7.4**  
**PUBLIC ANNOUNCEMENT**





News Release

**MediWound Enters into Exclusive License Agreement with Vericel for Commercial Rights to NexoBrid® in North America**

\$17.5 million upfront, sales royalties and up to \$132.5 million in potential milestones

Leverages Vericel's Commercial Capabilities and Presence in U.S. Burn Care Market

Biologics License Application (BLA) Filing Planned for Fourth Quarter of 2019

*Company to Host a Conference Call Today at 8:00 am ET*

**Yavne, Israel, May 7, 2019** - MediWound Ltd. (Nasdaq: **MDWD**), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced that it has entered into exclusive license and supply agreements with Vericel Corporation (Nasdaq: **VCEL**) to commercialize NexoBrid® in North America (NA). NexoBrid is a topically-administered biologic product that removes eschar in patients with deep partial and full-thickness thermal burns, which is approved in the European Union and other international markets. The pivotal U.S. phase 3 DETECT clinical study met its primary and all secondary endpoints, and the submission of the Biological License Application (BLA) to the U.S. Food and Drug Administration (FDA) is planned for the fourth quarter of 2019.

Pursuant to the agreements, MediWound will be responsible for the development activities of NexoBrid to obtain U.S. marketing approval from the FDA, supported and funded by BARDA, as well as the manufacture and supply of NexoBrid. MediWound retains the commercial rights to NexoBrid in all non-North American territories. Under the terms of the license agreement, Vericel will make an upfront payment to MediWound of \$17.5 million, with an additional \$7.5 million payment contingent upon U.S. BLA approval and up to \$125 million in payments contingent upon meeting certain annual sales milestones. Vericel will also pay MediWound tiered royalties on net sales ranging from high single-digit to low double-digit percentages, a split of gross profits on committed BARDA procurement orders and a double-digit royalty on any additional future BARDA purchases of NexoBrid. Under the terms of the supply agreement, Vericel will procure NexoBrid from MediWound at a transfer price of cost plus a fixed margin percentage.

"We are very pleased with this collaboration with Vericel, a company with significant expertise and commercial infrastructure in place in the burn care community. This deal is strategic for both parties and we believe Vericel is the ideal commercial partner to drive market penetration to

maximize the medical and commercial potential of NexoBrid in North America," stated Stephen T. Wills, MediWound's Chairman.

Mr. Wills continued, "As our comprehensive strategic process evolved, we concluded that licensing NexoBrid was the right first step towards monetizing our development programs and create near-term value. The cash flow from this transaction provides us with the funds to significantly advance EscharEx, our topical biologic drug candidate for the debridement of chronic and other hard-to-heal wounds, through BLA filing. Based on the multiple indications of interest EscharEx received during the strategic process, we believe that EscharEx has the potential to have a meaningful impact on wound care treatment and become a dominant debriding agent in the marketplace. While we will always assess potential strategic opportunities, this licensing deal gives us flexibility regarding the timing to monetize EscharEx and maximize shareholder value."

Sharon Malka, MediWound's Chief Executive Officer, commented, "The collaboration with Vericel, an active player with commercial presence in the U.S. burn care market, further validates the clinical and commercial value of NexoBrid as a new paradigm in burn care management. We have an upcoming pre-BLA meeting scheduled with the FDA, and subject to FDA concurrence, plan to file the BLA later this year. Regarding NexoBrid in non-North American territories, we will be directing our attention towards greater market penetration by adding new distributors and obtaining additional marketing approvals. Importantly, we believe that the proceeds generated from this collaboration, combined with existing cash on hand, will allow us to advance and optimize the ongoing development of EscharEx through BLA filing. We expect to commence the next step of the EscharEx clinical development program in the second quarter of 2019."

"We are very pleased with this agreement to commercialize NexoBrid in North America," stated Nick Colangelo, President and Chief Executive Officer of Vericel. "We are excited to collaborate with the MediWound team to obtain FDA approval for NexoBrid and integrate this innovative and critical product into our burn product portfolio. We believe that NexoBrid is an excellent strategic fit that can help increase penetration of Epicel and enable us to treat additional patients and capture a larger share of the North American burn care market."

MediWound announced in January 2019 that it met its primary and all secondary endpoints in its pivotal U.S. Phase 3 DETECT clinical study with NexoBrid to treat patients with deep partial thickness and full thickness thermal burns. DETECT was a prospective, controlled, multi-center, multi-national assessor-blinded Phase 3 study in 175 patients at 44 burn centers randomized to either NexoBrid, Standard of Care, or the Gel Vehicle placebo at a ratio of 3:3:1, with 12- and 24- month long-term safety follow-up. The study met Its primary endpoint of complete eschar removal, as well as secondary endpoints of reduction in the need for surgical eschar removal (surgical burden), earlier eschar removal, and blood loss.

The BLA currently is targeted for submission to the FDA in the fourth quarter of 2019 based on the acute primary, secondary and safety data, with the analysis of the twelve-month safety follow up data submitted during the BLA review and the twenty-four month safety follow-up data

submitted as BLA supplements, subject to FDA concurrence at a pre-BLA meeting planned for the second quarter of 2019.

Funding and support for NexoBrid development costs required to obtain marketing approval in the U.S., including the ongoing DETECT study and a Phase 3 pediatric (CIDS) study is provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C and HHSO100201800023C. The contracts also include a \$16.5 million commitment for procurement of NexoBrid contingent upon FDA eligibility for use in an emergency or FDA marketing approval. The contract provides an option to fund up to \$50 million for additional NexoBrid procurement.

Moelis & Company acted as financial advisor to MediWound.

#### **Conference Call**

MediWound management will host a conference call for investors today, May 7, 2019 beginning at 8:00 am Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing 877-602-7189 (in the U.S.), or 678-894-3057 (outside the U.S.) and entering passcode 2358328. The call will also be broadcast live on the Company's website an investor deck will be available in the Company's IR website at [http://ir.mediwound.com/events and-presentations](http://ir.mediwound.com/events-and-presentations).

A replay of the call will be accessible two hours after its completion through May 21, 2019 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering the passcode 2358328. The call will also be archived on the Company website for 90 days at [www.mediwound.com](http://www.mediwound.com).

#### **About MediWound Ltd.**

MediWound is a fully-integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel therapeutics based on its patented proteolytic enzyme technology to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid® demonstrated in clinical trials, with statistical significance the ability to non-surgically and rapidly remove the eschar earlier and, without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean and Russian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid®. In two Phase 2 studies, EscharEx® has demonstrated safety and efficacy in the debridement of chronic and other hard-to-heal wounds, within a few daily applications. For more information, please visit [www.mediwound.com](http://www.mediwound.com).

#### **About Vericel Corporation**

Vericel is a leader in advanced cell therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in the United States. MAGI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized

scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Epicel® (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. For more information, please visit the company's website at [www.vcel.com](http://www.vcel.com).

### **Cautionary Note Regarding Forward-Looking Statements**

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the US Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions and results related to timing of regulatory filings and submissions; Vericel's ability to commercialize NexoBrid; expected payments under the license and supply agreements; anticipated uses of such payments; benefits to shareholders as a result of the collaboration with Vericel; the regulatory authorizations and launch dates. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on MediWound's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. In particular, you should consider that we may not submit the BLA to FDA in the timeframe expected, or at all; FDA may not provide marketing approval for NexoBrid in the United States and, if such approval is obtained, Vericel may not be able to successfully commercialize NexoBrid in the United States; and the risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2018 as well as information contained in other documents filed with or furnished to the Securities and Exchange Commission. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. The forward-looking statements made herein speak only as of the date of this announcement and MediWound undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

**Contacts:**                      **Jeremy Feffer**  
Sharon Malka                      Managing Director  
Chief Executive Officer              LifeSci Advisors  
MediWound Ltd.                      212-915-2568  
   [ir@mediwound.com](mailto:ir@mediwound.com)

[jeremy@lifesciadvisors.com](mailto:jeremy@lifesciadvisors.com)





**Vericel Corporation**  
64 Sidney Street Cambridge, MA 02139  
T (617) 588-5555 F (617) 588-5554  
www.vcel.com

## **Vericel Enters into Exclusive License Agreement with MediWound for North American Rights to NexoBrid, a Biological Orphan Product for Debridement of Severe Thermal Burns**

### **Pivotal U.S. Phase 3 Clinical Study Met Primary and All Secondary Endpoints**

### **Highly Synergistic with Existing Commercial Franchise and Significantly Expands Vericel's Presence in the Severe Burn Care Market**

CAMBRIDGE, Mass., May 7, 2019 (GLOBE NEWSWIRE) — Vericel Corporation (NASDAQ:VCEL), a leader in advanced cell therapies for the sports medicine and severe burn care markets, today announced that it has entered into exclusive license and supply agreements with MediWound Ltd. to commercialize NexoBrid® in North America. NexoBrid is a topically-administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns within four hours of application without harming viable tissue. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic in the United States.

In January 2019, MediWound announced positive top-line results from the pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with deep partial- and full-thickness thermal burns up to 30% of total body surface area. The study met its primary endpoint of complete eschar removal as well as all secondary endpoints, including shorter time to eschar removal, a lower incidence of surgical eschar removal, and lower blood loss compared to standard of care (SOC). A key safety endpoint, non-inferiority in time to complete wound closure compared with patients treated with SOC, was also achieved. Planned twelve-month and twenty-four month safety follow-ups are ongoing for cosmesis, function, quality of life and other safety measurements.

“We are delighted to expand our burn care franchise with the addition of NexoBrid, a highly innovative product with compelling clinical and pharmacoeconomic data that represents a paradigm shift in burn care for hospitalized patients,” said Nick Colangelo, president and CEO of Vericel.

“NexoBrid is an excellent strategic fit with our advanced therapy portfolio and is highly synergistic with our existing commercial franchise. The addition of NexoBrid significantly expands our target addressable market and supports a broader commercial footprint to both drive NexoBrid uptake and increase Epicel penetration as we broaden our focus to a significantly larger segment of hospitalized burn patients. We look forward to working closely with the MediWound team to bring NexoBrid to the U.S. market.”

The U.S. Biomedical Advanced Research and Development Authority (BARDA) has awarded MediWound a contract valued at up to \$132 million for the advancement of the development and manufacturing, as well as the procurement, of NexoBrid in the United States. Under the contract, BARDA provides technical assistance and \$56 million in funding support towards NexoBrid development costs including the ongoing DETECT study and a Phase 3 pediatric (CIDS) study to obtain U.S. marketing approval from the Food and Drug Administration (FDA). The

contract also includes a \$16.5 million commitment for procurement of NexoBrid contingent upon FDA eligibility for use in an emergency or FDA marketing approval. The contract provides an option to fund up to \$50 million for additional NexoBrid procurement. Independently, BARDA also awarded a different contract to MediWound for up to \$43 million to support the development of NexoBrid as a debridement product to treat sulfur mustard injuries.

Under the terms of the license agreement, Vericel will make an upfront payment to MediWound of \$17.5 million, with an additional \$7.5 million payment contingent upon U.S. approval and up to \$125 million contingent upon meeting certain annual sales milestones. The first sales milestone of \$7.5 million would be triggered when NexoBrid annual net sales in North America exceed \$75 million. Vericel also will pay MediWound tiered royalties on net sales ranging from single-digit to low double-digit percentages, and a percentage of gross profits on initial committed BARDA procurement orders and a royalty on any additional BARDA purchases of NexoBrid. Vericel also entered into a supply agreement with MediWound under which MediWound will manufacture NexoBrid for Vericel for a supply price of cost plus a fixed margin percentage.

“In addition to the clear strategic fit with our burn care franchise, this transaction is attractive from a financial perspective as well,” said Nick Colangelo. “The performance-based deal structure, together with BARDA funding support for development expenses to obtain U.S. marketing approval and medical countermeasure procurement, makes the transaction essentially neutral to adjusted EBITDA in the near-term and generates longer-term margins consistent with expected margins for our current portfolio.”

Approximately 40,000 burn patients are hospitalized in the U.S. each year<sup>1</sup>, most of whom require the debridement of burn eschar to facilitate healing and reduce the risk of infection.<sup>2</sup> Surgical excision of eschar, or escharectomy, is currently standard of care and is performed through repeated use of a large surgical blade to remove necrotic tissue until bleeding, healthy tissue is reached.<sup>2</sup> While effective, surgical debridement is not selective, results in the loss of both viable tissue and blood, and requires general anesthesia for the patient and operating facilities for the burn center or hospital.<sup>3</sup> Currently available enzymatic debridement agents require a minimum of once daily application<sup>4</sup> with dressing changes over a number of days. NexoBrid enables the rapid and early removal of eschar while reducing patients' surgical burden and the related loss of blood and healthy tissue associated with escharectomy.<sup>5</sup>

“MediWound is excited to partner with Vericel, a company that shares our commitment to bringing innovative therapies to the market to meet the needs of burn patients,” said Stephen T. Wills, Chairman of MediWound. “Vericel’s proven track record of commercializing novel products and changing standard of care, as well as their strong history with the burn community, gives us confidence that they are the ideal partner to realize the full potential of NexoBrid in North America.”

The U.S. Biologics License Application (BLA) currently is targeted for submission to the FDA in the fourth quarter of 2019 based on the acute primary, secondary and safety data, with the analysis of the twelve-month safety follow-up data submitted during the BLA review and the twenty-four month safety follow-up data submitted as a BLA supplement, subject to FDA concurrence at a pre-BLA meeting planned for the first half of 2019.

For more information on this transaction please refer to the Form 8-K filed today with the U.S Securities and Exchange Commission (SEC).

#### **About Vericel Corporation**

Vericel is a leader in advanced cell therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in the United States. MACI<sup>®</sup> (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Epicel<sup>®</sup> (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. For more information, please visit the company's website at [www.vcel.com](http://www.vcel.com).

## **About BARDA**

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. Funding and support for development of NexoBrid has been provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C and HHSO100201800023C.

Epicel® and MACI® are registered trademarks of Vericel Corporation. © 2019 Vericel Corporation. All rights reserved.

NexoBrid® is a registered trademark of MediWound Ltd. and is used under license to Vericel Corporation.

*This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of Vericel products, intended product development, clinical activity timing, regulatory process, and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "targeted" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "can continue," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with timing and conduct of clinical trial and product development activities, timing or likelihood of regulatory submissions or approvals, availability of funding from BARDA, potential payments under the license and supply agreements, growth in revenue, profit and margins, impact to adjusted EBITDA, estimating the commercial potential of our products and product candidates, increasing market penetration for Epicel, competitive developments, market demand for our products and product candidates, product performance, and our ability to supply or meet customer demand for our products. These and other significant factors are discussed in greater detail in Vericel's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission ("SEC") on February 26, 2019, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Vericel does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.*

## **References**

American Burn Association - <https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>.

Plast Aesthet Res 2018;5:33.

Total Burn Care (Fifth Edition), 2018, Pages 131-157.

Santyl Prescribing Information.

Burns 43 (2017) 1640 – 1653; Annals of Burns and Fire Disasters - vol. XXVIII - n. 4 - December 2015; Burns 2014; 40: 466-474.

## **Global Media Contacts:**

David Schull

Russo Partners LLC

David.schull@russopartnersllc.com

+1 212-845-4271 (office)

+1 858-717-2310 (mobile)

Karen Chase  
Russo Partners LLC  
Karen.chase@russopartnersllc.com  
+1 646-942-5627 (office)  
+1 917-547-0434 (mobile)

**Investor Contacts:**

Chad Rubin  
Solebury Trout  
crubin@troutgroup.com  
+1 (646) 378-2947

Lee Stern  
Solebury Trout  
lstern@troutgroup.com  
+1 (646) 378-2922

**SCHEDULE 8.2.3**

**MEDIWOUND PATENT RIGHTS**

[\*\*\*]



\*\*\*

8976368.33

76

8976368/35

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[\*\*\*]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

**SUPPLY AGREEMENT**

**by and between**

**MEDIWOUND LTD.**

**and**

**VERICEL CORPORATION**

**May 6, 2019**



## TABLE OF CONTENTS

**Page**

|   |    |
|---|----|
| ARTICLE 1 DEFINITIONS                               | 1  |
| ARTICLE 2 SUPPLY OF PRODUCTS                        | 5  |
| 2.1 Scope of Agreement                              | 5  |
| 2.2 Exclusive Supply                                | 6  |
| 2.3 Materials                                       | 6  |
| 2.4 Labeling  | 6  |
| 2.5 Subcontracting                                  | 7  |
| 2.6 Facilities                                      | 8  |
| 2.7 Establishment of Second Source                  | 9  |
| 2.8 Forecasting and Ordering                        | 9  |
| 2.9 Delivery  | 11 |
| 2.10 Dating   | 12 |
| 2.11 Safety Stock                                   | 12 |
| 2.12 Non-Conforming Product                         | 12 |
| 2.13 Shortages                                      | 13 |
| 2.14 Supply Failures                                | 13 |
| ARTICLE 3 COMPLIANCE, QUALITY AND ENVIRONMENTAL     | 14 |
| 3.1 Certificates of Analysis; Release               | 14 |
| 3.2 Records   | 14 |
| 3.3 Regulatory Compliance                           | 14 |
| 3.4 Audit   | 15 |
| 3.5 Results of Audits and /or Regulatory Inspection | 16 |
| 3.6 Regulatory Information                          | 16 |
| 3.7 Recall  | 16 |
| 3.8 Quality Agreement                               | 16 |
| ARTICLE 4 CHANGES                                   | 17 |
| 4.1 Changes   | 17 |
| 4.2 Changes to Facility                             | 17 |
| 4.3 Discretionary Manufacturing Changes             | 17 |
| 4.4 Regulatory Changes                              | 18 |
| 4.5 Ongoing Regulatory Assistance                   | 18 |
| ARTICLE 5 PRICE AND PAYMENT TERMS                   | 19 |
| 5.1 Supply Price                                    | 19 |
| 5.2 Price Mechanics                                 | 19 |
| 5.3 Cost Savings                                    | 19 |
| 5.4 Payments  | 20 |

|   |   |    |
|---|---|----|
| 5.5   | Late Payments                                       | 20 |
| 5.6   | Taxes   | 20 |
| ARTICLE 6 REPRESENTATIONS, WARRANTIES AND COVENANTS |   | 21 |
| 6.1   | Mutual Representations and Warranties               | 21 |
| 6.2   | Compliance with Law                                 | 21 |
| 6.3   | Product Warranty                                    | 21 |
| 6.4   | No Liens  | 21 |
| 6.5   | Debarment   | 21 |
| ARTICLE 7 INDEMNITY, INSURANCE                      |   | 22 |
| 7.1   | Indemnification by MediWound                        | 22 |
| 7.2   | Indemnification by Vericel                          | 22 |
| 7.3   | No Right of Indemnification under License Agreement | 23 |
| 7.4   | Procedure   | 23 |
| 7.5   | Disclaimer  | 24 |
| 7.6   | LIMITATION OF LIABILITY                             | 24 |
| 7.7   | Insurance   | 25 |
| ARTICLE 8 TERM AND TERMINATION                      |   | 25 |
| 8.1   | Term  | 25 |
| 8.2   | Automatic Termination                               | 25 |
| 8.3   | Termination for Breach                              | 25 |
| 8.4   | Termination by Vericel                              | 25 |
| 8.5   | Termination by MediWound                            | 26 |
| 8.6   | Effects of Termination                              | 26 |
| 8.7   | Survival  | 26 |
| ARTICLE 9 INTELLECTUAL PROPERTY RIGHTS              |   | 27 |
| 9.1   | Manufacturing License Grant                         | 27 |
| 9.2   | Trademarks License Grant.                           | 27 |
| 9.3   | Ownership   | 27 |
| ARTICLE 10 FORCE MAJEURE                            |   | 27 |
| 10.1  | Excusing Performance                                | 27 |
| 10.2  | Notice of Force Majeure Event                       | 27 |
| 10.3  | Resumption; Termination                             | 27 |
| ARTICLE 11 MISCELLANEOUS                            |   | 28 |
| 11.1  | Assignment  | 28 |
| 11.2  | Further Actions                                     | 28 |
| 11.3  | Notices   | 28 |
| 11.4  | Amendment   | 29 |
| 11.5  | Waiver  | 29 |

|       |                                      |    |
|-------|--------------------------------------|----|
| 11.6  | Severability                         | 29 |
| 11.7  | Descriptive Headings                 | 29 |
| 11.8  | Interpretation                       | 29 |
| 11.9  | Governing Law                        | 30 |
| 11.10 | Consent to Jurisdiction              | 30 |
| 11.11 | Entire Agreement                     | 31 |
| 11.12 | Representation by Legal Counsel      | 31 |
| 11.13 | Counterparts                         | 31 |
| 11.14 | No Third Party Rights or Obligations | 31 |
| 11.15 | Confidentiality                      | 31 |
| 11.16 | Bankruptcy                           | 32 |

## SUPPLY AGREEMENT

**THIS SUPPLY AGREEMENT** (the “**Agreement**”) is entered into as of May 6, 2019 (the “**Effective Date**”), by and between Vericel Corporation, a corporation organized and existing under the laws of Michigan and having a principal place of business at 64 Sidney Street, Cambridge, MA 02139 (“**Vericel**”) and MediWound Ltd., a corporation organized and existing under the laws of Israel and having a principal place of business at 42 Hayarkon Street, Yavne, Israel 8122745 (“**MediWound**”). Vericel and MediWound may each be referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

### RECITALS

**WHEREAS**, Vericel and MediWound are parties to that certain License Agreement of even date herewith (the “**License Agreement**”), pursuant to which Vericel acquired an exclusive license to certain rights from MediWound; and

**WHEREAS**, in connection with the License Agreement, the Parties contemplate that during the Term, MediWound will provide certain manufacturing and other related services to Vericel in accordance with the terms and conditions set forth herein.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

### Article 1

#### DEFINITIONS

The following terms have the meanings set forth below. Capitalized terms which are used but not defined herein have the meanings ascribed to such terms in the License Agreement.

1.1 “**Additional Service**” shall mean any service in addition to the Manufacture of a Product, as such services are identified on Exhibit B attached hereto, or such other service as may be requested by Vericel and agreed to by MediWound from time to time.

1.2 “**Additional Service Fee**” shall mean the fee, cost and/or expense to be paid by Vericel to MediWound for the performance of Additional Services, as such fee, cost and/or expense is agreed to by Vericel and MediWound in writing in respect of such Additional Services (plus VAT or similar taxes, if applicable).

1.3 “**Agreement**” has the meaning set forth in the Preamble.

1.4 “**Batch**” shall mean one (1) production lot of a Product.

1.5 “**Binding Forecast**” has the meaning set forth in Section 2.8(a).

1.6 “**Binding Orders**” has the meaning set forth in Section 2.8(b).

1.7 “**BLA**” means (a) a Biologics License Application as defined in the FD&C Act and the regulations promulgated thereunder, or (b) any equivalent or comparable application, registration or certification in any other country or region in the Territory.

1.8 “**Bulk Vehicle Gel**” means the formulated NexoBrid product gel in bulk form, prior to filling and finishing, as further described in the applicable Specifications.

1.9 “**Business Day**” means a day other than a Friday, Saturday, Sunday or bank or other public holiday in New York, New York or Yavne, Israel.

1.10 “**cGMP**” means the then-current good manufacturing practices for pharmaceuticals, as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations promulgated thereunder, as amended from time to time, and such equivalent or similar standards for good manufacturing practice as are required by other Governmental Authorities in countries in which Products are intended to be manufactured or sold.

1.11 “**Change Notification Period**” has the meaning set forth in Section 4.1.

1.12 “**Confidential Information**” has the meaning set forth in the License Agreement insofar as such information is disclosed pursuant to this Agreement. The terms of this Agreement are the Confidential Information of both Parties, subject to Section 11.15.

1.13 “**Conforming Product**” means, with respect to the applicable Product, that, as of the date of delivery to Vericel or its designated Affiliate or contractor in accordance with Section 2.9(c) hereof, such Product (a) meets, and was Manufactured in accordance with, the applicable Specifications, Regulatory Standards (including cGMP where applicable) and the requirements set forth in the Quality Agreement, (b) is free from defects in materials and workmanship, (c) is not adulterated or misbranded within the meaning of the FD&C Act (or similar requirements of the countries for which the Product will be distributed), and (d) is not an article which may not, under the provisions of the FD&C Act, be introduced into interstate commerce.

1.14 “**Cost Savings Change**” has the meaning set forth in Section 5.3.

1.15 “**Discretionary Manufacturing Changes**” has the meaning set forth in Section 4.1.

1.16 “**Effective Date**” has the meaning set forth in the Preamble.

1.17 “**Excess Amount**” has the meaning set forth in Section 2.8(b).

1.18 “**Facility**” means MediWound facility located at 42 Hayarkon Street, Yavne, Israel 8122745 and any other facility approved by Vericel in accordance with Section 2.6.

1.19 “**Finished Product**” means finished NexoBrid product, comprising the Intermediate Drug Product filled into unit packages and Bulk Vehicle Gel filled into unit packages and sterilized, including labeling and packaging, as further described in the applicable Specifications.

1.20 “**First Commercial Sale**” means, with respect to any Licensed Product and with respect to any country of the Territory, the first sale of such Licensed Product by Vericel or an Affiliate or Sublicensee of Vericel to a Third Party in such country after such Licensed Product has been granted Regulatory Approval by the appropriate Regulatory Authority(ies) for such country.

1.21 “**Force Majeure Event**” has the meaning set forth in Section 10.1.

1.22 “**Initial Term**” has the meaning set forth in Section 8.1.

1.23 “**Intermediate Drug Product**” means the formulated Intermediate Drug Substance as a bulk lyophilized powder, prior to filling and finishing, for use in the Product, as further described in the applicable Specifications.

1.24 “**Intermediate Drug Substance**” means formulated mixture of proteolytic enzymes enriched in bromelain in solution manufactured for use in manufacturing the Intermediate Drug Product.

1.25 “**Key Material**” means, with respect to a given Product, those key Materials for the Manufacture of such Product as designated by the Parties. Schedule 1.26 will include a list of the then-current Key Materials, as designated by the Parties, which will be updated by the Parties from time to time during the Term to reflect additions and deletions thereof.

1.26 “**Key Materials Suppliers**” means, with respect to a given Product, the entities that MediWound, its Affiliate or its Third Party manufacturer has engaged (whether as of the Effective Date or from time to time during the Term) to manufacture, supply, furnish or provide the Key Materials for such Product. Schedule 1.26 will include a list of the then-current Key Materials Suppliers for each Product, which will be updated by MediWound from time to time during the Term to reflect additions and deletions thereof.

1.27 “**Latent Defect**” means, with respect to a Product supplied by MediWound to Vericel hereunder, a defect existing at the time of delivery of such Product to Vericel that causes such Product to fail to conform to the corresponding Product Warranty for such Product, which defect is not reasonably obvious to Vericel upon inspection of such Product during the [\*\*\*] period pursuant to Section 2.12 following such delivery but is discovered at a later time.

1.28 “**Liability**” has the meaning set forth in Section 7.1.

1.29 “**License Agreement**” has the meaning set forth in the recitals of this Agreement.

1.30 “**Manufacture**” or “**Manufacturing**” means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release a compound or product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing a compound or product or any component thereof.

1.31 “**Materials**” means, with respect to a given Product, all raw materials, Bulk Vehicle Gel (where MediWound is supplying a Product other than Bulk Vehicle Gel), Intermediate Drug Product (where MediWound is supplying a Product other than Intermediate Drug Product), supplies, components, excipients, and intermediates, labels and packaging materials necessary to Manufacture and ship such Product in accordance with the applicable Specifications.

1.32 “**Maximum Capacity**” has the meaning set forth in [Section 2.6](#).

1.33 “**MediWound**” has the meaning set forth in the Preamble.

1.34 “**MediWound Indemnified Party**” has the meaning set forth in [Section 7.2](#).

1.35 “**Minimum Shelf Life**” has the meaning set forth in [Section 2.10](#).

1.36 “**Non-Conforming Product**” has the meaning set forth in [Section 2.12](#).

1.37 “**Parties**” has the meaning set forth in the Preamble.

1.38 “**Product**” means, as applicable, the (a) Intermediate Drug Product, (b) Bulk Vehicle Gel and (c) Finished Product.

1.39 “**Product Warranty**” has the meaning set forth in [Section 6.3](#).

1.40 “**Purchase Order**” shall mean a firm, written order for purchase of one or more Products submitted by Vericel to MediWound that complies with the terms and conditions of this Agreement.

1.41 “**Quality Agreement**” has the meaning set forth in [Section 3.8](#).

1.42 “**Recall**” means a recall, withdrawal or field correction of a Product.

1.43 “**Regulatory Change**” has the meaning set forth in [Section 4.4](#).

1.44 “**Regulatory Standards**” means all applicable Laws within the Territory applicable to the Manufacturing and shipment of the Product or any aspect thereof and the obligations of MediWound hereunder, including, without limitation, (a) the FD&C Act (or similar requirements of the countries for which the Product will be distributed), (b) cGMPs, and (c) the rules and regulations promulgated under or by a Regulatory Authority or any successor agency or other comparable agency thereto as each may be amended from time to time.

1.45 “**Remediation Plan**” means a reasonably detailed corrective action plan that would outline remediation of a Supply Failure that include the date by which MediWound will implement such remediation and remedy such Supply Failure.

1.46 “**Renewal Term**” has the meaning set forth in [Section 8.1](#).

1.47 “**Rolling Forecast**” has the meaning set forth in [Section 2.8\(a\)](#).

1.48 “**Safety Stock**” has the meaning set forth in Section 2.11.

1.49 “**Second Source**” has the meaning set forth in Section 2.7.

1.50 “**Specifications**” means, with respect to a given Product, the written specifications for such Product set forth in the applicable Regulatory Approval corresponding thereto as defined in the Quality Agreement, which specifications may be amended from time to time in accordance with this Agreement.

1.51 “**Suppliers**” has the meaning set forth in Section 2.3.

1.52 “**Supply Failure**” means, with respect to a given Product, MediWound’s failure to timely deliver to Vericel (i) at least [\*\*\*] of the quantity of such Product ordered in accordance with the Binding Orders for such Product (for avoidance of doubt, in determining the percentage of Product delivered for purposes of this clause (i), only Product that conforms to the Product Warranty and is delivered by MediWound in accordance with this Agreement, shall be included), as measured over a period of any [\*\*\*], or (ii) a cessation or suspension of Manufacturing of Product by MediWound that is not cured by MediWound in accordance with Section 2.14, that is reasonably likely to result in a failure by MediWound to timely deliver Product to Vericel as described in the foregoing clause (i), that, in either case (the foregoing clause (i) or clause (ii)), is not caused by a breach of this Agreement by Vericel.

1.53 “**Supply Price**” has the meaning set forth in Section 5.1.

1.54 “**Term**” has the meaning set forth in Section 8.1.

1.55 “**Territory**” means the United States, Canada and Mexico.

1.56 “**Third Party**” shall mean any Person other than Vericel, MediWound or their respective Affiliates.

1.57 “**Third Party Claims**” has the meaning set forth in Section 7.1.

1.58 “**Third Party Supply Agreement**” means any agreement between MediWound (or any of its Affiliates) and any Third Party that relates to Manufacture or supply of a Licensed Product.

1.59 “**Vericel**” has the meaning set forth in the Preamble.

1.60 “**Vericel Indemnified Party**” has the meaning set forth in Section 7.1.

## ARTICLE 2 SUPPLY OF PRODUCTS

2.1 Scope of Agreement. Subject to the terms and conditions of this Agreement, MediWound shall Manufacture (or have Manufactured) Product for clinical and commercial use by Vericel and perform the Additional Services as required for completion of the activities



contemplated under this Agreement and the License Agreement in accordance with the applicable Specifications, Regulatory Standards and the Quality Agreement. MediWound shall Manufacture and supply Product in exchange for the Supply Price and shall perform the Additional Services for the Additional Service Fees.

2.2 Exclusive Supply. During the first five (5) years of the Term, with respect to the Bulk Vehicle Gel, Intermediate Drug Product and Finished Product, Vericel shall order and purchase such Products exclusively from MediWound in accordance with the terms of this Agreement; *provided, however*, Vericel may Manufacture or have Manufactured the Products (a) upon the occurrence of a Supply Failure with respect to any Product hereunder, or (b) as otherwise permitted under the terms of the License Agreement or this Agreement. The Parties agree that nothing in this Section 2.2 is intended to limit the identification, evaluation, technology transfer or validation by Vericel of (x) a Second Source for the Manufacture and supply of Product or (y) a provider of filling and packaging services for Product, and that such activities are expressly permitted hereunder.

2.3 Materials. MediWound shall purchase at its cost and expense all Materials required for Manufacture by MediWound of the Product for supply to Vericel for the Territory pursuant to this Agreement. Any and all forecasts and purchase orders for such Materials shall be placed at MediWound's sole expense and under its sole responsibility. MediWound shall place such purchase orders on a timely basis in order to avoid any undue delay, interruption or other discontinuance in the Manufacture or delivery of the Product. MediWound shall manage and be responsible for all contracts or other arrangements with MediWound's suppliers of Materials ("**Suppliers**"). Subject to the terms of this Agreement and the Quality Agreement, as between the Parties, MediWound shall be responsible and have liability for all actions and omissions of, and the failure to comply with the applicable terms of this Agreement, applicable Law or Regulatory Standards by the Suppliers in performance of Manufacturing activities for the supply of Products to Vericel for the Territory on behalf of MediWound hereunder. MediWound shall ensure that all Materials conform to the terms of this Agreement, including the applicable Specifications and to the terms of the Quality Agreement.

2.4 Labeling. Vericel shall be responsible for supplying MediWound with copy for labeling. Upon its receipt of labeling copy from Vericel, MediWound shall provide artwork of the labeling to Vericel for its review and approval. Vericel's review time shall not exceed [\*\*\*] after its receipt of the artwork from MediWound. In the event that Vericel requests any changes to the labeling, MediWound shall make such changes as promptly as possible and return such labeling artwork to Vericel for its final review and approval, which it shall complete with [\*\*\*] after its receipt of the modified artwork. MediWound shall be responsible for ordering, at its expense, sufficient quantities of labeling as forecasted to be required, based upon the [\*\*\*] of the then-current Rolling Forecast. MediWound shall store the labeling as required by Regulatory Standards and shall use the labeling in Product packaging as set forth in the Specifications. Vericel shall be permitted to require changes to the labeling artwork from time-to-time at its cost, but will be required to reimburse MediWound for the cost of any quantities of labeling procured by MediWound that is rendered unusable by such changes, up to the quantities of labeling as

forecasted to be required, based upon the [\*\*\*] of the then-current Rolling Forecast as of the date of such change by Vericel of the labeling artwork. [\*\*\*].

## 2.5 Subcontracting.

(a) [\*\*\*]. No Third Party service provider or subcontractor shall be provided with Vericel's Confidential Information without first executing a confidentiality agreement that contains terms and conditions that are at least as protective as the confidentiality terms, conditions and restrictions set forth in this Agreement. Notwithstanding the foregoing, MediWound shall remain liable for the performance of all Third Party subcontractors and its Affiliates under this Agreement.

(b) MediWound shall use commercially reasonable efforts to ensure that any Third Party Supply Agreement [\*\*\*].

(c) If the forecasting or order timing or other provisions of a Third Party Supply Agreement do not align with the corresponding provisions of this Agreement then the Parties shall discuss in good faith appropriate modifications to this Agreement or to such Third Party Supply Agreement, to bring the relevant provisions into alignment; *provided, however*, that Vericel or MediWound shall have no obligation to agree to any amendment to this Agreement or such Third Party Supply Agreement that can reasonably be expected to materially disadvantage Vericel or MediWound, respectively.

## 2.6 Facilities.

(a) Current and Expanded Capacity. The Parties agree and acknowledge that, as of the Effective Date, MediWound's current Facility can fill orders from Vericel for use in the Territory up to [\*\*\*] of Intermediate Drug Product, whether provided in that form or in the form of the equivalent amount of Finished Product within a calendar year ("**Maximum Capacity**"). The Parties agree and acknowledge that the Facility will require either expansion or modification (which may include moving to or adding another location) to meet future capacity requirements for the Product. By no later than [\*\*\*], MediWound shall fund, at its sole cost, the expansion of its annual manufacturing capacity to be [\*\*\*] of Intermediate Drug Product (whether provided in that form or in the form of the equivalent amount of Finished Product). The Parties will in good faith review existing market research to mutually agree on peak anticipated volume prior to [\*\*\*]. After the foregoing expansion, the expanded capacity shall be deemed the "Maximum Capacity" for purposes of this Agreement. As part of the expansion of the Facility, the Parties will discuss any shut down or transfer to another facility made in connection therewith.

(b) Shut-Down or Expansion of Facility; Transfer to Another Facility. In the event that MediWound desires to cease or shut down operations at a Facility, expand or modify a Facility, or transfer the Manufacturing of a Product to another facility which would reasonably be anticipated to result in inability (permanent or temporary) of MediWound to Manufacture, supply or otherwise perform its obligations hereunder, MediWound shall provide prior written notice to Vericel within the applicable Change Notification Period of such planned shut-down, cessation, expansion, modification or transfer. During such Change Notification Period, Vericel

will have the right to order, and in such case MediWound will manufacture, up to [\*\*\*] of quantities of Product set forth in the Rolling Forecast with respect to such Change Notification Period which in any event will not exceed the Maximum Capacity. Notwithstanding the foregoing, MediWound shall remain obligated to supply Product at the then current Facility and will not supply Product to Vericel from a new facility unless and until MediWound can perform the Manufacturing and supply Product from such new Facility in accordance with the terms of this Agreement and any modifications to the regulatory filings for such Product are approved by the relevant Regulatory Authorities. MediWound shall bear all costs incurred in connection with the shut-down, cessation, expansion or modification of the Facility or transfer of the Manufacturing of a Product to a new facility pursuant to this Section 2.6(b), including any costs associated with changes to the regulatory filings. Once such new facility is able to Manufacture in accordance with the terms of this Agreement and all required regulatory changes have been approved, such new facility shall be the Facility for purposes of such Product under this Agreement.

## 2.7 Establishment of Second Source.

(a) Within [\*\*\*] of the Effective Date, MediWound must provide Vericel with true and accurate copies of all documents consistent with Schedule 2.7. If MediWound does not provide all documents within [\*\*\*] of the Effective Date, Vericel's obligation under Section 8.1 regarding the time period to provide MediWound with a notice of an extension of the Initial Term shall be extended by the amount of time beyond [\*\*\*] taken by MediWound to provide the required documents.

(b) Within [\*\*\*] of a request by Vericel to initiate technology transfer or as soon as reasonably practicable upon request by Vericel in connection with a Supply Failure, MediWound shall provide Vericel, at Vericel's cost consistent with Schedule 4.5, with information necessary for Vericel to qualify a second or back-up supplier identified by Vericel for the Manufacture and supply of Product (a "**Second Source**") and facilitate technology transfer to such Second Source so that Vericel can consistently manufacture intermediate and final product that meets all specifications. MediWound will notify the IIA in accordance with applicable Israeli Laws upon the commencement of Manufacture of Product by such Second Source. MediWound will provide Vericel with access to the manufacturing process and information and any and all original processes, records, and any other information required to manufacture, package and test the Product in accordance with the Specifications. Second Source manufacturers shall be permitted to manufacture Product for Vericel, its Affiliates and Sublicensees as provided in Section 9.1 and the License Agreement; *provided* that such Second Source manufacturers: [\*\*\*].

## 2.8 Forecasting and Ordering.

(a) Forecasting. Vericel shall furnish MediWound with a [\*\*\*] rolling forecast of the quantities of each Product that Vericel intends to order during the succeeding [\*\*\*] period (each, a "**Rolling Forecast**") which in any event will not exceed the Maximum Capacity for the Binding Forecast. No later than [\*\*\*] after the filing of a BLA, Vericel shall

furnish MediWound the first rolling Forecast. Subject to this Section 2.8, the [\*\*\*] of each Rolling Forecast shall constitute a binding order for the quantities of Product specified (“**Binding Forecast**”). The remaining [\*\*\*] of each Rolling Forecast shall be non-binding, but shall represent Vericel’s good faith estimate, as of the date of its submission of the Rolling Forecast, of its forecasted requirements of the Product during such period. MediWound shall maintain at all times the manufacturing capacity at the relevant Facility to manufacture [\*\*\*] of the quantities of Product set forth in the current Calendar Year of the Rolling Forecast (as was set forth at the Rolling Forecast submitted immediately prior to the beginning of such Calendar Year) which in any event will not exceed the Maximum Capacity.

(b) Purchase Orders. On a Calendar Quarter basis, Vericel shall issue at least one Purchase Order for the number and unit size of each Product specified in the Binding Forecast. Vericel is not limited to one Purchase Order per Calendar Quarter. Each Purchase Order shall specify (i) a purchase order number; (ii) the quantity of units of each Product to be Manufactured; and (iii) the requested delivery date of such Product (which in no event shall be earlier than [\*\*\*] days following the date the applicable Purchase Order was received by MediWound). MediWound shall respond to each Purchase Order within [\*\*\*] of receipt by: (i) accepting such Purchase Order if it conforms to the requirements of this Agreement or (ii) notifying Vericel if such Purchase Order does not conform to the requirements of this Agreement. If MediWound timely notifies Vericel that a Purchase Order does not conform to the requirements of this Agreement, the Parties shall confer as soon as reasonably practicable to resolve any issues related to such purported nonconformity. If MediWound fails to respond to a Purchase Order that is consistent with the Binding Forecast within [\*\*\*] after receiving it, Vericel will, within [\*\*\*] thereafter, confirm with MediWound that such Purchase Order was received by MediWound, and if such Purchase Order is consistent with the Binding Forecast and was properly submitted by Vericel in accordance with this Section 2.8(b), MediWound shall be deemed to have accepted such Purchase Order (“**Binding Order**”) as of the date of MediWound’s receipt of such Purchase Order. If a Purchase Order contains quantities of Products in excess of the quantity of such Product forecasted for such quarter (as was set forth at the Rolling Forecast submitted immediately prior to the beginning of such Calendar Year) by an amount greater than [\*\*\*] of the Binding Forecast (“**Excess Amount**”), MediWound will accept the Purchase Order up to, but not including the Excess Amount which in any event will not exceed the Maximum Capacity. Should Vericel place a Purchase Order to procure a given Product in a given Calendar Quarter which includes an Excess Amount, MediWound shall use commercially reasonable efforts to meet Vericel’s request. If there is a conflict between this Agreement and any Purchase Order, this Agreement shall govern.

(c) Minimum Purchase Obligation. In each Calendar Year following Vericel’s submission of the first Rolling Forecast, Vericel shall issue Purchase Orders for at least [\*\*\*] of the quantities of each Product set forth in the current Calendar Year of the Rolling Forecast (as was set forth at the Rolling Forecast submitted immediately prior to the beginning of such Calendar Year).

(d) BARDA. As of the Effective Date, MediWound is a party to BARDA Contract HHSO100201500035C and BARDA Contract HHSO100201800023C (collectively, the

“**BARDA Agreements**”) with the Biomedical Advanced Research and Development Authority (“**BARDA**”). The Parties agree that until commercial obligations under such BARDA Agreements are transferred to Vericel, MediWound shall remain responsible for the supply and other obligations and shall manage the forecasts and production schedule for such BARDA Agreements. During such period, any Product ordered by BARDA from MediWound will not be included in Purchase Orders, Binding Orders, Rolling Forecasts or the minimum purchase obligation set forth in Section 2.8(c); *provided* that the Product ordered by BARDA from MediWound will be included in the Maximum Capacity and thus the applicable Maximum Capacity for the Binding Orders will be adjusted accordingly. If and when commercial obligations under such BARDA Agreements are transferred to Vericel, then Vericel shall become responsible for including the applicable purchases by BARDA in its Purchase Orders, Binding Orders and Rolling Forecasts and such purchases will be included in the Maximum Capacity and the minimum purchase obligation set forth in Section 2.8(c).

## 2.9 Delivery.

(a) Shipping. MediWound shall only ship Products that have been Manufactured and released in accordance with the Specifications. Unless agreed in advance by Vericel and MediWound in writing, MediWound shall not ship (or permit such Third Party packager to ship) any Products prior to approval and release by MediWound in accordance with the Quality Agreement and Regulatory Standards. Unless otherwise agreed upon by the Parties, Products shall be delivered to Vericel Ex-Works (Incoterms 2010), at MediWound’s facility (the “**Delivery Site**”) at which point, the title and risk of loss shall transfer to Vericel which shall transfer the Products from the Delivery Site in accordance with cGMP as applicable. MediWound shall notify (or cause such Third Party packager to notify) Vericel at least [\*\*\*] prior to any shipment of Products.

(b) Delivery Amount. MediWound shall deliver Product within [\*\*\*] of the units set out on the relevant Purchase Order. To the extent that a delivery is in excess of [\*\*\*] of the amount set out on the relevant Purchase Order, Vericel may accept such excess Product provided that if Vericel accepts such excess, Vericel shall be entitled, (i) where commercially reasonable for Vericel, to vary the delivery date agreed between Vericel and MediWound in accordance with Section 2.8 for the immediately following shipment(s) of the applicable Product to the extent reasonably required due to the acceptance of such excess, and (ii) to reduce subsequent Purchase Orders and take credits for the amount of excess Product received against the minimum purchase obligation set forth in Section 2.8(c). To the extent that a delivery is less than [\*\*\*] but at least [\*\*\*] of the amount set out on the relevant Purchase Order, Vericel shall accept such delivery and shall be entitled, (A) where commercially reasonable for Vericel, to vary the delivery date agreed between Vericel and MediWound in accordance with Section 2.8 for the immediately following shipment(s) of the applicable Product due to the acceptance of such delivery, and (B) to increase subsequent Purchase Orders with the applicable shortage quantities.

(c) On Time Delivery. MediWound’s performance with respect to “on time delivery” will be measured as delivery to Vericel [\*\*\*] before or after the delivery date agreed

between Vericel and MediWound in accordance with Section 2.8; *provided* that MediWound shall be deemed to have made a delivery during the “on time delivery” window if the delay in delivery to Vericel is due to Vericel’s failure to comply with its obligations under this Agreement (including in connection with Vericel’s review of the Batch records).

2.10 Dating. The remaining shelf-life for each Product for the Territory shall be at least [\*\*\*] of the FDA approved shelf-life of such Product, as measured from the time of delivery of such Product to Vericel (the “**Minimum Shelf Life**”).

2.11 Safety Stock. MediWound shall be entitled to meet its obligation to maintain as safety stock not less than [\*\*\*] of the Rolling Forecast demand of stock of each of the Key Materials (the “**Safety Stock**”) so long as the Minimum Shelf Life has been satisfied by holding either Product or an equivalent quantity of Materials, or a mixture of the two. The Parties will cooperate to set minimum inventory levels of Key Materials held by Key Materials Suppliers. Vericel shall maintain an inventory of [\*\*\*] supply of unlabeled or labeled Finished Product in order to supply its commercial requirements in accordance with the Rolling Forecast, which may be stored at Facility at Vericel’s option, cost and risk.

2.12 Non-Conforming Product.

(a) Rejection Notice. Unless otherwise mutually agreed by the Parties in writing, within [\*\*\*] after receipt of a delivery of Product hereunder, Vericel shall give MediWound written notice of rejection (“**Rejection Notice**”) (i) if the Product does not constitute Conforming Product (“**Non-Conforming Product**”) or (ii) of any shortage in quantity of such delivery of Product. Any such Rejection Notice provided with respect to any quantity of Product shall be deemed to apply to the full Batch of such Product unless otherwise specified by Vericel. Vericel shall be deemed to have accepted such shipment of Product as Conforming Product and any shortage in quantity if it does not provide Rejection Notice within [\*\*\*] after receipt of delivery describing the reasons for such rejections in reasonable detail, *provided, however*, that such [\*\*\*] period shall not apply to any Latent Defects, in which case Vericel shall notify MediWound of any such failure as soon as reasonably possible, but in any event within [\*\*\*] after the Latent Defect is confirmed by Vericel and prior to expiration of the shelf-life for such Product.

(b) Disputes. In the event that MediWound disagrees with Vericel’s claim that Product fails to constitute Conforming Product, then the Parties shall promptly attempt to resolve such dispute. If the Parties cannot resolve such dispute, a sample of such Product shall be submitted by MediWound and Vericel to a mutually agreeable qualified Third Party laboratory for testing against the applicable Specifications, Regulatory Standards and other standards and controls in the Quality Agreement and the test results obtained by such laboratory shall be final and controlling (absent manifest error). Test results must be furnished to both Parties within [\*\*\*] of concluding such testing. The fees and expenses of such laboratory testing and any obsolescence due to short dating shall be borne entirely by the Party whose original Product analysis was in error.

(c) Remedy. On receipt of Vericel's Rejection Notice pursuant to Section 2.12(a), subject to Section 2.12(b), MediWound shall, [\*\*\*] (except if such Non-Conforming Product is due to MediWound's gross negligence or willful misconduct):

(i) deliver the appropriate shortage quantities of Conforming Product as promptly as possible, at no additional cost or expense (including, without limitation, freight costs) to Vericel;

(ii) replace the Non-Conforming Product with Conforming Product as promptly as possible, at no additional cost or expense (including, without limitation, freight costs) to Vericel; or

(iii) promptly grant Vericel a credit in an amount equal to the amount paid or payable by Vericel with respect to reasonable out of pocket expenses directly associated with the Non-Conforming Product to the extent applicable (e.g. shipment costs, destruction fees, and restocking fees) and any such shortage or Non-Conforming Product, including, without limitation, but solely in the case of Non-Conforming Product, expenses associated with destruction or return at MediWound's instruction. This subsection (iii) shall additionally apply in the event Vericel elects as its option the foregoing (i) or (ii), as applicable, and such delivery or replace of Product thereunder is not practicable within a reasonable period of time (as reasonably determined by MediWound).

### 2.13 Shortages.

(a) Without limiting any other rights or remedies available to Vericel, in the event of any shortage in the supply of any Materials or Product, or if MediWound is for any other reason unable to supply Product in compliance with the terms of this Agreement, then MediWound will promptly notify Vericel and, in the event such inability is caused by a shortage of any Materials and/or capacity required for the Manufacture of any Product, will take all commercially reasonable steps to (i) procure adequate quantities of Materials from Third Party suppliers reasonably acceptable to Vericel, and (ii) use commercially reasonable efforts to fulfill all Binding Orders for Product.

(b) Prior to a Second Source commencing supply of Product, in the event of a shortage of (i) any Materials required to Manufacture Product or (ii) Product, MediWound will allocate the available Materials to the Manufacture of Product for sale to Vericel and will allocate the available Product for sale to Vericel, in each case ((i) or (ii)), to the extent any Binding Orders then in place prior to allocating such materials to the Manufacture of any other product (including EscharEx), or for any entity other than Vericel.

(c) After a Second Source commences supply of Product, in the event of a shortage of Materials or Product, MediWound will allocate to Vericel its pro rata share of MediWound's supply of the same in a manner no less favorable than those of its equivalently situated customers or MediWound's own similarly situated products.

(d) The Parties will cooperate to discuss expansion plans, address capacity and any other product supply issues, including efficient use of resources, manufacturing schedules and shipping schedules.

2.14 Supply Failures. In the event that MediWound becomes aware of the existence of a situation that may lead to a Supply Failure, then MediWound shall promptly (and in no event later than [\*\*\*] from the date of such awareness) notify Vericel of the particular circumstances. MediWound and Vericel shall promptly discuss how to resolve such circumstances in an effort to avoid or mitigate such potential Supply Failure. MediWound shall investigate the root cause of the anticipated Supply Failure and prepare and provide to Vericel a Remediation Plan within [\*\*\*] of MediWound's notice to Vericel. If the Remediation Plan is acceptable to Vericel, and MediWound is able to reasonably assure Vericel of MediWound's ability to Manufacture Product and, thereby, (a) avoid a Supply Failure or (b) supply Product in accordance with the Rolling Forecast within [\*\*\*], then MediWound shall continue to Manufacture Product for Vericel. In all other cases, Vericel shall be permitted to take such measures as are reasonably determined in good faith by Vericel to ensure the supply of Product to the marketplace including cancelling or revising outstanding Purchase Orders and, at Vericel's option, Vericel's obligations under Section 2.8(a), (b) and (c) shall be deemed terminated.

### **ARTICLE 3 COMPLIANCE, QUALITY AND ENVIRONMENTAL**

3.1 Certificates of Analysis; Release. MediWound shall perform, or cause to be performed testing and other activities on each Batch of Product Manufactured pursuant to this Agreement before delivery to Vericel or Vericel's designated Affiliate or contractor and consistent with the testing and procedures specified in the Quality Agreement. In the event of any change in Specifications, the certificate of analysis shall contain the required information in accordance with the then-approved release tests in conjunction with applicable change control procedures in accordance with this Agreement and the Quality Agreement. MediWound shall send, or cause to be sent, such certificates to Vericel prior to delivery of each such Batch unless otherwise agreed by the Parties in writing or specified in the Quality Agreement.

3.2 Records. MediWound shall maintain and shall cause each Supplier to maintain all Manufacturing records, including packaging, analytical and stability records, all records of shipment, and all validation data relating to the Product Manufactured and supplied to Vericel hereunder for the Territory to the extent and for the time periods required by applicable Regulatory Standards with respect to such Product. MediWound shall make such records and data available for Vericel's review on Vericel's reasonable request as mutually agreed by the Parties.

3.3 Regulatory Compliance. MediWound shall advise Vericel promptly, but in any event within [\*\*\*] on becoming aware of an authorized agent of a Regulatory Authority visit or inspection to its or any of the Suppliers' Facilities where the Products are being Manufactured for supply to Vericel for the Territory hereunder and in connection with the Manufacturing of the Products. MediWound agrees to use commercially reasonable efforts to permit one or more



Vericel representatives to be present for all or part of such visit or inspection if Vericel so requests. MediWound shall use commercially reasonable efforts to furnish to Vericel a copy of all material information supplied and/or issued by any Regulatory Authority to the extent that such report relates to the Manufacture or supply of Product to Vericel for the Territory, or the ability of MediWound or the Suppliers to so Manufacture or supply hereunder, within [\*\*\*] of its receipt of such information. Before MediWound or any Supplier responds to any Regulatory Authority where such correspondence would reasonably be expected to have a material impact on the Manufacture or supply of Product to Vericel for the Territory, Vericel will be provided a reasonable opportunity, unless prohibited by applicable Law, to review and comment on the portion of such response related thereto, *provided* that Vericel shall conduct such review and provide such comments reasonably in advance of when any such response is due to such Regulatory Authority, and further provided that nothing herein, including failure by Vericel to provide such timely review and comment, shall in any way restrict MediWound or its Suppliers from taking, and MediWound and its Suppliers shall at all times be permitted to take, such actions or inactions necessary for its and their compliance with applicable Law. With respect to any and all requirements of a Regulatory Authority for the Manufacture of Product for Commercialization in the Territory following the First Commercial Sale of the Product in a country in the Territory, the Parties shall discuss in good faith such requirements and allocation of responsibility between the Parties.

### 3.4 Audit.

(a) Vericel shall have the right from time to time during the Term of this Agreement, but not more than [\*\*\*] (unless (i) otherwise agreed between the Parties or (ii) if Section 3.4(b) below applies) during normal business hours and upon not less than [\*\*\*] prior notice (unless Section 3.4(b)(iv) applies), to enter and inspect any Facility and any related utilities and/or services used in Manufacturing Product in order to carry out a cGMP quality and compliance audit of those parts of the Facility involved in or which could have any impact on Manufacture of such Product (including those used for storing, warehousing and/or testing and utilities), including for the purpose of confirming that no types of product which could reasonably be expected to impact the quality of the Product are being manufactured on site in deviation of cGMP.

(b) In addition to the rights set out in Section 3.4(a), where (i) any audit carried out in accordance with this Section 3.4 has identified any breach of this Agreement, (ii) Vericel has a reasonable basis to suspect a breach of this Agreement, (iii) any previous audit carried out in accordance with this Section 3.4 has identified any major or critical findings, or (iv) if such audit is in response to or following an audit from a regulatory agency, and such audit resulted in a 483 or equivalent citation, then Vericel shall have the right to carry out, upon reasonable prior notice and during normal business hours, follow up compliance audit(s).

(c) MediWound shall be solely responsible for ensuring the cGMP compliance status of subcontractors (where such subcontractors are carrying out activities to which cGMP applies) used in relation to the performance of its obligations under this Agreement.

(d) MediWound shall use commercially reasonable efforts to procure the right for Vericel to have the same inspection rights described in this Section 3.4 at the premises of any such subcontractor, and if unable to procure such rights, shall carry out such audits itself and shall report its non-confidential findings to Vericel.

(e) The above obligations of MediWound and rights of Vericel shall apply, *mutatis mutandis*, to the rights of MediWound and obligations of Vericel with respect to the undertaking of Vericel and its Affiliates, Sublicensees and Distributors to comply with the cGMP as applicable to their activities and the related audit rights to ensure such compliance.

3.5 Results of Audits and /or Regulatory Inspection. Observations and conclusions of Vericel's audits will be issued to MediWound, which materials shall be deemed Confidential Information, *provided* that any Confidential Information of MediWound contained therein or upon which such observations and conclusions are based shall remain the Confidential Information of MediWound. MediWound and Vericel shall, at Vericel's expense (unless the result is due to a material breach of MediWound of any of its obligations under this Agreement), (a) cooperate to determine the cause for any identified issues, (b) work together in good faith to develop a corrective action, and (c) endeavor to implement such corrective action within a mutually agreed time period thereafter.

3.6 Regulatory Information. MediWound shall promptly disclose to Vericel, upon its request, information in MediWound's possession required for Vericel to obtain and maintain any and all needed permits, approvals, or licenses issued by any and all Regulatory Authorities relating to the Manufacture, storage, packaging, and sale of a Product, as the case may be. MediWound shall use reasonable commercial efforts to cause Suppliers to, provide to Vericel in a reasonable, timely manner (including within a reasonable period prior to the due date of Vericel's annual report to an applicable Regulatory Authority with respect to the Product), all information in its or their respective possession which Vericel requires regarding the Product in order to comply with such Regulatory Standards. MediWound shall provide new regulatory correspondence related to the Product as soon as possible but in no event less than [\*\*\*].

3.7 Recall. Any decision to initiate a Recall of a Product in a country in the Territory shall be made by the marketing approval holder and shall be made in compliance with and to the extent permitted by applicable Law, after consultation between the Parties. Vericel's and its Affiliates', Sublicensees' and Distributors' costs (including internal costs of Vericel) associated with any such Recall shall be borne solely by Vericel (including refunds to customers); *provided, however*, that all out of pocket expenses associated with a Recall (including those of Vericel and its Affiliates, Sublicensees and Distributors and refunds to customers) shall be borne solely by MediWound to the extent such Recall (a) arises from or is caused directly by any breach by MediWound of this Agreement, the License Agreement or the Quality Agreement, or MediWound's or any of its Affiliates', Suppliers' or subcontractors' negligence or willful misconduct; or (b) resulting directly from MediWound's failure to supply Product that conforms to the applicable Product Warranty. MediWound shall cooperate in the implementation of any Recall of Product in the Territory, as required by applicable Law or reasonably requested by Vericel and, for such a Recall, the cost of such cooperation shall be at Vericel's reasonable

expense (except to the extent the Recall results from the matters described in the foregoing clauses (a) or (b)).

3.8 Quality Agreement. Each Party shall perform the duties required of it pursuant to a quality agreement to be entered into by the Parties within [\*\*\*] of the execution of this Agreement (the “**Quality Agreement**”). To the extent the Quality Agreement either conflicts with this Agreement or is silent on an issue addressed, this Agreement shall control, except to the extent the matter is strictly a quality matter, in which event the Quality Agreement shall supersede this Agreement solely with respect to such quality matter.

#### **ARTICLE 4 CHANGES**

4.1 Changes. MediWound shall not change the Specifications or Manufacturing process for the Manufacture of Product for supply to Vericel for the Territory hereunder except as expressly permitted pursuant to this Article 4. Each Party shall notify the other Party of any change in the Regulatory Standards applicable to the Manufacturing of Product for the supply to Vericel for the Territory that could reasonably affect the obligations of MediWound under this Agreement. All changes shall include an assessment of the need for regulatory submission and approval by a method to be defined in the Quality Agreement. The applicable notification period for any change or proposed change by a Party to the Manufacturing process or Specifications for a Product or Key Materials, the Facility and other Manufacturing changes (the “**Change Notification Period**”) is set forth on Schedule 4.1.

4.2 Changes to Facility. Except as expressly permitted pursuant to Section 2.6 and this Article 4, MediWound shall not perform any change of any part of any Facility, change the physical location within the Facility for Manufacturing any Products or change the Facility at which the Manufacturing of any Products takes place, if such change would reasonably be expected to (a) impact the Regulatory Approval for one or more of the Products or any regulatory compliance program; or (b) result in inability (permanent or temporary) of MediWound to Manufacture, supply or otherwise perform its obligations per Vericel’s Rolling Forecast in accordance with this Agreement. For any change in the Facility at which the Manufacturing of any Products takes place, MediWound shall (i) give Vericel notice within the applicable Change Notification Period, and (ii) provide Vericel a plan for avoiding any interruption in supply that may result from such change. In the event of a “Major” change to the Facility (as detailed in Schedule 4.1), such change will be treated in accordance with Section 2.6(b).

4.3 Discretionary Manufacturing Changes. Vericel may propose changes to the Specifications or Manufacturing process for the supply of Product to Vericel for the Territory that are not Regulatory Changes (any such change, a “**Discretionary Manufacturing Change**”). If agreed to by MediWound, MediWound or its Suppliers will use commercially reasonable efforts to make such proposed changes, and Vericel will bear [\*\*\*] of the costs associated with such changes. MediWound may propose changes to the Specifications or Manufacturing process for the supply of Product for the Territory that are not Regulatory Changes. MediWound shall propose any such Discretionary Manufacturing Change in accordance with the applicable

Change Notification Period prior to the proposed implementation. [\*\*\*]. Vericel shall, within [\*\*\*] of receipt of MediWound's notice, notify MediWound in writing whether Vericel accepts or rejects the proposed change, such consent not to be unreasonably withheld, conditioned or delayed unless consultations with regulatory authorities are required to assess the impact of such proposed change.

#### 4.4 Regulatory Changes.

(a) Notwithstanding any other provision under this Agreement to the contrary, if either Party receives notice, or is otherwise informed of, any change to the Manufacturing process or Specifications for a Product or Key Materials, the Facility or any change that has an impact of the obligations of Vericel or MediWound under this Agreement that is required by applicable Law or that is otherwise required by any applicable Regulatory Authority (any such change, a "**Regulatory Change**"), such Party shall promptly deliver notice thereof to the other Party. Within the applicable Change Notification Period, MediWound shall notify Vericel in writing of MediWound's good faith and reasonable determination as to (i) whether MediWound is technically able to comply with such Regulatory Change, (ii) whether the Regulatory Change would adversely affect MediWound's ability to timely manufacture and supply any Product supplied hereunder and (iii) the costs to implement such Regulatory Change. MediWound shall use commercially reasonable efforts to cause Key Material Suppliers to provide such notice of any Regulatory Change to MediWound or Vericel.

(b) If MediWound determines it is technically unable to comply with the Regulatory Change at the Facility in the timeframe required by the applicable Regulatory Authority, then, in MediWound's discretion, it shall have the right to transfer the Manufacturing of the applicable Product to an alternative facility of MediWound that is qualified and approved for Manufacturing such Product in accordance with this Agreement, if available. In the event MediWound is unable to supply Product as a result of such Regulatory Change, Vericel, in its sole discretion, shall be entitled to source all or any portion of Vericel's requirements of the applicable Product, until MediWound regains the ability to supply Product, from a Third Party, including from the Second Source. Notwithstanding anything to the contrary contained in this Agreement, if as a result of a Regulatory Change, MediWound is unable to Manufacture and supply a Product to Vericel, Vericel shall be entitled to source such Product, until MediWound regains the ability to supply Product, from a Third Party or Second Source in accordance with this Section 4.4(b), in which case MediWound shall use commercially reasonable efforts to provide Vericel with reasonable technical assistance with regard to transferring the technology relating to the Product to such Third Party, and the Parties shall discuss the allocation of such costs related to such transfer, including MediWound's expenses and any incremental costs of supply of such Product and Materials from such Third Party consistent with Schedule 4.5.

(c) If MediWound determines it is technically able to implement a Regulatory Change required by a Regulatory Authority in the Territory, the costs for such Regulatory Change shall be borne by Vericel consistent with Schedule 4.5.

4.5 Ongoing Regulatory Assistance. Within [\*\*\*] following Vericel's request, MediWound shall provide technical data and assistance in answering Vericel's questions (a) for regulatory filings and for process changes initiated by MediWound at no cost to Vericel, (b) for process changes initiated by Vericel at the cost of Vericel for the applicable number of hours at a Full Time Equivalent rate described in Schedule 4.5, (c) for new regulatory registrations, which shall be at Vericel's cost, and (d) for periodic regulatory reporting and questions from regulatory authorities, which shall be at the cost of Vericel.

## ARTICLE 5 PRICE AND PAYMENT TERMS

5.1 Supply Price. On a Product-by-Product basis, the price payable in U.S. Dollars by Vericel for supply of such Product for a given Calendar Year shall be as set forth on a per unit basis on Exhibit A (with respect to each Product, the "**Supply Price**"), which shall be updated on a Calendar Year basis in accordance with Section 5.2 below.

### 5.2 Price Mechanics.

(a) Beginning on [\*\*\*] (each, a "**Re-Pricing Date**"), MediWound may annually increase the Supply Price for a Calendar Year in accordance with the terms of this Section 5.2. MediWound may increase the Supply Price for a Calendar Year if the United States Producer Price Index (Chemical Manufacturing) published by the Bureau of Labor Statistics (the "**PPI**") [\*\*\*] and (b) in the event the PPI [\*\*\*]. MediWound shall give Vericel at least [\*\*\*] prior written notice of any such adjustment to the Supply Price.

(b) In addition to the foregoing price adjustment mechanism, MediWound may propose an adjustment to the Supply Price to reflect changes that substantially affect MediWound's costs or ability to supply Product. MediWound shall provide Vericel with written notice of such changes and its proposed adjustment and provide appropriate documentation demonstrating that the price adjustment is required. Following Vericel's receipt of such notice and documentation, the Parties will engage in good faith discussions to negotiate a mutually agreed upon adjustment to the Supply Price, if any.

(c) Unless otherwise agreed by the Parties, the adjusted Supply Price will be the Supply Price for the next applicable Purchase Order placed after Vericel's receipt of notification of the adjusted Supply Price, and shall apply to each Purchase Order placed thereafter until the next adjustment is made (if any) in accordance with the above mechanism.

5.3 Cost Savings. Either Party may propose changes to any Manufacturing process in order to obtain efficiencies and cost savings in such process ("**Cost Savings Change**"). The proposing Party shall submit to the other Party a proposal detailing the Cost Savings Change, the implementation of such Cost Savings Change, and the analysis of the expected efficiencies and cost savings from such Cost Savings Change. If Vericel proposes a Cost Savings Change and (a) MediWound determines it is technically able to implement the Cost Savings Change, (b) the Cost Savings Change would not materially adversely affect the applicable Facility, and (c) Vericel agrees to pay the costs to implement such Costs Saving Change as an Additional Service Fee,

MediWound shall agree to implement such proposed change which MediWound shall not unreasonably decline to implement. If MediWound proposes a Cost Savings Change and the Parties agree to its implementation, (i) Vericel shall pay MediWound the agreed amount to implement such change as an Additional Service Fee prior to the implementation of such Cost Savings Change; and (ii) MediWound shall make its reasonable commercial efforts to implement such Cost Savings Change pursuant to a mutually agreed upon schedule. In the event cost savings are actually achieved, then the cost saving will be [\*\*\*] between the Parties (i.e. [\*\*\*] of the cost savings shall be added to the new discounted Supply Price).

5.4 Payments. Unless specified otherwise, any payment to be made by Vericel under this Agreement shall be made within [\*\*\*] from date of invoice. It is hereby agreed that the invoice with respect to any shipment will be issued upon the delivery date. The Parties' respective rights and responsibilities under Sections 5.6.5 and 5.6.6 of the License Agreement shall apply as such Section pertains to the Parties' performance under this Agreement, and are hereby incorporated by reference.

5.5 Late Payments. Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. In the event that any payment due under this Agreement is not made when due, the amount due shall accrue interest beginning on the [\*\*\*] following the date on which such payment was due, calculated at the [\*\*\*] for the due date, or, if lower, the maximum rate permitted by law, calculated from the due date until paid in full. Each payment made after the due date shall be accompanied by all interest so accrued. Notwithstanding the foregoing, a Party shall have recourse to any other remedy available at law or in equity with respect to any delinquent payment, subject to the terms of this Agreement.

5.6 Taxes. Vericel shall be responsible for the payment of any value added or similar tax (but excluding, for avoidance of doubt, any tax on the income of MediWound) on the Products delivered by MediWound to Vericel, to the extent such taxes are itemized and included on a valid invoice and required to be collected from Vericel under applicable Law. In addition, in the event any payments made by Vericel pursuant to this Agreement become subject to withholding taxes under the Laws or regulations of any jurisdiction or Governmental Authority, Vericel shall deduct and withhold the amount of such taxes for the account of MediWound to the extent required by applicable Laws or regulations; such amounts payable to MediWound shall be reduced by the amount of taxes deducted and withheld; and Vericel shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and transmit to MediWound an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld. Any such withholding taxes required under applicable Laws or regulations to be paid or withheld shall be an expense of, and borne solely by, MediWound. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable Laws. Vericel will provide MediWound with reasonable assistance to enable MediWound to recover such taxes as permitted by applicable Laws or regulations.

**ARTICLE 6**  
**REPRESENTATIONS, WARRANTIES AND COVENANTS**

6.1 **Mutual Representations and Warranties.** As of the Effective Date unless otherwise specified, each of MediWound and Vericel hereby represents and warrants to the other Party that:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

(b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms; and

(e) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any agreement or arrangement with any Third Party existing as of the Effective Date.

6.2 **Compliance with Law.** During the Term of this Agreement, each Party shall comply in all material respects with all applicable Laws (including Regulatory Standards, cGMP as applicable to MediWound and cGMP to the extent applicable to Vericel) applicable to its performance under this Agreement.

6.3 **Product Warranty.** MediWound represents and warrants to Vericel that, at the time of delivery of the given Product to the Delivery Site pursuant to Section 2.9(c), such Product so delivered pursuant to this Agreement will constitute Conforming Product and, except with respect to Section 2.13, will have a shelf life equal to or exceeding the Minimum Shelf Life (the “**Product Warranty**”).

6.4 **No Liens.** MediWound represents, warrants and covenants that all Product delivered to Vericel (or its designated Affiliate or contractor) pursuant to this Agreement will, at the time of such delivery, be free and clear of all liens, encumbrances, security interests and other encumbrances.

6.5 **Debarment.** As of the Effective Date hereof and at all times during the Term of the Agreement, each Party represents and warrants to the other Party that neither it nor, to its knowledge, any of its existing subcontractors or Suppliers, is debarred as of the Effective Date, and neither it nor any of its subcontractors or Suppliers shall, during the Term, use in any

capacity the services of any Person debarred by any Regulatory Authority, including under Subsection 306(a) or (b) of the Generic Drug Enforcement Act of 1992 or any other equivalent Regulatory Standard. In the event either Party learns that it, any of its employees or contractors, any Supplier or any of a Supplier's employees or contractors has been debarred, it shall notify the other Party promptly, and in any event within [\*\*\*] of learning of such debarment. In the event that MediWound, any of its employees or contractors, any Supplier or any of a Supplier's employees or contractors has been debarred, MediWound shall immediately remove or have removed such Person from thereafter performing Manufacturing or supply activities under this Agreement with respect to the Product upon learning of such debarment. In the event that Vericel, any of its employees or contractors, any Sublicensee or any of such Sublicensee's employees or contractors has been debarred, it shall immediately remove or have removed such Person from thereafter performing distribution activities under this Agreement with respect to the Product upon learning of such debarment.

## **ARTICLE 7 INDEMNITY, INSURANCE**

7.1 Indemnification by MediWound. MediWound will indemnify, defend and hold harmless Vericel, its Affiliates, Sublicensees, contractors, Distributors and each of its and their respective employees, officers, directors and agents (each, a "**Vericel Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, "**Liability**") that the Vericel Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

(a) the material breach by MediWound of any of its representations, warranties or covenants set forth in Article 6;

(b) any Recall or withdrawal of Product to the extent attributable to MediWound's breach of this Agreement or the Quality Agreement; or

(c) the gross negligence or willful misconduct of MediWound or any subcontractor or Supplier acting on behalf of MediWound relating to its activities in connection with this Agreement; except, in each case, to the extent (y) caused by the negligence, recklessness or intentional acts of Vericel or any Vericel Indemnified Party or (z) Vericel is required to indemnify MediWound pursuant to Section 7.2.

7.2 Indemnification by Vericel. Vericel will indemnify, defend and hold harmless MediWound, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "**MediWound Indemnified Party**") from and against any and all Liability that the MediWound Indemnified Party may be required to pay to one or more Third Parties (other than shareholders of MediWound or its Affiliates) resulting from or arising out of:

(a) the material breach by Vericel of any of its representations, warranties or covenants set forth in Article 6;



(b) any Recall or withdrawal of Product to the extent attributable to Vericel's breach of this Agreement or the Quality Agreement; or

(c) the gross negligence or willful misconduct of Vericel or any subcontractor or Supplier acting on behalf of Vericel relating to its activities in connection with this Agreement; except, in each case, to the extent (y) caused by the negligence, recklessness or intentional acts of MediWound or any MediWound Indemnified Party or (z) MediWound is required to indemnify Vericel pursuant to Section 7.1.

7.3 No Right of Indemnification under License Agreement. No right of indemnification shall exist under the License Agreement for claims arising out of the performance of this Agreement, it being the intent of the Parties that such claims shall be solely governed by the provisions of this Agreement and, for the avoidance of doubt, except as set forth in Section 7.6, no limits on indemnification or liability set forth in the License Agreement shall apply to this Agreement.

#### 7.4 Procedure.

(a) Notice. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the "**Indemnified Party**") is entitled to indemnification hereunder (a "**Third Party Claim**"), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the "**Indemnifying Party**") thereof; *provided, however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

(b) Control. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within [\*\*\*] after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (i) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (ii) the Third Party Claim seeks solely monetary damages and (iii) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (i), (ii) and (iii) above are collectively referred to as the "**Litigation Conditions**"). Within [\*\*\*] after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party shall give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party shall continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as

such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party shall be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall cooperate, and shall cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within [\*\*\*] after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

(c) Settlement. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party shall not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other party, and the Indemnified Party shall use reasonable efforts to mitigate liabilities arising from such Third Party Claim.

7.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, WITH RESPECT TO THIS AGREEMENT (INCLUDING THE MANUFACTURE AND SUPPLY OF PRODUCT HEREUNDER), EXPRESS, IMPLIED OR STATUTORY, INCLUDING, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7.6 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING LOST PROFITS) REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, SUFFERED BY THE OTHER PARTY, EVEN IF THAT PARTY HAS BEEN INFORMED OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. [\*\*\*].

7.7 Insurance. For the duration of this Agreement and for a period of [\*\*\*] following its termination, each Party agrees to obtain and maintain, during the Term, commercial general liability insurance, including product liability insurance, with reputable and financially secure insurance carriers (or pursuant to a program of self-insurance reasonably satisfactory to the other Party) to cover its indemnification obligations under Section 7.1 or Section 7.2, as applicable, in each case with limits of not less than [\*\*\*] per occurrence and in the aggregate. Insurance shall be procured with carriers having an A.M. Best Rating of A-VII or better.

## **ARTICLE 8 TERM AND TERMINATION**

8.1 Term. The term of this Agreement will commence upon the Effective Date and will continue until the fifth (5th) anniversary of the Effective Date, unless earlier terminated or extended under this Article 8 (the “**Initial Term**”). At least twenty-four (24) months from the end of the Initial Term, Vericel shall provide MediWound notice whether Vericel elects to extend the Initial Term of the Agreement by an additional twenty four (24) months. After the Initial Term (including any extension thereto made in accordance with the preceding sentence), the Agreement may be extended on a yearly basis up to ten (10) years at Vericel’s sole discretion, with renewal notice to be provided to MediWound no later than twelve (12) months prior to the expiry of any yearly extension (the “**Renewal Term**”, and the Initial Term, together with the Renewal Term, if any, the “**Term**”); *provided* that unless otherwise agreed by the Parties, the Term of this Agreement (including the Initial Term, any extension of the Initial Term and any Renewal Terms) shall be no more than fifteen (15) years in total.

8.2 Automatic Termination. This Agreement will automatically immediately terminate in the event of the expiration or termination of the License Agreement.

8.3 Termination for Breach. Subject to the provisions of Article 10 below, either Party may terminate this Agreement in its entirety if the other Party materially breaches a material provision and does not cure such breach, or does not take reasonable steps required under the circumstances to cure such breach going forward, within [\*\*\*] after receiving notice of the breach.

8.4 Termination by Vericel. Following the Initial Term, Vericel may, without penalty or prejudice to any other rights or remedies Vericel may have, in its sole discretion terminate or reduce the scope of any individual activities contemplated by this Agreement or any Additional Service or with respect to any Product or terminate this Agreement as a whole with or without cause, upon [\*\*\*] prior written notice of such termination or reduction (which such written notice may be provided during the Initial Term).

8.5 Termination by MediWound. Following the Initial Term, MediWound may terminate this Agreement by notice in writing to Vericel upon on at least [\*\*\*] advanced written notice (or such longer period of time as reasonably necessary to avoid a supply disruption) if MediWound determines to cease Manufacturing the applicable Product for the Territory, but in such case MediWound will reasonably cooperate with Vericel to enable Vericel to establish its own source for the Product (including, to the extent requested by Vericel and within

MediWound's ability to do so, by transferring MediWound's applicable Third Party manufacturing relationships to Vericel).

8.6 Effects of Termination. Any expiration or termination of this Agreement shall not affect any claims that have accrued or outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the Parties may have under this Agreement. In addition, upon the expiration or earlier termination of this Agreement:

(a) if Vericel terminates the Agreement for breach or MediWound terminates in accordance with Section 8.5, Vericel shall have the option of [\*\*\*]

(b) Vericel shall pay to MediWound: (i) all amounts outstanding and remaining to be paid for Product supplied prior to such expiration or termination or under any other obligation under the Agreement; (ii) all amounts for Product in the Binding Forecasts and Binding Orders prior to the expiration or termination, provided that MediWound delivers such Product in accordance with the terms of this Agreement; (iii) all amounts representing the purchase by MediWound of Materials in reliance upon the Binding Forecasts and Binding Orders (if MediWound is unable to cancel (without incurring any costs) or otherwise use such Materials); and (iv) all amounts representing remaining inventory of Product and all Product work in process undertaken in accordance with the Binding Forecasts or Binding Orders or undertaken otherwise in accordance with the terms of this Agreement.

(c) Following expiration of the Royalty Term (as defined in the License Agreement) for any Licensed Product in a given country, the license granted to Vericel under Section 9.1 of this Agreement with respect to such Licensed Product in such country shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.

8.7 Survival. Upon expiration or termination of this Agreement for any reason, the following terms of this Agreement shall survive: Article 1, Sections 3.2, 5.4, 5.5 and 5.6, Article 7, Article 8, Sections 9.1 and 9.2 (except in the event of termination of the License Agreement under Section 9.2, 9.3 or 9.4 thereof), Section 9.3, Article 10, and Article 11.

## **ARTICLE 9 INTELLECTUAL PROPERTY RIGHTS**

9.1 Manufacturing License Grant. Subject to the terms herein, MediWound hereby grants to Vericel a non-exclusive, sublicensable (subject to Section 4.2 of the License Agreement) license under the MediWound Technology and MediWound's interest in the Joint Technology, to Manufacture and have Manufactured Licensed Products in the Territory for use in the Field in the Territory.

9.2 Trademarks License Grant. MediWound hereby grants to Vericel an exclusive (even as to MediWound), sublicensable, royalty-free, fully paid-up, license in the Territory to use the Licensed Trademarks (as defined in the License Agreement) and a non-exclusive, sublicensable, royalty-free, fully paid-up, license to use the MediWound name and trademark, in

each case, in connection with the Manufacture of Licensed Products in or for the Territory. All uses of the Licensed Trademarks by Vericel (and its Affiliates, Sublicensees and Distributors) in connection with the Manufacture of Licensed Products in or for the Territory shall be in accordance with Regulatory Approvals and all applicable Laws and MediWound's quality control guidelines for the Licensed Trademarks, as may be amended from time to time. Vericel (and its Affiliates) shall only use the Licensed Trademarks licensed hereunder in connection with the Manufacture of Licensed Products in the Territory. Vericel shall not (and shall cause its Affiliates, Sublicensee and Distributors not to) use such Licensed Trademarks to identify, or in connection with the marketing of, any other products.

9.1 **Ownership.** Ownership of all inventions and discoveries made by the Parties in the course of Manufacturing and supply of the Product hereunder (including Manufacture and supply of Product) shall be determined in accordance with the terms of the License Agreement.

## **ARTICLE 10 FORCE MAJEURE**

10.1 **Excusing Performance.** Neither Party shall be liable for the failure to perform its obligations under this Agreement to the extent such failure is due to events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances involving the workforce of any Third Party, or acts of God (a "**Force Majeure Event**"). Notwithstanding anything to the contrary herein, the occurrence of a Force Majeure Event will not excuse or prevent a failure of MediWound to deliver Product from being deemed a "Supply Failure" or otherwise limit Vericel's rights, to the extent applicable, under Section 2.13.

10.2 **Notice of Force Majeure Event.** A Party claiming a right to be excused from performance under Section 10.1 shall immediately notify the other Party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event and the estimated likely period of time during which its performance will be affected.

10.3 **Resumption; Termination.** A non-performing Party as a result of a Force Majeure Event shall use reasonable best efforts, at its own expense, to eliminate the Force Majeure Event and to mitigate the effect of such cause and resume performance under this Agreement, in each case, as soon as practicable and for as long as such Force Majeure Event continues. Further, consistent with diligent risk management practices, MediWound will keep current a risk management program. If MediWound is affected by any Force Majeure Event, MediWound agrees to perform its obligations under this Section 10.3 to mitigate the effect thereof and resume performance under this Agreement in the same manner as MediWound would use to resolve any similar disruptions affecting its own products (including EscharEx). MediWound shall use reasonable best efforts to ensure that the impact of the Force Majeure Event shall not be relatively greater for Vericel than it is for MediWound with respect to MediWound's products (including EscharEx).

**ARTICLE 11**  
**MISCELLANEOUS**

11.1 Assignment. Neither this Agreement nor any interest hereunder shall be assignable by a Party without the prior written consent of the other Party, except as follows: (a) such Party may assign its rights and obligations under this Agreement to any of its Affiliates, *provided that* the assignee shall expressly agree to be bound by such Party's obligations under this Agreement and that such Party shall remain liable for all of its rights and obligations under this Agreement, and (b) either Party may assign its rights and obligations hereunder to a Third Party in connection with a permitted assignment or other permitted transfer of the License Agreement. Each Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 11.1. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.1 shall be void.

11.2 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

11.3 Notices. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) shall be in writing and shall be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), five days after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next Business Day if sent by overnight delivery using a nationally recognized express courier service and specifying next Business Day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as shall be specified by like notice, *provided, however*, that notices of a change of address shall be effective only upon receipt thereof):

All correspondence to Vericel shall be addressed as follows:

Vericel Corporation  
64 Sidney Street  
Cambridge, Massachusetts 02139  
Attention: Chief Financial Officer

with a copy to:

General Counsel

All correspondence to MediWound shall be addressed as follows:

MediWound Ltd.  
42 Hayarkon Street  
Yavne, Israel 8122745  
Attention: Chief Financial Officer

with a copy to:

General Counsel

11.4 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

11.5 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.6 Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

11.7 Descriptive Headings. The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

11.8 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to include the Person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules shall be construed to refer to Sections, Exhibits or Schedules of

this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

11.9 Governing Law. This Agreement, and all claims arising under or in connection therewith, shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof.

11.10 Consent to Jurisdiction. In the event of any dispute arising out of or relating to this Agreement other than a dispute arising under Section 2.7(b), the affected Party shall notify the other Party, and the parties shall attempt in good faith to resolve the matter within [\*\*\*] after the date of such notice (the “**Notice Date**”). Any disputes not resolved by good faith discussions shall be referred to senior executives of each party, who shall meet at a mutually acceptable time and location within [\*\*\*] after the Notice Date and attempt to negotiate a settlement. If the matter remains unresolved within [\*\*\*] after the Notice Date, each Party to this Agreement hereby (a) irrevocably submits to the exclusive jurisdiction of the state courts of the State of New York or the United States District Court for the Southern District of New York for the purpose of any and all actions, suits or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof, (b) waives to the extent not prohibited by applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) agrees not to commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise. Notwithstanding the foregoing, MediWound agrees that a final judgement in an action, suit or proceeding brought in one of the above-named courts may be enforced by Vericel in the competent courts of the State of Israel by suit on such judgment or in any other manner provided by applicable Law.

11.11 Entire Agreement. This Agreement together with the License Agreement and the Quality Agreement, constitutes and contains the complete, final and exclusive understanding and



agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

11.12 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

11.13 Counterparts. This Agreement may be executed in two counterparts, each of which shall be an original and both of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile or PDF file, each of which shall be binding when received by the applicable Party.

11.14 No Third Party Rights or Obligations. No provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement.

11.15 Confidentiality.

(a) Section 7 of the License Agreement shall govern the use and disclosure of information disclosed by the Parties under this Agreement. Either Party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.15(a), the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure (which, at a minimum, shall include redaction of certain financial terms), with the disclosing Party providing as much advance notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 11.15(a), such Party shall, at its own expense, seek such confidential treatment of confidential portions of this Agreement, as may be reasonably requested by the other Party.

(b) No Party to this Agreement shall originate any publicity, news release or other similar public announcement, written or oral, whether relating to this Agreement or any documents or transactions contemplated hereby or the existence of any arrangement between the Parties, without the prior written consent of the other Party whether or not named in such publicity, news release or other similar public announcement, except to the extent permitted under the License Agreement.

11.16 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that Vericel and its Sublicensees,

as Sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto.

[SIGNATURE PAGE FOLLOWS]

**IN WITNESS WHEREOF**, the Parties hereto have each caused this Agreement to be duly executed as of the Effective Date.

**MEDIWOUND LTD.**

By: /s/ Stephen T. Wills  
Name: Stephen T. Wills  
Title: Chairman

**VERICEL CORPORATION**

By: /s/ Dominick Colangelo  
Name: Dominick Colangelo  
Title: President & CEO

**SCHEDULE 1.26**

**KEY MATERIALS & KEY MATERIALS SUPPLIERS**

***Bromelain special Production - CBC Taiwan***

[\*\*\*]

[\*\*\*]

**SCHEDULE 2.7**

**TECHNOLOGY TRANSFER DOCUMENTATION**

Technology Transfer documents include but are not limited to

[\*\*\*]

**SCHEDULE 4.1**

**CHANGE NOTIFICATION**

| Category of Change   |  | Minimum Notification prior to <b>effectiveness of implementation</b> of the change |
|--|--|--|
| <b>Section 4.2 : Changes in Facility</b>   |  |  |
| Major – Changes to facility have the potential to have an adverse effect on product quality that requires BLA Prior Approval Supplement.   |  | [***]  |
| <ul style="list-style-type: none"> <li>Moderate – Changes to facility have a moderate potential to have an adverse effect on product quality that requires Notification to the Regulatory Authority (e.g., CBE, CBE-30)</li> </ul> |  | [***]  |
| <ul style="list-style-type: none"> <li>Minor – Changes to facility have minimal potential to have an adverse effect on product quality that requires annual or periodic reporting to the FDA.</li> </ul>                           |  | [***]  |
| <b>Section 4.3: Discretionary Manufacturing changes</b>  |  |  |
| <ul style="list-style-type: none"> <li>Major – Changes have the potential to have an adverse effect on product quality that requires BLA Prior Approval Supplement.</li> </ul>   |  | [***]  |
| <ul style="list-style-type: none"> <li>Moderate – Changes have a moderate potential to have an adverse effect on product quality that requires Notification to the Regulatory Authority (e.g., CBE, CBE-30).</li> </ul>            |  | [***]  |

| Category of Change   |  | Minimum Notification prior to <b>effectiveness of implementation</b> of the change |
|--|--|--|
| <ul style="list-style-type: none"> <li>• Minor – Changes have minimal potential to have an adverse effect on product quality that requires annual or periodic reporting to the FDA.</li> </ul>   |  | [***]  |
| <ul style="list-style-type: none"> <li>• None – Changes have no potential to have an adverse effect on product quality and has no regulatory impact.</li> <li>• Example <ul style="list-style-type: none"> <li>o Clarification of internal SOPs</li> </ul> </li> </ul> |  | [***]  |
| Section 4.4 Changes required by a Regulatory Authority   |  | [***]  |

Example Timeline for Major Change (BLA Prior Approval Supplement Required)

Vericel Evaluation: [\*\*\*]

Pre-Submission discussions with FDA and/or BARDA: [\*\*\*]

Testing (presumes rate limitation is stability testing of > 6 months): [\*\*\*]

Submission drafting: [\*\*\*]

FDA Review: [\*\*\*]

Implementation: [\*\*\*]

Example Timeline for Moderate Change (BLA CBE-30 Required)

Vericel Evaluation: [\*\*\*]

Testing: [\*\*\*]

Submission drafting: [\*\*\*]

FDA Review: [\*\*\*]

Implementation: [\*\*\*]

**SCHEDULE 4.5**

**FULL-TIME EQUIVALENT**

FTE Rates for Reimbursement of Preapproved Activities Completed by MediWound per Section 4.5:

The FTE rate will be capped per [\*\*\*].

MediWound personnel will be reimbursed at the designated FTE with an overhead of [\*\*\*].

Consultants' costs will be reimbursed only if pre-approved by Vericel before any work is conducted. [\*\*\*].

Subcontractor costs will be reimbursed only if pre-approved by Vericel before any work is conducted. [\*\*\*].

Total invoices including FTE wages, applicable overhead, consultant costs and subcontractor costs will be subject [\*\*\*].



## **EXHIBIT A**

### **UNIT PRICES**

- 5 gram units of Finished Product at [\*\*\*] per unit
- 2 gram units of Finished Product at [\*\*\*] per unit

**EXHIBIT B**

**ADDITIONAL SERVICES**

| <b>ADDITIONAL SERVICE</b>        | <b>COST</b>                                       |
|----------------------------------|---|
| <b>Other Additional Services</b> | <b>At the FTE Rates set forth on Schedule 4.5</b> |

AMENDED AND RESTATED  
EMPLOYMENT AGREEMENT

This Employment Agreement (“Agreement”) is made as of the 14th day of September, 2017, between Vericel Corporation, a Michigan corporation (the “Company”), and Michael Halpin (the “Executive”).

WHEREAS, the Company and the Executive previously entered into that certain offer letter dated as of February 17, 2017 (the “Prior Agreement”), and both parties desire to amend and restate the Prior Agreement as set forth herein; and

WHEREAS, the Company desires to continue to employ the Executive and the Executive desires to be employed by the Company on the terms contained herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree that the Prior Agreement is hereby amended and restated in its entirety as follows:

1. Position and Duties. The Executive shall continue to serve as the Senior Vice President, Quality and Regulatory Affairs of the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer of the Company (the “CEO”) or other authorized executive. The Executive shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities as long as such services and activities are disclosed to the CEO and do not materially interfere with the Executive’s performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. The Executive’s annual base salary shall be \$315,000. The Executive’s base salary may be redetermined by the Company’s Compensation Committee, after consultation with the CEO. The base salary in effect at any given time is referred to herein as “Base Salary.” The Base Salary shall be payable in a manner that is consistent with the Company’s usual payroll practices for senior executives.

(b) Incentive Compensation. The Executive shall be eligible to receive cash incentive compensation as determined by the Company’s Compensation Committee from time to time. The Executive’s target annual incentive compensation shall be Thirty-Five Percent (35%) of his Base Salary, and the actual bonus amount shall be determined by the Company’s Compensation Committee. The target annual incentive compensation in effect at any given time is referred to herein as “Target Bonus.” The Target Bonus may be redetermined by the Company’s Compensation Committee, after consultation with the CEO. To be eligible for incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Equity Compensation. From time to time and at the discretion of the Company's Compensation Committee, the Company may grant to the Executive equity compensation, including options to purchase shares of the Company's common stock at an exercise price equal to the fair market value of the Company's common stock on the effective date of grant.

(d) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable business expenses incurred by him in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its senior executive officers.

(e) Customary Fringe Benefits. The Executive shall be entitled to such fringe benefits as the Company customarily makes available to the Company's senior executives (collectively, "Fringe Benefits"). The Fringe Benefits shall include sick leave, health insurance coverage, and 401(k) plan participation, in accordance with the terms and provisions of such plans, policies and arrangements as adopted by the Company from time to time during the term of this Agreement. The Company reserves the right to change the Fringe Benefits on a prospective basis, at any time, effective upon delivery of written notice to Executive. Executive shall not be entitled to receive payments in lieu of Fringe Benefits, other than for earned and accumulated but unused vacation at the time the employment relationship terminates.

(f) Paid Time Off. Executive is entitled to 16.67 hours per month, equaling twenty five (25) days per year, of paid time off (including statutory sick leave), pro-rated for any partial calendar year during the term of this Agreement, in accordance with the Company's Paid Time Off policy ("Paid Time Off"). Executive also shall be entitled to such paid holidays as are established by the Company for all regular full-time employees.

3. Termination. The Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon his death.

(b) Disability. The Company may terminate the Executive's employment if he is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification,

the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq.* and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Executive constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries and affiliates if he were retained in his position; (iii) continued non-performance by the Executive of his duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than 15 days following written notice from the CEO (or the CEO's designee); (iv) a breach by the Executive of any of the provisions contained in Section 7 of this Agreement, including without limitation the Restrictive Covenant Agreement incorporated by reference to Section 7 of this Agreement; (v) a material violation by the Executive of the Company's written employment policies, or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation. Any determination of Cause by the Company shall be conclusive.

(d) Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate his employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) the material breach of this Agreement by the Company; or (iv) any change in the location of Executive's locus of employment that is more than fifty (50) miles from the current headquarters of the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing

of the first occurrence of the Good Reason condition within 30 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates his employment within 30 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by his death, the date of his death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b), by the Company for Cause under Section 3(c) or by the Company without Cause under Section 3(d), the date on which Notice of Termination is given unless another date is specified therein; (iii) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (iv) if the Executive's employment is terminated by the Executive under Section 3(e) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

#### 4. Compensation Upon Termination.

(a) Termination Generally. If the Executive's employment with the Company terminates for any reason, the Company shall pay or provide to the Executive (or to his authorized representative or estate) any earned but unpaid Base Salary, unpaid expense reimbursements, accrued but unused Paid Time Off all through the Date of Termination, and any vested benefits the Executive may have under any employee benefit plan of the Company (the "Accrued Benefit") on or before the time required by law but in no event more than 30 days after the Executive's Date of Termination.

(b) Termination by the Company Without Cause or by the Executive with Good Reason. If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates his employment for Good Reason as provided in Section 3(e), then the Company shall, through the Date of Termination, pay the Executive his Accrued Benefit. In addition, subject to the Executive signing a separation agreement in a form and manner satisfactory to the Company which includes a general release of claims in favor of the Company and related persons and entities (the "Release") and such Release becoming irrevocable within the time period set forth in such Release, but in no event later than 60 days following the Date of Termination:

(i) the Company shall pay the Executive an amount equal to twelve (12) months of the Executive's Base Salary (the "Severance Amount"). Notwithstanding the foregoing, if the Executive breaches any of the provisions contained in Section 7 of this Agreement, including without limitation the Restrictive Covenant Agreement incorporated by reference to Section 7 of this Agreement, in addition to all legal and equitable remedies, the Company shall have the right to cease payments of the Severance Amount;

(ii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall pay to the Executive a monthly cash payment for twelve (12) months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company. The Executive may continue to participate in COBRA benefits following the expiration of the twelve (12) months, at his sole cost, provided that he remains eligible for such participation; and

(iii) the amounts payable under this Section 4(b) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over twelve (12) months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b) (2).

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within eighteen (18) months after the occurrence of the first event constituting a Change in Control (the "Change in Control Period"). These provisions shall terminate and be of no further force or effect beginning eighteen (18) months after the occurrence of a Change in Control.

(a) Change in Control. If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates his employment for Good Reason as provided in Section 3(e), and the Date of Termination occurs within the Change in Control Period, then, subject to the signing of the Release by the Executive and such Release becoming irrevocable within the period set forth in such Release, but in no event later than 60 days following the Date of Termination:

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to one (1) multiplied by the sum of (A) the Executive's then-effective Base Salary, and (B) the Executive's Target Bonus for the year during which the Date of Termination occurs;

(ii) the Company shall pay a prorated annual performance bonus (the "Prorated Annual Bonus") equal to (x) the Executive's Target Bonus for the year during which the Date of Termination occurs multiplied by (y) a fraction, the numerator of which is the number of days in the fiscal year in which the Executive was employed through the Date of Termination and the denominator of which is 365, provided that the Prorated Annual Bonus shall be less the amount of any annual performance bonus, or advance thereof, previously paid for the period associated with the Prorated Annual Bonus.

(iii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other stock-based awards held by the Executive shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination; and

(iv) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Executive a monthly cash payment for twelve (12) months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company. The Executive may continue to participate in COBRA benefits following the expiration of the twelve (12) months, at his sole cost, provided that he remains eligible for such participation.

(v) The amounts payable under this Section 5(a) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Severance Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, the following provisions shall apply:

(A) If the Severance Payments, reduced by the sum of (1) the Excise Tax and (2) the total of the Federal, state, and local income and employment taxes payable by the Executive on the amount of the Severance Payments which are in excess of the Threshold Amount, are greater than or equal to the Threshold Amount, the Executive shall be entitled to the full benefits payable under this Agreement.



(B) If the Threshold Amount is less than (x) the Severance Payments, but greater than (y) the Severance Payments reduced by the sum of (1) the Excise Tax and (2) the total of the Federal, state, and local income and employment taxes on the amount of the Severance Payments which are in excess of the Threshold Amount, then the Severance Payments shall be reduced (but not below zero) to the extent necessary so that the sum of all Severance Payments shall not exceed the Threshold Amount. In such event, the Severance Payments shall be reduced in the following order: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits. To the extent any payment is to be made over time (e.g., in installments, etc.), then the payments shall be reduced in reverse chronological order.

(ii) For the purposes of this Section 5(b), “Threshold Amount” shall mean three times the Executive’s “base amount” within the meaning of Section 280G(b)(3) of the Code and the regulations promulgated thereunder less one dollar (\$1.00); and “Excise Tax” shall mean the excise tax imposed by Section 4999 of the Code, and any interest or penalties incurred by the Executive with respect to such excise tax.

(iii) The determination as to which of the alternative provisions of Section 5(b)(i) shall apply to the Executive shall be made by a nationally recognized accounting firm selected by the Company (the “Accounting Firm”), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. For purposes of determining which of the alternative provisions of Section 5(b)(i) shall apply, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in the state and locality of the Executive’s residence on the Date of Termination, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(b) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

“Change in Control” shall mean any of the following:

(i) any “person,” as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the “Act”) (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all “affiliates” and “associates” (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the “beneficial owner” (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company’s then outstanding securities having the right to vote in

an election of the Board (“Voting Securities”) (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a “Change in Control” shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a “Change in Control” shall be deemed to have occurred for purposes of the foregoing clause (i).

#### 6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive’s separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a “specified employee” within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive’s separation from service would be considered deferred compensation subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive’s separation from service, or (B) the Executive’s death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes “non-qualified deferred compensation” under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive’s termination of employment, then such payments or benefits shall be payable only upon the Executive’s “separation from service.” The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

#### 7. Confidential Information, Noncompetition and Cooperation.

(a) Restrictive Covenant Agreement. The terms of the Restrictive Covenant Agreement, by and between the Company and the Executive and attached hereto as Exhibit A (the “Restrictive Covenant Agreement”), shall be in full force and effect and are incorporated by reference as material terms of this Agreement.

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive’s use or disclosure of information or the Executive’s engagement in any business. The Executive represents to the Company that the Executive’s execution of this Agreement, the Executive’s employment with the Company and the performance of the Executive’s proposed duties for the Company will not violate any obligations

the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 7(c).

(d) Injunction. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

(e) Protected Disclosure. The Executive understands that nothing contained in this Agreement limits the Executive's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Consent to Jurisdiction. The parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including without limitation, the Prior Agreement; *provided* that the Restrictive Covenant Agreement, the Acknowledgment regarding the Statement of Company Policy on Insider Trading and Disclosure, the Acknowledgment of the Statement of Company

Policy on the Code of Business Conduct and Ethics and the Acknowledgement regarding the Company's Colleague Handbook shall remain in full force and effect.

10. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

11. Successor to the Executive. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Executive's death after his termination of employment but prior to the completion by the Company of all payments due him under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Executive fails to make such designation).

12. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

13. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

14. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

15. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

16. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

17. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such State. With respect to any disputes

concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

18. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

19. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

20. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

VERICEL CORPORATION

/s/ Dominick C. Colangelo

By: Dominick C. Colangelo

Its: President and Chief Executive Officer

EXECUTIVE

/s/ Michael Halpin

Michael Halpin

## Exhibit A

### Restrictive Covenant Agreement

In consideration and as a condition of my employment as well benefits set forth in my Employment Agreement with Vericel Corporation (including its subsidiaries and/or affiliates and its and their successors and assigns, the "Company"), I agree as follows:

1. **Proprietary Information.** I agree that all information, whether or not in writing, concerning the Company's business, technology, business relationships or financial affairs which the Company has not released to the general public (collectively, "Proprietary Information") is and will be the exclusive property of the Company. By way of illustration, Proprietary Information may include information or material which has not been made generally available to the public, such as: (a) corporate information, including plans, strategies, methods, policies, resolutions, negotiations or litigation; (b) marketing information, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) financial information, including cost and performance data, debt arrangements, equity structure, investors and holdings, purchasing and sales data and price lists; (d) operational and technological information, including plans, specifications, manuals, forms, templates, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, concepts and ideas; and (e) personnel information, including personnel lists, reporting or organizational structure, resumes, personnel data, performance evaluations and termination arrangements or documents. Proprietary Information also includes information received in confidence by the Company from its customers or suppliers or other third parties.

2. **Recognition of Company's Rights.** I will not, at any time, without the Company's prior written permission, either during or after my employment, disclose any Proprietary Information to anyone outside of the Company, or use or permit to be used any Proprietary Information for any purpose other than the performance of my duties as an employee of the Company. I will cooperate with the Company and use my best efforts to prevent the unauthorized disclosure of all Proprietary Information. I will deliver to the Company all copies of Proprietary Information in my possession or control upon the earlier of a request by the Company or termination of my employment.

3. **Rights of Others.** I understand that the Company is now and may hereafter be subject to non-disclosure or confidentiality agreements with third persons which require the Company to protect or refrain from use of proprietary information. I agree to be bound by the terms of such agreements in the event I have access to such proprietary information.

4. **Commitment to Company; Avoidance of Conflict of Interest.** While an employee of the Company, I will devote my full-time efforts to the Company's business and I will not engage in any other business activity without prior written permission of an authorized representative of the Company. I will advise the General Counsel of the Company or his or her nominee at such time as any activity of either the Company or another business presents me with a conflict of interest or the appearance of a conflict of interest as an employee of the Company. I will take whatever action is requested of me by the Company to resolve any conflict or appearance of conflict which it finds to exist.

5. **Developments.** I will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "Developments"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by me (alone or jointly with others) or under my direction during the period of my employment. I acknowledge that all work performed by me is on a "work for hire" basis, and I hereby do assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all my right, title and interest in all Developments that (a) relate to the business of the Company or any of the products or services being researched, developed, manufactured or sold by the Company or which may be used with such products or services; or (b) result from tasks assigned to me by the Company; or (c) result from the use of premises or personal property (whether tangible or intangible) owned

or premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Company ("Company-Related Developments"), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("Intellectual Property Rights").

To preclude any possible uncertainty, I have set forth on Schedule A attached hereto a complete list of Developments that I have, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of my employment with the Company that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement ("Prior Inventions"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in Schedule A but am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. I have also listed on Schedule A all patents and patent applications in which I am named as an inventor, other than those which have been assigned to the Company ("Other Patent Rights"). If no such disclosure is attached, I represent that there are no Prior Inventions or Other Patent Rights. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine or

ACTIVE/92048264.4



other work done for the Company, I hereby grant to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, I will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

This Agreement does not obligate me to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on my own time and does not relate to the business efforts or research and development efforts in which, during the period of my employment, the Company actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Company. However, I will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. I understand that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this paragraph 5 will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. I also hereby waive all claims to any moral rights or other special rights which I may have or accrue in any Company-Related Developments.

6. **Documents and Other Materials.** I will keep and maintain adequate and current records of all Proprietary Information and Company-Related Developments developed by me during my employment, which records will be available to and remain the sole property of the Company at all times.

All files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, program listings, blueprints, models, prototypes, or other written, photographic or other tangible material containing Proprietary Information, whether created by me or others, which come into my custody or possession, are the exclusive property of the Company to be used by me only in the performance of my duties for the Company. Any property situated on the Company's premises and owned by the Company, including without limitation computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice. In the event of the termination of my employment for any reason, I will deliver to the Company all Company property and equipment in my possession, custody or control, including all files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, program listings, blueprints, models, prototypes, or other written, photographic or other tangible material containing Proprietary Information, and other materials of any nature pertaining to the Proprietary Information of the Company and to my work, and will not take or keep in my possession any of the foregoing or any copies.

7. **Enforcement of Intellectual Property Rights.** I will cooperate fully with the Company, both during and after my employment with the Company, with respect to the procurement, maintenance and enforcement of Intellectual Property Rights in Company-Related Developments. I will sign, both during and after the term of this Agreement, all papers, including without limitation copyright applications, patent applications, declarations, oaths, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development. If the Company is unable, after reasonable effort, to secure my signature on any such papers, I hereby irrevocably designate and appoint each officer of the Company as my agent and attorney-in-fact to execute any such papers on my behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development.

8. **Non-Competition and Non-Solicitation.** In order to protect the Company's Proprietary Information and good will, during my employment and (i) with respect to clause (a) below, for a period of twelve (12) months following the termination of my employment or other service relationship with the Company for any reason and (ii) with respect to clauses (b) and (c) below, for a period of twelve (12) months following the termination of my employment or other service relationship with the Company for any reason (the "Restricted Period").

(a) I will not directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, engage, participate or invest in any business activity anywhere in the United States that is competitive with the Company's development programs, including product candidates developed thereunder, or technologies or commercial products, at such time of my termination of employment; provided that this shall not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the stock of such company.

(b) I will not, directly or indirectly, in any manner, other than for the benefit of the Company or for solely non-competitive purposes, call upon, solicit, divert, take away, accept or conduct any business from or with any of the customers or prospective customers of the Company.

(c) I will not, directly or indirectly, in any manner, solicit, entice, attempt to persuade any other employee or consultant of the Company to leave the Company for any reason or otherwise participate in or facilitate the hire, directly or through another entity, of any person who is employed or engaged by the Company or who was employed or engaged by the Company within six months of any attempt to hire such person.

I acknowledge and agree that if I violate any of the provisions of this paragraph 8 after my employment ends, the running of the Restricted Period will be extended until there is a period of in which there is no violation of this paragraph 8.

9. **Government Contracts.** I acknowledge that the Company may have from time to time agreements with other persons or with the United States Government or its agencies which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to comply with any such obligations or restrictions upon the direction of the Company. In addition to the rights assigned under paragraph 5, I also assign to the Company (or any of its nominees) all rights which I have or acquired in any Developments, full title to which is required to be in the United States under any contract between the Company and the United States or any of its agencies.

10. **Prior Agreements.** I hereby represent that, except as I have fully disclosed previously in writing to the Company, I am not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that my performance of all the terms of this Agreement as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to my employment with the Company. I will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

11. **Remedies Upon Breach.** I understand that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and I consider them to be reasonable for such purpose. Any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of such breach, the Company, in addition to such other remedies which may be available, will be entitled to specific performance and other injunctive relief, without the posting of a bond. If I violate this Agreement, in addition to all other remedies available to the Company at law, in equity, and under contract, I agree that I am obligated to pay all the Company's costs of enforcement of this Agreement, including attorneys' fees and expenses.

12. **Use of Voice, Image and Likeness.** I give the Company permission to use any and all of my voice, image and likeness, with or without using my name, in connection with the products and/or services of the Company, for the purposes of advertising and promoting such products and/or services and/or the Company, and/or for other purposes deemed appropriate by the Company in its reasonable discretion, except to the extent expressly prohibited by law.

13. **No Employment Obligation.** I understand that this Agreement does not create an obligation on the Company or any other person to continue my employment. I acknowledge that, unless otherwise agreed in a formal written employment agreement signed on behalf of the Company by an authorized officer, my employment with the Company is at will and therefore may be terminated by the Company or me at any time and for any reason, with or without cause.

14. **Survival and Assignment by the Company.** I understand that my obligations under this Agreement will continue in accordance with its express terms regardless of any changes in my title, position, duties, salary, compensation or benefits or other terms and conditions of employment. I further understand that my obligations under this Agreement will continue following the termination of my employment regardless of the manner of such termination and will be binding upon my heirs, executors and administrators. The Company will have the right to assign this Agreement to its affiliates, successors and assigns. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any parent, subsidiary or affiliate to whose employ I may be transferred without the necessity that this Agreement be resigned at the time of such transfer.

15. **Post-Employment Notifications.** For twelve (12) months following termination of my employment, I will notify the Company of any change in my address and of each subsequent employment or business activity, including the name and address of my employer or other past Company

including the name and address of my employer or other post-Company employment plans and the nature of my activities.

16. **Disclosure to Future Employers.** I will provide a copy of this Agreement to any prospective employer, partner or coventurer prior to entering into an employment, partnership or other business relationship with such person or entity.

17. **Severability.** In case any provisions (or portions thereof) contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

18. **Interpretation; Consent to Jurisdiction.** This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced and governed under the laws of the Commonwealth of Massachusetts.

I hereby consent to personal jurisdiction of the state and federal courts situated within Massachusetts for purposes of enforcing this Agreement, and waive any objection that I might have to personal jurisdiction or venue in those courts.

19. **Protected Disclosures.** I understand that nothing contained in this Agreement limits my ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

20. **Defend Trade Secrets Act of 2016.** I understand that pursuant to the federal Defend Trade Secrets Act of 2016, I shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

21. **Other Agreements and Obligations.** This Agreement constitutes the entire agreement between me and the Company regarding the subject matter hereof, and supersedes any previous agreements or understandings that I had or may have had between me and the Company regarding the subject matter, except any confidentiality and/or assignment of inventions agreement (including the Employee Proprietary Information and Non-Disclosure and Assignment of Intellectual Property Rights Agreement) that I entered into with the Company shall continue to be in full force and effect and shall be supplemental to this Agreement.

[Remainder of Page Intentionally Left Blank]

**I UNDERSTAND THAT THIS AGREEMENT AFFECTS IMPORTANT RIGHTS. BY SIGNING BELOW, I CERTIFY THAT I HAVE READ IT CAREFULLY AND AM SATISFIED THAT I UNDERSTAND IT COMPLETELY.**

IN WITNESS WHEREOF, the undersigned has executed this agreement as a sealed instrument as of the date set forth below.

Signed:  /s/ Michael Halpin  
(Employee's full name)

Type or print name: Michael Halpin

Date: 9/14/17

ACTIVE/92048264.4

SCHEDULE A

To: **Vericel Corporation**

From: Michael Halpin

Date: 09/14/17

SUBJECT: **Prior Inventions**

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

---

---

---

Additional sheets attached

The following is a list of all patents and patent applications in which I have been named as an inventor:

None

See below:

---

---

---

**FIRST AMENDMENT  
TO  
EXECUTIVE EMPLOYMENT AGREEMENT**

This First Amendment to Executive Employment Agreement (this "Amendment") is entered into and effective as of June 3, 2019, by and between Michael Halpin ("Executive"), and Vericel Corporation, a Michigan corporation (the "Company").

**WHEREAS**, the Company and Executive are parties to an Executive Employment Agreement, dated as of September 14, 2017 (the "Employment Agreement");

**WHEREAS**, the Company and Executive wish to amend certain provisions of the Employment Agreement; and

**WHEREAS**, capitalized terms used herein and not otherwise defined herein shall have the meanings ascribed to them in the Employment Agreement.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which are hereby accepted and acknowledged by Executive and the Company, the parties agree as follows:

1. The first sentence of Section 1 of the Employment Agreement is hereby amended and restated in its entirety as follows:

The Executive shall serve as the Chief Operating Officer of the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO") or other authorized executive.

2. The first sentence of Section 2(a) of the Employment Agreement is hereby amended and restated in its entirety as follows:

The Executive's annual base salary shall be \$370,000.

3. The second sentence of Section 2(b) of the Employment Agreement is hereby amended and restated in its entirety as follows:

The Executive's target annual incentive compensation shall be Forty-Five Percent (45%) of his Base Salary, and the actual bonus amount shall be determined by the Company's Compensation Committee.

4. All other provisions of the Employment Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the Employment Agreement except to the extent specifically provided for herein.



5. The validity, interpretation, construction and performance of this Amendment, and the Employment Agreement, as amended herein, shall be governed by the laws of the Commonwealth of Massachusetts without regard to principles of conflict of laws of such state that would require the application of the laws of any other jurisdiction. The parties hereby consent to personal jurisdiction of the state and federal courts situated within Cambridge, Massachusetts for purposes of enforcing this Amendment, and waive any objection that he, she or it might have to personal jurisdiction or venue in those courts.

6. This Amendment may be executed in several counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first set forth above.

**VERICEL CORPORATION**

By: /s/ Dominick C. Colangelo

Name: Dominick C. Colangelo

Title: President and Chief Executive Officer

**EXECUTIVE**

/s/ Michael Halpin

Michael Halpin

*[Signature Page to First Amendment to Executive Employment Agreement (Halpin)]*

## CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;

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 13a-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 6, 2019

/s/ DOMINICK C. COLANGELO

---

Dominick C. Colangelo  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Gerard Michel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vericel Corporation;

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 13a-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 6, 2019

/s/ GERARD MICHEL

---

Gerard Michel

*Chief Financial Officer and Vice President, Corporate Development  
(Principal Financial Officer)*

**18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Vericel Corporation (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; 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 6, 2019

/s/ DOMINICK C. COLANGELO

---

Dominick C. Colangelo  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

**18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Vericel Corporation (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), the following:

- (1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; 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 6, 2019

/s/ GERARD MICHEL

---

Gerard Michel

*Chief Financial Officer and Vice President, Corporate Development  
(Principal Financial Officer)*

A signed original of this written statement required by Section 906 has been provided to Vericel Corporation and will be retained by Vericel Corporation and furnished to the Securities and Exchange Commission or its staff upon request.