UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36395

DARÉ BIOSCIENCE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware		**20-4139823**
(State or Other Jurisdiction of Incorporation)		(IRS Employer Identification No.)
3655 Nobel Drive, Suite 260 San Diego, CA	**(858) 926-7655**	**92122**
(Address of Principal Executive Offices)	(Registrant's telephone number, including area code)	(Zip Code)

(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	**DARE**	**Nasdaq Capital Market**

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company, or 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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	o		

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 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 Act). Yes ☐ No x

As of May 10, 2022, 84,711,346 shares of the Registrant's Common Stock, par value $0.0001, were issued and outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, in particular "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations," of Part I. Financial Information, and the information incorporated by reference herein contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, projected revenue, funding and expenses, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "pursue," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors described in Part II, Item 1A, "Risk Factors", in this report, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:

- *Inability to raise additional capital, under favorable terms or at all, and continue as a going concern;*
- *Failure to complete development of our product candidates, submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval and commercialize our products candidates on projected timelines or budgets, or at all;*
- *Inability to demonstrate sufficient safety and efficacy of our product candidates;*
- *The ability of third parties on which we rely to timely supply and manufacture our commercial product and our clinical trial supplies, including their components as well as the finished product, in the quantities needed in accordance with current good manufacturing practices, our specifications and other applicable requirements;*
- *The performance of third parties on which we rely to conduct nonclinical studies and clinical trials of our product candidates;*
- *The terms and conditions of our strategic collaborations, including our out-license agreements for commercialization of XACIATO™ and Ovaprene®;*
- *A decision by a commercial collaborator to discontinue its interest in our product or product candidate or to terminate our license agreement, or the failure of such license agreement to become fully effective;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with establishing and maintaining collaborations relating to the development and/or commercialization of our product candidates on a timely basis or on acceptable terms, or at all;*
- *Our loss of, or inability to attract, key personnel;*
- *The degree of market acceptance that XACIATO and any future product achieves;*
- *Coverage and reimbursement levels for XACIATO and any future product by government health care programs, private health insurance companies and other third-party payors;*
- *A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket application for potential marketing approval of Ovaprene;*
- *A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FDA's 505(b)(2) pathway;*
- *Unsuccessful clinical trial outcomes stemming from clinical trial designs, failure to enroll a sufficient number of patients, higher than anticipated patient dropout rates, failure to meet established clinical endpoints, undesirable side effects and other safety concerns;*
- *Adverse differences between preliminary, interim or topline clinical study data reported by us and final study results;*

- *Communication from the FDA or another regulatory authority, including a complete response letter, that it does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that it interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;*
- *Failure to monetize our portfolio candidates through licenses, partnerships or other types of commercialization agreements, or on our own;*
- *Failure to select product candidates that capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas within women's health including due to our limited financial resources;*
- *Loss or impairment of our in-licensed rights to develop and commercialize XACIATO and our product candidates ;*
- *Our payment and other obligations under our in-license and acquisition agreements for XACIATO and our product candidates;*
- *Developments by our competitors that make XACIATO or any potential product less competitive or obsolete;*
- *The impact of the macroeconomic conditions, geopolitical events, the COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat or natural disasters on our business, operations and financial condition, or on those of third parties on which we rely;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems or the technology systems of third parties on which we rely;*
- *Difficulty in introducing branded products in a market made up of generic products;*
- *Inability to adequately protect or enforce our, or our licensor's, intellectual property rights;*
- *Lack of patent protection for the active ingredients in XACIATO and certain of our product candidates that expose those product candidates to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Dependence on grant funding for pre-clinical development of DARE-LARC1;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results or that differ from investors' expectations for such results;*
- *Price and volume fluctuations in the stock market, and in our stock in particular, which could cause investors to experience losses and subject us to securities class-action litigation;*
- *Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;*
- *Development of unexpected safety concerns related to our product or product candidates, or third-party products or product candidates that share similar characteristics or drug substances;*
- *Product liability claims or governmental investigations;*
- *Strict government regulations on our business, including various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act;*
- *Regulations governing the production or marketing of XACIATO and any future products; and*
- *Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.*

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as required by law.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 39,316,911	$ 51,674,087
Other receivables	1,729,851	1,145,317
Prepaid expenses	6,770,426	2,476,612
Total current assets	47,817,188	55,296,016
Property and equipment, net	25,366	26,041
Other non-current assets	1,344,028	485,120
Total assets	$ 49,186,582	$ 55,807,177
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,830,866	$ 2,103,083
Accrued expenses	3,537,856	3,136,244
Deferred grant funding	9,731,363	10,542,983
Current portion of lease liabilities	294,474	270,546
Total current liabilities	16,394,559	16,052,856
Deferred license revenue	1,000,000	1,000,000
Lease liabilities long-term	913,113	—
Total liabilities	18,307,672	17,052,856
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized; 83,944,119 shares issued and outstanding at March 31, 2022 and December 31, 2021	8,394	8,394
Accumulated other comprehensive loss	(164,123)	(154,973)
Additional paid-in capital	149,560,211	149,027,802
Accumulated deficit	(118,525,572)	(110,126,902)
Total stockholders' equity	30,878,910	38,754,321
Total liabilities and stockholders' equity	$ 49,186,582	$ 55,807,177

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Loss
(**Unaudited**)

	Three months ended March 31,	
	2022	**2021**
Operating expenses		
General and administrative	$ 2,569,987	$ 1,940,328
Research and development	5,805,462	5,728,206
License fees	25,000	25,000
Total operating expenses	8,400,449	7,693,534
Loss from operations	(8,400,449)	(7,693,534)
Other income	1,779	3
Gain on extinguishment of note payable	—	369,887
Net loss	$ (8,398,670)	$ (7,323,644)
Foreign currency translation adjustments	(9,150)	(6,841)
Comprehensive loss	$ (8,407,820)	$ (7,330,485)
Loss per common share - basic and diluted	$ (0.10)	$ (0.16)
Weighted average number of common shares outstanding:		
Basic and diluted	83,944,119	44,502,582

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

Three Months Ended March 31, 2022

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity
Balance at December 31, 2021	**83,944,119**	**$ 8,394**	**$ 149,027,802**	**$ (154,973)**	**$ (110,126,902)**	**$ 38,754,321**
Stock-based compensation	—	—	532,409	—	—	532,409
Net loss	—	—	—	—	(8,398,670)	(8,398,670)
Foreign currency translation adjustments	—	—	—	(9,150)	—	(9,150)
Balance at March 31, 2022	**83,944,119**	**$ 8,394**	**$ 149,560,211**	**$ (164,123)**	**$ (118,525,572)**	**$ 30,878,910**

Three Months Ended March 31, 2021

	Common stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Shares	Amount	capital	loss	deficit	equity
Balance at December 31, 2020	**41,596,253**	**$ 4,159**	**$ 70,366,293**	**$ (91,388)**	**$ (71,430,797)**	**$ (1,151,733)**
Stock-based compensation	—	—	365,911	—	—	365,911
Issuance of common stock, net of issuance costs	5,664,069	567	11,323,573	—	—	11,324,140
Issuance of common stock from the exercise of warrants	52,500	5	50,395	—	—	50,400
Net loss	—	—	—	—	(7,323,644)	(7,323,644)
Foreign currency translation adjustments	—	—	—	(6,841)	—	(6,841)
Balance at March 31, 2021	**47,312,822**	**$ 4,731**	**$ 82,106,172**	**$ (98,229)**	**$ (78,754,441)**	**$ 3,258,233**

See accompanying notes.

Daré Bioscience, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (8,398,670)	$ (7,323,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,227	6,410
Stock-based compensation	532,409	365,911
Non-cash operating lease cost	(9,758)	(24,224)
Gain on extinguishment of notes payable and accrued interest	—	(369,887)
Changes in operating assets and liabilities:		
Other receivables	(584,534)	158,333
Prepaid expenses	(4,293,814)	217,188
Other non-current assets	87,891	(128,086)
Accounts payable	727,783	450,298
Accrued expenses	401,613	(837,191)
Deferred grant funding	(811,620)	(892,123)
Net cash used in operating activities	(12,343,473)	(8,377,015)
Cash flows from investing activities		
Purchases of property and equipment	(4,553)	—
Net cash used in investing activities	(4,553)	—
Cash flows from financing activities		
Net proceeds from issuance of common stock	—	11,324,140
Proceeds from the exercise of common stock warrants	—	50,400
Net cash provided by financing activities	—	11,374,540
Effect of exchange rate changes on cash and cash equivalents	(9,150)	(6,841)
Net change in cash and cash equivalents	(12,357,176)	2,990,684
Cash and cash equivalents, beginning of period	51,674,087	4,669,467
Cash and cash equivalents, end of period	$ 39,316,911	$ 7,660,151
Supplemental disclosure of non-cash investing and financing activities:		
Forgiveness of Paycheck Protection Program note payable	$ —	$ 369,887
Operating right-of-use assets obtained in exchange for new operating lease liabilities	$ 1,043,590	$ 308,533

See accompanying notes.

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

Daré Bioscience, Inc. is a biopharmaceutical company committed to advancing innovative products for women's health. Daré Bioscience, Inc. and its wholly owned subsidiaries operate one segment. In this report, the "Company" refers collectively to Daré Bioscience, Inc. and its wholly owned subsidiaries, unless otherwise stated or the context otherwise requires.

The Company began assembling its diverse portfolio in 2017 through acquisitions, exclusive in-licenses and other collaborations. The Company's programs target unmet needs in women's health in the areas of contraception, fertility, and vaginal and sexual health, and aim to expand treatment options, enhance outcomes and improve ease of use for women.

To date, the Company has not generated any revenue. The Company's primary operations have consisted of, and are expected to continue to consist primarily of, research and development activities to advance its product candidates through clinical development and regulatory approval.

The Company's first product, XACIATO™ (clindamycin phosphate vaginal gel, 2%), was approved by the FDA in December 2021, as a single-dose prescription medication for the treatment of bacterial vaginosis in female patients 12 years of age and older. In March 2022, the Company entered into an exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO. XACIATO is expected to be available commercially in the United States in the fourth quarter of 2022.

The Company's portfolio includes drug and drug/device product candidates and potential product candidates in various stages of development, from pre-clinical to advanced clinical development.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as defined by the Financial Accounting Standards Board, or FASB, for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management's opinion, the accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results of the interim periods presented.

Interim financial results are not necessarily indicative of results anticipated for any other interim period or for the full year. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, or the 2021 10-K.

Going Concern

The Company prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company has a history of losses from operations, expects negative cash flows from its operations to continue for the foreseeable future, and expects that its net losses will continue for at least the next several years as it develops and seeks to bring to market its existing product candidates and to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of the Company's ability to continue as a going concern.

As of March 31, 2022, the Company had an accumulated deficit of approximately $118.5 million, cash and cash equivalents of approximately $39.3 million, and working capital of approximately $31.4 million. For the three months ended March 31, 2022, the Company incurred a net loss of approximately $8.4 million and had negative cash flow from operations of approximately $12.3 million.

The Company expects its primary uses of capital to be staff-related expenses, the cost of clinical trials and regulatory activities related to its product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments due to third-parties under the Company's in-license and acquisition agreements including upon the occurrence of commercial milestones for XACIATO and development milestones for the Company's product candidates, legal expenses, other regulatory expenses and general overhead costs. The Company's future funding requirements could also include significant costs related to commercialization of its product candidates, if approved, depending on the type, nature and terms of commercial collaborations the Company establishes.

The Company expects its expenses, and in particular its research and development expenses, to increase significantly in 2022 compared to 2021 as the Company continues to develop and seek to bring to market its product candidates, with a focus on its product candidates that have reached the human clinical study development phase.

To date, the Company has one FDA-approved product, XACIATO, and has generated no revenue. Commercial launch of XACIATO in the U.S. by the Company's licensee, Organon, is expected in the fourth quarter of 2022. Under the terms of its license agreement with Organon, the Company will receive a $10.0 million non-refundable and non-creditable payment following the effective date of the license agreement and will be entitled to receive tiered double-digit royalties based on net sales and up to $182.5 million in milestone payments as follows: $2.5 million following the first commercial sale of a licensed product in the United States; and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. The Company has devoted significant resources to building its portfolio of product candidates and to research and development activities related to these product candidates. The Company or its licensees must obtain regulatory approvals to market and sell any of its product candidates in the future and to market and sell XACIATO anywhere outside the U.S. The Company will need to generate sufficient safety and efficacy data on each of its product candidates in order to apply for regulatory approvals and for such assets to be attractive assets to potential strategic collaborators to license or to acquire, and for the Company to generate revenue through license fees, royalties on net revenues and commercial milestones related to such product candidates.

Based on the Company's current operating plan estimates, the Company does not have sufficient cash to satisfy its working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy. The Company may continue to seek to raise capital through the sale of shares of its common stock under its ATM sales agreement or through other types of equity transactions. However, when the Company can effect such sales and the amount of shares the Company can sell depends on a variety of factors including, among others, market conditions, the trading price of its common stock, its determination as to the appropriate sources of funding for its operations, and the number of authorized shares of common stock that are available for issuance, which is approximately 27 million as of the date hereof. For the foreseeable future, the Company will evaluate and may pursue a variety of capital raising options on an on-going basis, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements, to cover its operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. The amount and timing of the Company's capital needs have been and will continue to depend highly on many factors, including the product development programs the Company chooses to pursue, the pace and results of its clinical development efforts, and the nature and extent of expansion of its product candidate portfolio, if any. If the Company raises capital through collaborations, strategic alliances or other similar types of arrangements, it may have to relinquish, on terms that are not favorable to the Company, rights to some of its technologies or product candidates the Company would otherwise seek to develop or commercialize.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to the Company and its stockholders. In addition, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders, and debt financings may subject the Company to restrictive covenants, operational restrictions and security interests in its assets. If the Company cannot raise capital when needed, on favorable terms or at all, the Company will not be able to continue development of its product candidates, will need to reevaluate its planned operations and may need to delay, scale back or eliminate some or all of its development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If the Company becomes unable to continue as a going concern, the Company may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its condensed consolidated financial statements, and stockholders may lose all or part of their investment in the Company's common stock. The Company's condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company’s significant accounting policies are described in Note 1 to the consolidated financial statements included in the 2021 10-K. Since the date of those consolidated financial statements, there have been no material changes to the Company’s significant accounting policies.

Fair Value of Financial Instruments

GAAP defines fair value as the price that would be received for an asset or the exit price that would be paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date, and also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three-level hierarchy of valuation techniques established to measure fair value is defined as follows:

- Level 1: inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of assets or liabilities.
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables present the classification within the fair value hierarchy of financial assets and liabilities that are remeasured on a recurring basis as of March 31, 2022 and December 31, 2021. There were no financial assets or liabilities that were remeasured using a quoted price in active markets for identical assets (Level 2) or using unobservable inputs (Level 3) as of March 31, 2022 or December 31, 2021.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at March 31, 2022				
Current assets:				
Cash equivalents [1]	$ 36,330,411	$ —	$ —	$ 36,330,411
Balance at December 31, 2021				
Current assets:				
Cash equivalents [1]	$ 49,666,064	$ —	$ —	$ 49,666,064

[1] Represents cash held in money market funds.

Revenue Recognition

The Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligations. At contract inception, the Company assesses the goods or services agreed upon within each contract, assesses whether each good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company develops estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Collaboration Revenues. The Company enters into collaboration and licensing agreements under which it out-licenses certain rights to its products or product candidates to third parties. The terms of these arrangements typically include payment of one or more of the following to the Company: non-refundable, up-front license fees; development, regulatory and/or commercial milestone payments; and royalties on net sales of licensed products.

License Fees. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. To date, the Company has not recognized any license fee revenue.

Royalties. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue.

Product Supply. Arrangements that include a promise for future supply of product for commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company evaluates whether it is the principal or agent in the arrangement. The evaluation is based on the degree the Company controls the specified product at any time before transfer to the customer. Revenues are recognized on a gross basis if the Company is in the capacity of principal and on a net basis if the Company is in the capacity of an agent. To date, the Company has not recognized any revenue associated with product supply arrangements.

Milestones. At the inception of each arrangement in which the Company is a licensor and that includes developmental, regulatory or commercial milestones, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments not within the Company's control, such as where achievement of the specified milestone depends on activities of a third party or regulatory approval, are not considered probable of being achieved until the specified milestone occurs. To date, the Company has not recognized any milestone revenue.

3. STRATEGIC AGREEMENTS

Strategic Agreements for Product Commercialization

Organon Exclusive License Agreement

In March 2022, the Company entered into an exclusive license agreement with Organon pursuant to which Organon will obtain exclusive worldwide rights to develop, manufacture and commercialize XACIATO and other future intravaginal or urological products for human use formulated with clindamycin that rely on intellectual property controlled by the Company. The effective date of the agreement will occur following the satisfaction of closing conditions that include receipt of all applicable approvals, or the expiration or termination of all applicable waiting periods, required under applicable antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The following is a summary of other terms of the Organon license agreement:

Upfront Payment. The Company will receive a $10.0 million non-refundable and non-creditable payment following the effective date of the agreement.

Royalty and Milestone Payments. The Company will be entitled to receive tiered double-digit royalties based on net sales and up to $182.5 million in milestone payments as follows: $2.5 million following the first commercial sale of a licensed product in the United States; and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

The royalty period for each licensed product will continue on a country-by-country basis from the first commercial sale of the licensed product in the country until the expiration of the later of (i) the date that no valid patent claim would be infringed in the absence of the license granted under the agreement by the sale of the licensed product in the country, (ii) 10 years after the end of the month in which the first commercial sale of the licensed product in the country occurred, and (iii) the expiration of regulatory market exclusivity for the licensed product in that country.

Regulatory Interactions and Product Supply. The Company will be responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumes such responsibilities. Until such time, Organon will purchase all of its product requirements of XACIATO from the Company at a transfer price equal to the Company's manufacturing costs plus a single-digit percentage markup.

Term. Unless terminated earlier, the agreement will expire on a product-by-product and country-by-country basis upon expiration of the applicable royalty period for each licensed product. In addition to customary termination rights for both parties, following the first anniversary of the effective date of the agreement, Organon may terminate the agreement in its entirety or on a country-by-country basis at any time in Organon's sole discretion on 120 days' advance written notice.

Other. The terms of the agreement provide Organon exclusive worldwide rights of first negotiation for specified potential future products of the Company.

Bayer HealthCare License Agreement

In January 2020, the Company entered into a license agreement with Bayer, regarding the further development and commercialization of Ovaprene in the U.S. The Company received a $1.0 million upfront non-refundable license fee payment from Bayer, and Bayer agreed to support the Company in development and regulatory activities by providing the equivalent of two experts to advise the Company in clinical, regulatory, preclinical, commercial, CMC and product supply matters. Bayer, in its sole discretion, has the right to make the license effective by paying the Company an additional $20.0 million, referred to as the Clinical Trial and Manufacturing Activities Fee. Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with the Company with regard to development.

The Company concluded there was one significant performance obligation related to the $1.0 million upfront payment: a distinct license to commercialize Ovaprene effective upon the receipt of the $20.0 million fee. The $1.0 million upfront payment will be recorded as license revenue at the earlier of (1) the point in time the Company receives the $20.0 million fee, the license is transferred to Bayer and Bayer is able to use and benefit from the license and (2) the termination of the agreement. As of March 31, 2022, neither of the foregoing had occurred. The $1.0 million payment is recorded as long-term deferred license revenue in the Company's condensed consolidated balance sheet at March 31, 2022 and December 31, 2021.

The following is a summary of other terms of the Bayer license agreement:

Milestone & Royalty Payments. The Company will be entitled to receive (a) a milestone payment in the low double-digit millions upon the first commercial sale of Ovaprene in the U.S. and escalating milestone payments based on annual net sales of Ovaprene during a calendar year, totaling up to $310.0 million if all such milestones, including first commercial sale, are achieved, (b) tiered royalties starting in the low double digits based on annual net sales of Ovaprene during a calendar year, subject to customary royalty reductions and offsets, and (c) a percentage of sublicense revenue.

Efforts. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. After payment of the Clinical Trial and Manufacturing Activities Fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S.

Term. The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of (a) the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S.; or (b) 15 years from the first commercial sale of Ovaprene in the U.S. In addition to customary termination rights for both parties, Bayer may terminate the agreement at any time on 90 days' notice and the agreement will automatically terminate if the Company does not receive the Clinical Trial and Manufacturing Activities Fee if and when due.

Strategic Agreements for Pipeline Development

Hammock/MilanaPharm Assignment and License Agreement

In December 2018, the Company entered into (a) an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and (b) a First Amendment to License Agreement with TriLogic Pharma, LLC and MilanaPharm LLC, or the License Amendment. Both agreements relate to the Exclusive License Agreement among Hammock, TriLogic and MilanaPharm dated as of January 9, 2017, or the MilanaPharm License Agreement. Under the Assignment Agreement and the MilanaPharm License Agreement, as amended by the License Amendment, the Company acquired an exclusive, worldwide license under certain intellectual property to, among other things, develop and commercialize products for the diagnosis, treatment and prevention of human diseases or conditions in or through any intravaginal or urological applications. The licensed intellectual property relates to the hydrogel drug delivery platform of TriLogic and MilanaPharm known as TRI-726. In XACIATO, this proprietary technology is formulated with clindamycin for the treatment of bacterial vaginosis. Each of the Assignment Agreement and License Amendment was amended in December 2019 and the License Agreement was further amended in September 2021 and March 2022.

The following is a summary of other terms of the License Amendment, as amended:

License Fees. A total of $235,000 in license fees were payable to MilanaPharm, the final installment of which was $110,000 paid in 2020.

Milestone Payments. The Company paid MilanaPharm $300,000 in the aggregate upon achievement of certain clinical and regulatory development milestones, $50,000 of which was paid in 2020 and $250,000 of which was paid in 2021. The Company may also pay MilanaPharm up to $500,000 upon the first commercial sale in the United States of the first licensed product for each vaginal use and urological use, and up to $250,000 upon the first commercial sale in the United States of successive licensed products for vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products, the Company must pay $1.0 million to MilanaPharm.

Foreign Sublicense Income. The Company will pay MilanaPharm a low double-digit percentage of all income received by the Company or its affiliates in connection with any sublicense granted to a third party for use outside of the United States, subject to certain exclusions.

Royalty Payments. During the royalty term, the Company will pay MilanaPharm high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes. The royalty term, which is determined on a country-by-country basis and licensed product-by-product basis (or process-by-process basis), begins with the first commercial sale of a licensed product or process in a country and terminates on the latest of (1) the expiration date of the last valid claim of the licensed patent rights that cover the method of use of such product or process in such country, or (2) 10 years following the first commercial sale of such product or process in such country. Royalty payments are subject to reduction in certain circumstances, including as a result of generic competition, patent prosecution expenses incurred by the Company, or payments to third parties for rights or know-how required for the Company to exercise the licenses granted to it under the MilanaPharm License Agreement or that are strategically important or could add value to a licensed product or process in a manner expected to materially generate or increase sales.

Efforts. The Company must use commercially reasonable efforts and resources to (1) develop and commercialize at least one licensed product or process in the United States and at least one licensed product or process in at least one of Canada, the United Kingdom, France, Germany, Italy or Spain, and (2) continue to commercialize that product or process following the first commercial sale of a licensed product or process in the applicable jurisdiction.

Term. Unless earlier terminated, the license term continues until (1) on a licensed product-by-product (or process-by-process basis) and country-by-country basis, the date of expiration of the royalty term with respect to such licensed product in such country, and (2) the expiration of all applicable royalty terms under the MilanaPharm License Agreement with respect to all licensed products and processes in all countries. Upon expiration of the term with respect to any licensed product or process in a country (but not upon earlier termination of the MilanaPharm License Agreement), the licenses granted to the Company under the MilanaPharm License Agreement will convert automatically to an exclusive, fully paid-up, royalty-free, perpetual, non-terminable and irrevocable right and license under the licensed intellectual property.

In addition to customary termination rights for all parties, MilanaPharm may terminate the license granted to the Company solely with respect to a licensed product or process in a country if, after having launched such product or process in such country, (1) the Company or its affiliates or sublicensees discontinue the sale of such product or process in such country and MilanaPharm notifies the Company of such termination within 60 days of having first been notified by the Company of such discontinuation, or (2) the Company or its affiliates or sublicensees (A) discontinue all commercially reasonable marketing efforts to sell, and discontinue all sales of, such product or process in such country for nine months or more, (B) fail to resume such commercially reasonable marketing efforts within 120 days of having been notified of such failure by MilanaPharm, (C) fail to reasonably demonstrate a strategic justification for the discontinuation and failure to resume to MilanaPharm, and (D) MilanaPharm gives 90 days' notice to the Company.

The following is a summary of other terms of the Assignment Agreement, as amended:

Assignment; Technology Transfer. Hammock assigned and transferred to the Company all of its right, title and interest in and to the MilanaPharm License Agreement and agreed to cooperate to transfer to the Company all of the data, materials and the licensed technology in its possession pursuant to a technology transfer plan to be agreed upon by the parties, with a goal for the Company to independently practice the licensed intellectual property as soon as commercially practical in order to develop and commercialize the licensed products and processes.

Fees. A total of $512,500 in fees were payable to Hammock, the final installment of which was $137,500 paid in 2020.

Milestone Payments. The Company will pay Hammock up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $100,000 of which was paid in 2020 and $750,000 of which was paid in 2021. The remaining milestone does not relate to a bacterial vaginosis product.

Term. The Assignment Agreement will terminate upon the later of (1) completion of the parties' technology transfer plan, and (2) payment to Hammock of the last of the milestone payments.

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide. The Company must use commercially reasonable efforts to develop and commercialize Ovaprene and must meet certain minimum spending amounts per year, including $2.5 million per year to cover such activities until a final PMA is filed, or until the first commercial sale of Ovaprene, whichever occurs first. ADVA-Tec will conduct certain research and development work as necessary to allow the Company to seek a PMA from the FDA and will provide the Company with clinical trial and commercial supplies of Ovaprene, either directly or through a CMO, on commercially reasonable terms.

Under the license agreement, in addition to an exclusive license to ADVA-Tec's and its affiliates' intellectual property rights for all uses of Ovaprene as a human contraceptive device, the Company has a right of first refusal to license these patents and patent applications for additional indications.

The following is a summary of other terms of the ADVA-Tec license agreement:

Milestone Payments. The Company will pay to ADVA-Tec: (1) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $200,000 of which was paid in 2021; and (2) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones. The remaining development and regulatory milestones include: the FDA's approval to commence a pivotal clinical trial; successful completion of such pivotal clinical trial; the FDA's acceptance of a PMA filing for Ovaprene; the FDA's approval of the PMA for Ovaprene; CE Marking of Ovaprene in at least three designated European countries; obtaining regulatory approval in at least three designated European countries; and obtaining regulatory approval in Japan.

Royalty Payments. After the commercial launch of Ovaprene, the Company will pay to ADVA-Tec royalties based on aggregate annual net sales of Ovaprene in specified regions, at a royalty rate that will vary between 1% and 10% and will increase based on various net sales thresholds.

Term. Unless earlier terminated, the license the Company received under the agreement continues on a country-by-country basis until the later of the life of the licensed patents or the Company's last commercial sale of Ovaprene. In addition to customary termination rights for both parties: (A) the Company may terminate the agreement with or without cause in whole or on a country-by-country basis upon 60 days prior written notice; and (B) ADVA-Tec may terminate the agreement if the Company develops or commercializes any non-hormonal ring-based vaginal contraceptive device competitive to Ovaprene or if the Company fails to: (1) in certain limited circumstances, commercialize Ovaprene in certain designated countries within three years of the first commercial sale of Ovaprene; (2) satisfy the annual spending obligation described above, (3) use commercially reasonable efforts to complete all necessary pre-clinical and clinical studies required to support and submit a PMA, (4) conduct clinical trials as set forth in the development plan to which the Company and ADVA-Tec agree, and as may be modified by a joint research committee, unless such failure is caused by events outside of the Company’s reasonable control, or (5) enroll a patient in the first non-significant risk medical device study or clinical trial as allowed by an institutional review board within six months of the production and release of Ovaprene, unless such failure is caused by events outside of the Company’s reasonable control.

SST License and Collaboration Agreement

In February 2018, the Company entered into a license and collaboration agreement with Strategic Science & Technologies-D, LLC and Strategic Science & Technologies, LLC, referred to collectively as SST, under which the Company received an exclusive, royalty-bearing, sublicensable license to develop and commercialize, in all countries and geographic territories of the world, for all indications for women related to female sexual dysfunction and/or female reproductive health, including the treatment of female sexual arousal disorder, or the Field of Use, SST’s topical formulation of Sildenafil Cream, 3.6% as it existed as of the effective date of the agreement, or any other topically applied pharmaceutical product containing sildenafil or a salt thereof as a pharmaceutically active ingredient, alone or with other active ingredients, but specifically excluding any product containing ibuprofen or any salt derivative of ibuprofen, or the Licensed Products.

The following is a summary of other terms of the SST license and collaboration agreement:

Invention Ownership. The Company retains rights to inventions made by its employees, SST retains rights to inventions made by its employees, and each party owns a 50% undivided interest in all joint inventions.

Joint Development Committee. The parties will collaborate through a joint development committee that will determine the strategic objectives for, and generally oversee, the development efforts of both parties under the agreement.

Development. The Company must use commercially reasonable efforts to develop the Licensed Products in the Field of Use in accordance with a development plan in the agreement, and to commercialize the Licensed Products in the Field of Use. The Company is responsible for all reasonable internal and external costs and expenses incurred by SST in its performance of the development activities it must perform under the agreement.

Royalty Payments. SST will be eligible to receive tiered royalties based on percentages of annual net sales of Licensed Products in the single digits to the mid double digits, subject to customary royalty reductions and offsets, and a percentage of sublicense revenue.

Milestone Payments. SST will be eligible to receive payments (1) ranging from $0.5 million to $18.0 million in the aggregate on achieving certain clinical and regulatory milestones in the U.S. and worldwide, and (2) between $10.0 million to $100.0 million in the aggregate upon achieving certain commercial sales milestones. If the Company enters into strategic development or distribution partnerships related to the Licensed Products, additional milestone payments would be due to SST.

Term. The Company's license continues on a country-by-country basis until the later of 10 years from the date of the first commercial sale of such Licensed Product or the expiration of the last valid claim of patent rights covering the Licensed Product in the Field of Use. Upon expiration (but not termination) of the agreement in a particular country, the Company will have a fully paid-up license under the licensed intellectual property to develop and commercialize the applicable Licensed Products in the applicable country on a non-exclusive basis.

Termination. In addition to customary termination rights for both parties: (1) prior to receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA approval, the Company may terminate the agreement without cause upon 90 days prior written notice; (2) following receipt of approval by a regulatory authority necessary for commercialization of a Licensed Product in the corresponding jurisdiction, including NDA approval, the Company may terminate the agreement without cause upon 180 days prior written notice; and (3) SST may terminate the agreement with respect to the applicable Licensed Product(s) in the applicable country(ies) upon 30 days' notice if the Company fails to use commercially reasonable efforts to perform development activities in substantial accordance with the development plan and do not cure such failure within 60 days of receipt of SST's notice thereof.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc. (formerly known as Juniper Pharmaceuticals, Inc., and which the Company refers to as Catalent), under which Catalent granted the Company (a) an exclusive, royalty-bearing worldwide license under certain patent rights, either owned by or exclusively licensed to Catalent, to make, have made, use, have used, sell, have sold, import and have imported products and processes, and (b) a non-exclusive, royalty-bearing worldwide license to use certain technological information owned by Catalent to make, have made, use, have used, sell, have sold, import and have imported products and processes. The Company is entitled to sublicense the rights granted to it under this agreement.

Upfront Fee. The Company paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement.

Annual Maintenance Fee. The Company will pay an annual license maintenance fee to Catalent on each anniversary of the date of the agreement, the amount of which will be $50,000 for the first two years and $100,000 thereafter, and which will be creditable against royalties and other payments due to Catalent in the same calendar year but may not be carried forward to any other year. The Company made the first payments in April 2019.

Milestone Payments. The Company must make potential future development and sales milestone payments of (1) up to $13.5 million in the aggregate upon achieving certain clinical and regulatory milestones, $1.0 million of which became payable in the third quarter of 2021, and in accordance with the license agreement, the amount payable was offset by the $100,000 annual maintenance fee, resulting in a net amount of $900,000 paid during the third quarter of 2021, and (2) up to $30.3 million in the aggregate upon achieving certain commercial sales milestones for each product or process covered by the licenses granted under the agreement.

Royalty Payments. During the royalty term, the Company will pay Catalent mid-single-digit to low double-digit royalties based on worldwide net sales of products and processes covered by the licenses granted under the agreement. In lieu of such royalty payments, the Company will pay Catalent a low double-digit percentage of all sublicense income the Company receives for the sublicense of rights under the agreement to a third party. The royalty term, which is determined on a country-by-country basis and product-by-product basis (or process-by-process basis), begins with the first commercial sale of a product or process in a country and terminates on the latest of (1) the expiration date of the last valid claim within the licensed patent rights with respect to such product or process in such country, (2) 10 years following the first commercial sale of such product or process in such country, and (3) when one or more generic products for such product or process are commercially available in such country, except that if there is no such generic product by the 10th year following the first commercial sale in such country, then the royalty term will terminate on the 10-year anniversary of the first commercial sale in such country.

Efforts. The Company must use commercially reasonable efforts to develop and make at least one product or process available to the public, which efforts include achieving specific diligence requirements by specific dates specified in the agreement.

Term. Unless earlier terminated, the term of the agreement will continue on a country-by-country basis until the later of (1) the expiration date of the last valid claim within such country, or (2) 10 years from the date of first commercial sale of a product or process in such country. Upon expiration (but not early termination) of the agreement, the licenses granted thereunder will convert automatically to fully-paid irrevocable licenses. Catalent may terminate the agreement (1) upon 30 days' notice for the Company's uncured breach of any payment obligation under the agreement, (2) if the Company fails to maintain required insurance, (3) immediately upon the Company's insolvency or the making of an assignment for the benefit of the Company's creditors or if a bankruptcy petition is filed for or against the Company, which petition is not dismissed within 90 days, or (4) upon 60 days' notice for any uncured material breach by the Company of any of the Company's other obligations under the agreement. The Company may terminate the agreement on a country-by-country basis for any reason by giving 180 days' notice (or 90 days' notice if such termination occurs prior to receipt of marketing approval in the United States). If Catalent terminates the agreement for the reason described in clause (4) above or if the Company terminates the agreement, Catalent will have full access including the right to use and reference all product data generated during the term of the agreement that is owned by the Company.

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharma Solutions (formerly known as Adare Pharmaceuticals and Orbis Biosciences, and which the Company refers to as Adare), for the development of long-acting injectable etonogestrel contraceptive with 6- and 12-month durations (now known as ADARE-204 and ADARE-214, respectively). The agreement provides the Company with an option to negotiate an exclusive license agreement for the programs if the Company funds the conduct of specified development work by Adare.

MBI Acquisition

In November 2019, the Company acquired Dare MB Inc. (formerly, Microchips Biotech, Inc.), or MBI, to secure the rights to develop a long-acting reversible contraception method that a woman can turn on or off herself, according to her own needs. This candidate is now known as DARE-LARC1.

At the closing of the acquisition, the Company issued an aggregate of approximately 3.0 million shares of its common stock to the holders of shares of MBI's capital stock outstanding immediately prior to the effective time of the merger. The transaction was valued at $2.4 million, based on the fair value of the approximately 3.0 million shares issued at $0.79 per share, which was the closing price per share of the Company's common stock on the date of closing. The shares were issued in exchange for MBI's cash and cash equivalents of $6.1 million, less net liabilities of $3.5 million and transaction costs of $202,000, which was allocated based on the relative fair value of the assets acquired and the liabilities assumed.

The Company also agreed to pay the following additional consideration to the former MBI stockholders: (a) up to $46.5 million contingent upon the achievement of specified funding, product development and regulatory milestones; (b) up to $55.0 million contingent upon the achievement of specified amounts of aggregate net sales of products incorporating the intellectual property acquired by the Company in the merger; (c) tiered royalty payments ranging from low single-digit to low double-digit percentages of annual net sales of such products, subject to customary provisions permitting royalty reductions and offset; and (d) a percentage of sublicense revenue related to such products. The Company agreed to use commercially reasonable efforts to achieve specified development and regulatory objectives relating to DARE-LARC1. In June 2021, a total of $1.25 million of that potential additional consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was recorded as contingent consideration on the Company's consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which was expensed in 2021. In July 2021, the Company's board of directors elected to make these milestone payments in shares of the Company's common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021. See Note 7.

Pear Tree Acquisition

In May 2018, the Company completed its acquisition of Pear Tree Pharmaceuticals, Inc., or Pear Tree. The Company acquired Pear Tree to secure the rights to develop a proprietary vaginal formulation of tamoxifen, now known as DARE-VVA1, as a potential treatment for vulvar and vaginal atrophy.

Milestone Payments. The Company must make contingent payments to certain Pear Tree licensors and former stockholders of Pear Tree that become payable upon achievement of specified clinical, regulatory and commercial milestones, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock.

Royalty Payments. Subject to royalty reductions and offsets, (a) the former stockholders of Pear Tree will be eligible to receive tiered royalties based on percentages of net sales of certain products and a percentage of sublicense revenue and (b) certain Pear Tree licensors will be eligible to receive royalties based on percentages of net sales of certain products and a percentage of sublicense revenue.

4. STOCKHOLDERS' EQUITY

October 2021 ATM Sales Agreement

In October 2021, the Company entered into a sales agreement with SVB Leerink LLC to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which SVB Leerink acts as the Company's agent. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement, plus certain legal expenses. Shares of the Company's common stock sold under the agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-254862) and the base prospectus included therein, originally filed with the SEC on March 30, 2021, and declared effective on April 7, 2021, and the prospectus supplement dated October 13, 2021 relating to the offering of up to $50.0 million in shares of the Company's common stock under this sales agreement, and any subsequent prospectus supplement filed with the SEC related to this ATM equity offering program.

During the three months ended March 31, 2022, the Company sold no shares under this agreement.

April 2021 ATM Sales Agreement

In April 2021, the Company entered into a sales agreement with SVB Leerink LLC to sell shares of its common stock from time to time through an ATM, equity offering program under which SVB Leerink acts as the Company's agent. Under the sales agreement, the Company may issue and sell up to $50.0 million of shares of its common stock. The Company agreed to pay a commission equal to 3% of the gross proceeds of any common stock sold under the agreement, plus certain legal expenses. Any shares of the Company's common stock sold under the agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-254862) and the base prospectus included therein, originally filed with the SEC on March 30, 2021, and declared effective on April 7, 2021, and the prospectus supplement dated April 7, 2021 filed with the SEC on April 8, 2021.

During the three months ended March 31, 2022, the Company sold no shares under this agreement.

2018 ATM Sales Agreement

In January 2018 the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, or Wainwright, relating to the offering and sale of shares of its common stock from time to time in an ATM equity offering program through Wainwright, acting as sales agent. Under the agreement, Wainwright was entitled to a commission at a fixed commission rate equal to 3.0% of the gross proceeds per share sold under the agreement. In March 2021, the Company provided notice to Wainwright to terminate the agreement, and the agreement terminated in April 2021.

Equity Line

In April 2020, the Company entered into a purchase agreement, or the Purchase Agreement, and a registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, the Company had the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park was obligated to purchase up to $15.0 million of the Company's common stock. The Company incurred legal, accounting, and other fees related to the Purchase Agreement of approximately $374,000. These costs were amortized and expensed as shares were sold under the Purchase Agreement. As of December 31, 2021, the Company had sold and Lincoln Park had purchased $15.0 million of the Company's common stock under the Purchase Agreement, there were no unamortized costs, and no more shares of common stock may be sold by the Company to Lincoln Park under the Purchase Agreement.

Common Stock Warrants

In February 2018, the Company closed an underwritten public offering in connection with which the Company issued to the investors in that offering warrants exercisable through February 2023 and that initially had an exercise price of $3.00 per share. The warrants include a price-based anti-dilution provision, which provides that, subject to certain limited exceptions, the exercise price of the warrants will be reduced each time the Company issues or sells (or is deemed to issue or sell) securities for a net consideration per share less than the exercise price of those warrants in effect immediately prior to such issuance or sale. In addition, subject to certain exceptions, if the Company issues, sells or enters into any agreement to issue or sell securities at a price which varies or may vary with the market price of the shares of the Company's common stock, the warrant holders have the right to substitute such variable price for the exercise price of the warrant then in effect. These warrants are exercisable only for cash, unless a registration statement covering the shares issued upon exercise of the warrants is not effective, in which case the warrants may be exercised on a cashless basis. A registration statement covering the shares issued upon exercise of the warrants is currently effective. The Company estimated the fair value of the warrants as of February 15, 2018 to be approximately $3.0 million which was recorded in equity as of the grant date. The Company early adopted ASU 2017-11 as of January 1, 2018 and recorded the fair value of the warrants as equity.

In April 2019 and July 2020, in accordance with the price-based anti-dilution provision discussed above, the exercise price of these warrants was automatically reduced to $0.98 per share and to $0.96 per share, respectively, and as a result of the triggering of the anti-dilution provision, $0.8 million and $6,863, respectively, was recorded to additional paid-in capital.

During the three months ended March 31, 2022, no warrants were exercised. During the three months ended March 31, 2021, warrants to purchase 52,500 shares of common stock were exercised for gross proceeds of $50,000. As of March 31, 2022, the Company had the following warrants outstanding:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
6,500	$ 10.00	04/04/2026
1,374,515	$ 0.96	02/15/2023
1,381,015		

5. STOCK-BASED COMPENSATION

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or the ESPP, became effective in April 2014, but no offering period has been initiated thereunder since January 2017. There was no stock-based compensation related to the ESPP for the three months ended March 31, 2022 or March 31, 2021.

Amended and Restated 2014 Stock Incentive Plan

The Company maintains the Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, which provides for the grant of options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, officers and directors, and consultants and advisors. There were 2,046,885 shares of common stock authorized for issuance under the Amended 2014 Plan when it was approved by the Company's stockholders in July 2018. The number of authorized shares increases annually on the first day of each fiscal year until, and including, the fiscal year ending December 31, 2024 by the least of (i) 2,000,000, (ii) 4% of the number of outstanding shares of common stock on such date, or (iii) an amount determined by the Company's board of directors. On January 1, 2022, the number of authorized shares increased by 2,000,000 to 2,201,855.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Amended 2014 Plan and related information for the three months ended March 31, 2022. The exercise price of all options granted during the three months ended March 31, 2022 was equal to the market value of the Company's common stock on the date of grant. As of March 31, 2022, unamortized stock-based compensation expense of approximately $5.3 million will be amortized over a weighted average period of 2.98 years. At March 31, 2022, 642,175 shares of common stock were available for future awards granted under the Amended 2014 Plan.

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2021	4,717,602	$ 1.65
Granted	1,759,692	1.59
Exercised	—	—
Canceled/forfeited	(200,012)	1.96
Expired	—	—
Outstanding at March 31, 2022	6,277,282	$ 1.63
Exercisable at March 31, 2022	2,597,775	$ 1.45

Compensation Expense

Total stock-based compensation expense related to stock options granted to employees and directors recognized in the condensed consolidated statements of operations is as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 174,613	$ 115,625
General and administrative	$ 357,796	$ 250,286
Total	$ 532,409	$ 365,911

The assumptions used in the Black-Scholes option-pricing model for stock options granted to employees and to directors in respect of board services during the three months ended March 31, 2022 are as follows:

	Three Months Ended March 31, 2022
Expected life in years	6.02
Risk-free interest rate	1.65%
Expected volatility	122%
Forfeiture rate	0.0%
Dividend yield	0.0%
Weighted-average fair value of options granted	$1.38

6. LEASED PROPERTIES

The Company's lease for its corporate headquarters (3,169 square feet of office space) commenced on July 1, 2018. In February 2022, the Company entered into an amendment to extend the term of the lease for two years such that the term now expires on August 31, 2024.

MBI, a wholly owned subsidiary the Company acquired in November 2019, leases general office space in Lexington, Massachusetts and warehouse space in Billerica, Massachusetts. The Lexington lease commenced on July 1, 2013. In February 2022, the Company entered into an amendment to extend the term of the lease for three years such that the term now expires on December 31, 2025, subject to the landlord's right to terminate the lease on December 31, 2023. The Billerica lease commenced on October 1, 2016 and terminated on March 31, 2022.

Under the terms of each lease, the lessee pays base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. The leases do not require material variable lease payments, residual value guarantees or restrictive covenants.

The leases do not provide an implicit rate, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. The Company uses an incremental borrowing rate of 7% for operating leases that commenced prior to January 2019 (and all of the Company's operating leases commenced prior to such date). The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At March 31, 2022, the Company reported operating lease ROU assets of approximately $1.2 million in other non-current assets, and approximately $294,000 and $913,000, respectively, in current portion of lease liabilities and lease liabilities long-term on the condensed consolidated balance sheet.

Total operating lease costs were approximately $169,000 and $135,000 for the three months ended March 31, 2022 and March 31, 2021, respectively. Operating lease costs consist of monthly lease payments expense, common area maintenance and other repair and maintenance costs and are included in general and administrative expenses in the condensed consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities was approximately $123,000 and $112,000 for the three months ended March 31, 2022 and March 31, 2021, respectively. These amounts are included in operating activities in the condensed consolidated statements of cash flows. Further, at March 31, 2022, operating leases had a weighted average remaining lease term of 3.13 years.

As of March 31, 2022, future minimum lease payments under the Company's operating leases are as follows:

Remainder of 2022	$	288,000
2023		422,000
2024		384,000
2025		297,000
Total future minimum lease payments		1,391,000
Less: accreted interest		183,000
Total operating lease liabilities	$	1,208,000

7. COMMITMENTS AND CONTINGENCIES

CRADA with NICHD for the Pivotal Phase 3 Study of Ovaprene

In July 2021, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or NICHD, for the conduct of a multi-center, non-comparative, pivotal Phase 3 clinical study of Ovaprene, or the Ovaprene Phase 3. The Ovaprene Phase 3 will be conducted within NICHD's Contraceptive Clinical Trial Network with NICHD contractor Health Decisions Inc., a contract research organization, providing clinical coordination and data collection and management services for the Ovaprene Phase 3. The Company and NICHD will each provide medical oversight and final data review and analysis for the Ovaprene Phase 3 and will work together to prepare the final report of the results of the Ovaprene Phase 3. The Company is responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Ovaprene Phase 3. NICHD will be responsible for the other costs related to the conduct of the Ovaprene Phase 3. In accordance with the payment schedule under the CRADA, the Company has made aggregate payments of $5.0 million of the total amount payable to NICHD, $3.5 million of which was paid during the first quarter of 2022. At March 31, 2022, the remaining amount of the Company's payment obligation under the CRADA was $0.5 million.

Contingent Consideration

As discussed in Note 3 above, in connection with the acquisition of MBI, the Company agreed to pay additional consideration of up to $46.5 million to the former stockholders of MBI contingent upon the achievement of specified funding, product development and regulatory milestones. In June 2021, $1.25 million of that potential additional consideration became payable upon the achievement of certain of the funding and product development milestone events, $1.0 million of which was previously recorded as contingent consideration on the Company's consolidated balance sheets upon the completion of the MBI acquisition and $250,000 of which was expensed in 2021. In July 2021, the Company's board of directors elected to make these milestone payments in shares of the Company's common stock, to the extent permissible under the terms of the merger agreement with MBI, and, in September 2021, the Company issued approximately 700,000 shares of its common stock to former stockholders of MBI and paid $75,000 to the stockholders' representative in accordance with the terms of the merger agreement in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

Note Payable

In April 2020, due to the economic uncertainty resulting from the impact of the COVID-19 pandemic on the Company's operations and to support its ongoing operations and retain all employees, the Company applied for and received a loan of $367,285 under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, administered by the U.S. Small Business Administration, or the SBA. Under the terms of the PPP, the loan proceeds could be used for "qualifying expenses" and, subject to specified limitations in the CARES Act and under the terms of the PPP, certain amounts of the loan, including accrued interest, may be forgiven if used for qualifying expenses. In January 2021, the Company was notified that the principal balance of its PPP loan and all accrued interest, which together totaled $369,887, were fully forgiven by the SBA. The Company recorded a gain on extinguishment of note payable and debt forgiveness income with respect to such loan forgiveness in the first quarter of 2021.

8. GRANT AWARDS

NICHD Non-Dilutive Grant Funding

The Company has received notices of awards and non-dilutive grant funding from NICHD to support the development of Ovaprene, DARE-PTB1 and DARE-LARC1. NICHD issues notices of awards to the Company for a specified amount, and the Company must incur and track expenses eligible for reimbursement under the award and submit a detailed accounting of such expenses to receive payment. If the Company receives payments under the award, the amounts of such payments are recognized in the statements of operations as a reduction to research and development activities as the related costs are incurred to meet those obligations over the period.

Ovaprene

From 2018 through 2021, the Company received approximately $1.9 million of non-dilutive grant funding from NICHD for clinical development efforts supporting Ovaprene. All funds under the final notice of award had been disbursed as of December 31, 2021.

DARE-PTB1

In August 2020, the Company received a notice of award of a grant from NICHD to support the development of DARE-PTB1. The award in the amount of $300,000 was for the "Phase I" segment of the project outlined in the Company's grant application, which is ongoing. Additional potential funding of up to approximately $2.0 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds. There is no guarantee the Company will receive any Phase II award.

The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $17,000 during the three months ended March 31, 2022. At March 31, 2022, the Company recorded a receivable of approximately $19,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant.

DARE-LARC1

In September 2021, the Company received a notice of award of a grant from NICHD to support the development of DARE-LARC1. The award in the amount of approximately $300,000 is to be used to explore device insertion and removal in non-clinical studies, which is to occur during the period of September 2021 through August 2022.

The Company recorded credits to research and development expense of approximately $165,000 for costs related to the NICHD award during the three months ended March 31, 2022. At March 31, 2022, the Company recorded a receivable of approximately $173,000 for expenses incurred through such date that it believes is eligible for reimbursement under the grant.

DARE-LARC1 Non-Dilutive Grant Funding

MBI Grant Agreement

The Company's wholly-owned subsidiary, MBI, was awarded $5.4 million to support the development of DARE-LARC1 under a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation. The funding period under this agreement ended on June 30, 2021. Expenses eligible for funding were incurred, tracked and reported to the Foundation. MBI received aggregate payments under this agreement of approximately $5.4 million. At June 30, 2021, all payments under this agreement associated with research and development expenses for DARE-LARC1 had been incurred and reported to the Foundation.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation, or the 2021 DARE-LARC1 Grant Agreement, under which the Company was awarded up to $48.95 million to support the development of DARE-LARC1. The 2021 DARE-LARC1 Grant Agreement will support technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 in non-clinical proof of principle studies. The Company received an initial payment of $11.45 million in July 2021. Additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones. At March 31, 2022, approximately $9.7 million of deferred grant funding liability under this agreement was recorded in the Company's condensed consolidated balance sheet.

9. NET LOSS PER SHARE

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Common share equivalents outstanding, determined using the treasury stock method, are comprised of shares that may be issued under outstanding options and warrants to purchase shares of the Company's common stock. Common share equivalents are excluded from the diluted net loss per share calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted net loss per common share for the period indicated because of their anti-dilutive effect:

Potentially dilutive securities	Three Months Ended March 31,	
	2022	2021
Stock options	6,277,282	4,311,291
Warrants	1,381,015	1,856,143
Total	7,658,297	6,167,434

10. SUBSEQUENT EVENTS

Sales of Common Stock

Between April 1, 2022 and May 10, 2022, the Company sold an aggregate of approximately 751,000 shares of common stock for net proceeds of approximately $1.2 million under its ATM equity offering program.

Commencement of Phase 1/2 Clinical Study of DARE-HRT1

In April 2022, the Company announced commencement of its Phase 1/2 clinical study of DARE-HRT1. The open-label study will evaluate the pharmacokinetics (PK) of two versions of DARE-HRT1 in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data. The study is being conducted by the Company's wholly owned subsidiary in Australia.

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

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021, or our 2021 10-K, filed with the Securities and Exchange Commission, or SEC, on March 31, 2022. Past operating results are not necessarily indicative of results that may occur in future periods.

The following discussion includes forward-looking statements. See "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS," above. Forward-looking statements are not guarantees of future performance and our actual results may differ materially from those currently anticipated and from historical results depending upon a variety of factors, including, but not limited to, those discussed in Part I, Item 1A. Risk Factors of our 2021 10-K, and in our subsequent filings with the SEC, including any discussed in Part II, Item 1A of this report under the heading "Risk Factors," which are incorporated herein by reference.

In this report, "we," "us," "our," "Daré" or the "Company" refer collectively to Daré Bioscience, Inc. and its wholly owned subsidiaries, unless otherwise stated or the context otherwise requires. All information presented in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

Daré Bioscience® is a registered trademark of Daré Bioscience, Inc. and XACIATO™ is a trademark of Daré Bioscience, Inc. with registration pending. Ovaprene® is a registered trademark licensed to Daré Bioscience, Inc. All other trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, service marks or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.

Business Overview

We are a biopharmaceutical company committed to advancing innovative products for women's health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility and vaginal and sexual health. Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid to late-stage clinical development or regulatory approval, and to establish and leverage strategic collaborations to achieve commercialization. We and our wholly owned subsidiaries operate in one business segment.

Our first product, XACIATO [zah-she-AH-toe] (clindamycin phosphate vaginal gel, 2%), was approved by the FDA in December 2021, as a single-dose prescription medication for the treatment of bacterial vaginosis in female patients 12 years of age and older. In March 2022, we entered into an exclusive global license agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, to commercialize XACIATO. XACIATO is expected to be available commercially in the United States in the fourth quarter of 2022.

Our product pipeline includes diverse programs that target unmet needs in women's health in the areas of contraception, fertility and vaginal and sexual health and aim to expand treatment options, enhance outcomes and improve ease of use for women. We are primarily focused on progressing the development of our existing product candidates. We are also exploring opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on women's health. Our current portfolio includes two product candidates in advanced clinical development:

- **Ovaprene**, a hormone-free, monthly contraceptive; and
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder, or FSAD.

Our portfolio also includes four product candidates in Phase 1 clinical development or that we believe are Phase 1-ready:

- **DARE-HRT1**, a combination bio-identical estradiol and progesterone intravaginal ring, or IVR, for the treatment of menopausal symptoms, including vasomotor symptoms, as part of hormone therapy following menopause;

- **DARE-VVA1**, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy as an option for women with hormone-receptor positive breast cancer;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for broader luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth.

In addition, our portfolio includes these pre-clinical stage potential product candidates:

- **DARE-LARC1**, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option;
- **ADARE-204 and ADARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through clinical development and regulatory approval. We expect our research and development expenses will continue to represent the majority of our operating expenses for at least the next twelve months. For the remainder of 2022, we expect to continue to focus our resources on advancement of Ovaprene and Sildenafil Cream, 3.6%, and our other product candidates that have reached the human clinical study development phase. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 program for the next several years, but we also expect such expenses will be supported by non-dilutive funding provided under a grant agreement we entered into in June 2021.

To date, we have not generated any revenue**.** We are subject to several risks common to biopharmaceutical companies, including dependence on key employees, dependence on third-party collaborators and service providers, competition from other companies, the need to develop commercially viable products in a timely and cost-effective manner, and the need to obtain adequate additional capital to fund the development of product candidates. We are also subject to several risks common to other companies in the industry, including rapid technology change, regulatory approval of products, uncertainty of market acceptance of products, success of third parties in the marketing, sale and distribution of our products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, and product liability.

The COVID-19 pandemic remains an evolving and uncertain risk to our business, operating results, financial condition and stock price. To date, we believe the pandemic contributed to a slower than expected initial pace of enrollment in our Phase 2b clinical study of Sildenafil Cream, 3.6% and delays in commencement of clinical studies and nonclinical testing for more than one of our earlier stage clinical programs, but has not had a material adverse effect on our business as a whole. Continued uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, healthcare systems, workplace environments and capital markets, preclude any prediction as to the ultimate effect of the pandemic on our business. See the risk factor in Part I, Item 1A of our 2021 10-K titled, *The COVID-19 pandemic has negatively impacted our business and, in the future, may materially and adversely affect our business, financial condition and results and stock price, including by increasing the cost and timelines for our clinical development programs.*

XACIATO

In March 2022, we entered into an exclusive license agreement with Organon pursuant to which Organon will obtain exclusive worldwide rights to develop, manufacture and commercialize XACIATO. The effective date of the agreement will occur following the satisfaction of closing conditions that include receipt of all applicable approvals, or the expiration or termination of all applicable waiting periods, required under applicable antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. We will receive a $10.0 million non-refundable and non-creditable payment from Organon following the effective date of the agreement, which is expected to occur in the second quarter of 2022, and we are entitled to receive a $2.5 million milestone payment following the first commercial sale of a licensed product in the United States. XACIATO is expected to be available commercially in the U.S. in the fourth quarter of 2022. We will also be eligible to receive future potential milestone payments of up to $180.0 million and tiered double-digit royalties based on net sales.

Under the agreement, we will be responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumes such responsibilities. Until such time, Organon will purchase all of its product requirements of XACIATO from us at a transfer price equal to our manufacturing costs plus a single-digit percentage markup. We will fulfill our commercial supply obligations through the contract manufacturer that provided clinical supplies of XACIATO for our pivotal Phase 3 DARE-BVFREE clinical study of XACIATO. We will not be responsible for other costs of commercializing XACIATO.

Our Pipeline: Clinical-Stage Programs

Ovaprene

In January 2022, we initiated an Investigational Device Exemption, or IDE, review process with the FDA for a multi-center, non-comparative, pivotal Phase 3 clinical study of the safety and efficacy of Ovaprene to prevent pregnancy. Our IDE submission was subsequently converted to an IDE pre-submission so that the FDA could engage in a collaborative discussion with us regarding items that must be addressed prior to enrollment of any subjects in the Phase 3 study. This process is ongoing and we believe it will allow us to finalize the protocol and design of the study as the registration study to support a future PMA submission. Based on communications with the FDA, in terms of study sample size and duration, we expect that at least 200 subjects completing 12 months of Ovaprene use will be adequate. We are targeting commencement of the Phase 3 study during 2022.

The planned Phase 3 clinical study will be conducted under our Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, or the NICHD, part of the National Institutes of Health, and within NICHD's Contraceptive Clinical Trial Network. We and NICHD will each provide medical oversight and final data review and analysis for the study and will work together to prepare the final report of the results of the study. We are responsible for providing clinical supplies of Ovaprene, coordinating interactions with the FDA, preparing and submitting supportive regulatory documentation, and providing a total of $5.5 million in payments to NICHD to be applied toward the costs of conducting the Phase 3 study of which a total of $5.0 million has been paid. NICHD will be responsible for the other costs related to the conduct of the Phase 3 study and will manage the payment of expenses to contract research organization Health Decisions Inc., the clinical sites, and other parties involved with the study. If the Phase 3 study is successful, we expect the data to support a pre-market approval submission to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

Sildenafil Cream, 3.6%

Our ongoing Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% in women with FSAD is designed to evaluate Sildenafil Cream, 3.6% compared to placebo cream over 12 weeks of dosing in the participants' home setting following both a non-drug and placebo run-in period. The primary efficacy endpoint of the study is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. The study is expected to randomize 400 to 590 subjects into the double-blind dosing period at 40 to 50 clinical sites in the U.S. to ensure a total of 300 (150:150) to 440 (220:220) subjects complete the 12-week double-blind dosing period. The final size of the study will be determined by a single interim analysis for unblinded sample size re-estimation, based on the study's adaptive design. An adaptive design implemented in accordance with the FDA's Guidance for Industry on adaptive designs for clinical trials of drugs mitigates the risk of the study being underpowered if the true treatment effect and variability are significantly different from estimates based on published data but are still clinically meaningful. We anticipate that the planned interim analysis will be conducted in 2022, after which we should be able to provide an updated timeframe for announcement of topline data from this trial.

DARE-HRT1

In April 2022, we announced initiation of our Phase 1/2 clinical study of DARE-HRT1. The open-label study will evaluate the pharmacokinetics (PK) of two versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data. The study is being conducted by our wholly owned subsidiary in Australia. In 2021, we reported positive topline data from a Phase 1 clinical study that evaluated the PK of the same two versions of DARE-HRT1 over 28 days. We anticipate reporting topline data from the Phase 1/2 study in the fourth quarter of 2022.

DARE-VVA1

In September 2021, we announced initiation of our Phase 1/2 clinical study of DARE-VVA1. The randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study is designed to evaluate the safety, tolerability, PK, and pharmacodynamics (PD) of DARE-VVA1 in postmenopausal participants with moderate to severe VVA and is being conducted by our wholly owned Australian subsidiary. We expect the study will enroll approximately 40 postmenopausal women with VVA, including a cohort of women with a history of hormone-receptor positive breast cancer, at approximately three study sites. Eligible participants will be randomly allocated to one of the five treatment groups (approximately 8 participants per group) that will evaluate four dose levels (1 mg, 5 mg, 10 mg, and 20 mg) and a placebo. Following a screening visit, DARE-VVA1 will be self-administered intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants will have serial blood sampling for PK analysis and undergo safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants will attend a safety follow-up visit. The primary endpoints of the study will evaluate the safety and tolerability of DARE-VVA1 by vaginal administration and determine the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints will evaluate the preliminary efficacy and PD of DARE-VVA1 in terms of the most bothersome symptom and changes in vaginal cytology and pH. We anticipate reporting topline data from the study in the second half of 2022.

DARE-FRT1 and DARE-PTB1

We are conducting development activities in preparation for Phase 1 clinical studies of DARE-FRT1 and DARE-PTB1. We do not expect to commence clinical development of these product candidates in 2022.

Our currently anticipated timelines and aggregate costs for the development of our product candidates could be delayed and could increase as a result of the COVID-19 pandemic, or otherwise. See the risk factor titled, *The COVID-19 pandemic has negatively impacted our business and, in the future, may materially and adversely affect our business, financial condition and results and stock price, including by increasing the cost and timelines for our clinical development programs,* in Part I, Item 1A, Risk Factors of our 2021 10-K.

Recent Events

Global License Agreement with Organon to Commercialize XACIATO

In March 2022, we entered into an exclusive license agreement with Organon, pursuant to which Organon will obtain exclusive worldwide rights to develop, manufacture and commercialize XACIATO. See “Strategic Agreements for Product Commercialization – Organon License Agreement“ in Part I, Item 1. Business of our 2021 10-K for a description of the terms of the license agreement. As discussed above, we will receive a $10.0 million non-refundable and non-creditable payment from Organon following the effective date of the agreement, which is expected to occur in the second quarter of 2022, and we are entitled to receive a $2.5 million milestone payment following the first commercial sale of a licensed product in the United States, which is expected to occur in the fourth quarter of 2022. We currently cannot predict with any reasonable certainty the timing or amount of other potential payments from Organon under the license agreement in future periods.

Initiation of Phase 1/2 Clinical Study of DARE-HRT1

As discussed above, in April 2022, we announced initiation of our Phase 1/2 clinical study of DARE-HRT1 in Australia.

Financial Overview

Revenue

To date we have not generated any revenue. In the future, we may generate revenue from royalties and commercial milestones based on the net sales of XACIATO, from product sales of other approved products, if any, and from license fees, milestone payments, research and development payments in connection with strategic collaborations. Our ability to generate such revenue, with respect to XACIATO, will depend on the extent to which its commercialization is successful, and with respect to our product candidates, will depend on their successful clinical development, the receipt of regulatory approvals to market such product candidates and the eventual successful commercialization of products. If the commercialization of XACIATO is not successful or we fail to complete the development of product candidates in a timely manner, or to receive regulatory approval for such product candidates, our ability to generate future revenue and our results of operations would be materially adversely affected.

Research and Development Expenses

Research and development expenses include research and development costs for our product candidates and transaction costs related to our acquisitions. We recognize all research and development expenses as they are incurred. Research and development expenses consist primarily of:

- expenses incurred under agreements with clinical trial sites and consultants that conduct research and development and regulatory affairs activities on our behalf;
- laboratory and vendor expenses related to the execution of nonclinical studies and clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies;
- transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets;
- milestone payments due to third parties under acquisition and in-licensing arrangements we incur, or the incurrence of which we deem probable; and
- internal costs associated with activities performed by our research and development organization and generally benefit multiple programs.

In 2021, our research and development expenses consisted primarily of costs associated with the continued development of XACIATO, Ovaprene and Sildenafil Cream, 3.6% and during the first quarter of 2022, our research and development expenses consisted primarily of costs associated with the continued development of Ovaprene and Sildenafil Cream 3.6%. We expect research and development expenses to increase in the future as we continue to invest in the development of and seek regulatory approval for our clinical-stage and Phase 1-ready product candidates and as any other potential product candidates we may develop are advanced into and through clinical trials in the pursuit of regulatory approvals. Such activities will require a significant increase in investment in regulatory support, clinical supplies, inventory build-up related costs, and the payment of success-based milestones to licensors. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to, among other factors, license fee and/or milestone payments.

Conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may not obtain regulatory approval for any product candidate on a timely or cost-effective basis, or at all. The probability of success of our product candidates may be affected by numerous factors, including clinical results and data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we cannot accurately determine the duration and completion costs of development projects or when and to what extent we will generate revenue from the commercialization of any of our product candidates.

License Fees

License fees consist of up-front license fees and annual license fees due under our in-licensing arrangements.

General and Administrative Expense

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs.

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based on our interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Preparing these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated interim financial statements, refer to Item 7 in Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 1 to our financial statements contained in our 2021 10-K, and Note 2 to our unaudited condensed consolidated financial statements contained in this report.

Results of Operations

Comparison of Three Months Ended March 31, 2022 and 2021 (Unaudited)

The following table summarizes our condensed consolidated results of operations for the periods indicated, together with the changes in those items in dollars:

	Three Months Ended March 31,		Change	
	2022	2021	$	%
Operating expenses:				
General and administrative	$ 2,569,987	$ 1,940,328	$ 629,659	32 %
Research and development	5,805,462	5,728,206	77,256	1 %
License fees	25,000	25,000	—	— %
Total operating expenses	8,400,449	7,693,534	706,915	9 %
Loss from operations	(8,400,449)	(7,693,534)	(706,915)	9 %
Other income	1,779	3	1,776	59200 %
Gain on extinguishment of note payable	—	369,887	(369,887)	(100) %
Net loss	$ (8,398,670)	$ (7,323,644)	$ (1,075,026)	15 %
Other comprehensive loss:				
Foreign currency translation adjustments	(9,150)	(6,841)	(2,309)	34 %
Comprehensive loss	$ (8,407,820)	$ (7,330,485)	$ (1,077,335)	15 %

Revenues

We did not recognize any revenues for either of the three months ended March 31, 2022 or 2021.

General and administrative expenses

The increase of approximately $0.6 million in general and administrative expenses for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 was primarily attributable to increases in (i) professional services expense of approximately $351,000, (ii) stock-based compensation expense of approximately 108,000, (iii) personnel costs of approximately $101,000, and (iv) commercial-readiness expenses of approximately $92,000. Such increases were partially offset by a decrease in rent and facilities expenses of $80,000 attributable to the allocation of a portion of rent and facilities expense included in general and administrative in 2021 to research and development in 2022.

We expect an increase in general and administrative expenses of approximately 20% in 2022 compared to 2021 primarily due to increased personnel expenses and other general corporate overhead. Our general and administrative expenses in 2021 were approximately $8.4 million. Our 2022 general and administrative expenses will include costs related to commercial-readiness activities and obtaining commercial supplies of XACIATO from our contract manufacturer. Following commercial launch of XACIATO, we expect our general and administrative expenses will include payments by us to a third-party licensor, including royalty payments at rates in the high single-digit to low double-digits based on annual net sales of XACIATO. In 2022, in connection with commercialization of XACIATO in the U.S., these payments may include a milestone payment in the mid six-figures and royalty payments on net sales at a high single digit royalty rate.

Research and development expenses

The increase of approximately $0.1 million in research and development expenses for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 was primarily attributable to increased costs for two of our clinical-stage product candidates, Sildenafil Cream 3.6% and Ovaprene, with approximately $1.6 million related to the ongoing Sildenafil Cream, 3.6% Phase 2b RESPOND clinical trial and manufacturing and regulatory affairs activities for Ovaprene. Also contributing to the increase were increases in (a) personnel costs of approximately $248,000, (b) rent and facilities expenses of $171,000 attributable to the allocation of a portion of rent and facilities expense included in general and administrative in 2021 to research and development in 2022, and (c) stock-based compensation expense of approximately $59,000. Such increases were partially offset by (i) a decrease in development costs of approximately $873,000 as a result of the completion of the Phase 3 clinical trial for XACIATO in December 2020, (ii) a decrease in costs related to development activities for our Phase 1 and Phase 1-ready programs of approximately $843,000, and (iii) a decrease in costs related to development activities for our preclinical programs of approximately $271,000.

As previously reported, we expect research and development expenses to increase significantly in 2022 as we continue to develop our product candidates. Our research and development expenses in 2021 were approximately $30.6 million. If we advance our programs as currently planned, our research and development expenses for 2022 could be more than double our research and development expenses for 2021. Our 2022 research and development expenses could include up to $4.0 million in milestone payments payable by us to third parties under license and acquisition agreements related to certain of our product candidates, up to $1.0 million of which we may elect to pay in shares of our common stock. As discussed below in the section titled “Liquidity and Capital Resources,” we will need to raise substantial additional capital to continue to fund our operations and successfully execute our current operating plan. The pace and extent of our research and development activities and, therefore, our research and development spend, will depend on our cash resources. We expect our research and development spend to vary across our fiscal quarters. In regard to Sildenafil Cream, 3.6%, we anticipate that the costs of the Phase 2b RESPOND clinical trial will be approximately $20.0 million, approximately $9.5 million of which was recorded in prior fiscal years.

License fees

For each of the three months ended March 31, 2022 and March 31, 2021, we accrued $25,000 of the $100,000 annual license maintenance fee payable under our license agreement related to DARE-HRT1.

For further discussion of these license fees, see Note 3 to our unaudited condensed consolidated financial statements contained in this report.

Other income

The increase of $1,776 in other income for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 was primarily due to an increase in interest earned on cash balances in the current period.

Gain on extinguishment of note payable

The $369,887 recorded as a gain on extinguishment of note payable and debt forgiveness income in the first quarter of 2021 represents the forgiveness of all the principal and accrued interest of the loan we obtained under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security Act, administered by the U.S. Small Business Administration.

Liquidity and Capital Resources

Plan of Operations and Future Funding Requirements

We prepared the accompanying condensed consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. We have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for at least the next several years as we develop and seek to bring to market our existing product candidates and as we seek to potentially acquire, license and develop additional product candidates. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

At March 31, 2022, our accumulated deficit was approximately $118.5 million, our cash and cash equivalents were approximately $39.3 million, and our working capital was approximately $31.4 million. We incurred a loss from operations of approximately $8.4 million, and had negative cash flow from operations of approximately $12.3 million during the three months ended March 31, 2022.

We expect our primary uses of capital to be staff-related expenses, the cost of clinical trials and regulatory activities related to our product candidates, costs associated with contract manufacturing services and third-party clinical research and development services, payments to third-parties upon the occurrence of commercial milestones for XACIATO and development milestones for our product candidates pursuant to terms of the agreements under which we acquired or in-licensed rights to those programs, legal expenses, other regulatory expenses and general overhead costs. Our future funding requirements could also include significant costs related to commercialization of our product candidates, if approved, depending on the type, nature and terms of commercial collaborations we establish.

As discussed above, we expect our expenses, and in particular our research and development expenses, to increase significantly in 2022 compared to 2021 as we continue to develop and seek to bring to market our product candidates, with a focus on our product candidates that have reached the human clinical study development phase. Under the terms of our license agreement with Organon, Organon will purchase all of its product requirements of XACIATO from us at a price equal to our manufacturing costs plus a single digit percentage markup. As a result, we do not anticipate our costs of providing XACIATO commercial supplies will have a material impact on our cash resources and requirements.

Based on our current operating plan estimates, we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying condensed consolidated financial statements. Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock. During the three months ended March 31, 2022, we did not generate any proceeds from sales of our common stock. Subsequent to March 31, 2022 and through May 10, 2022 we received approximately $1.2 million in net proceeds from ATM sales of shares of our common stock.

We will need to raise substantial additional capital to continue to fund our operations and to successfully execute our current business strategy. During 2022, we may receive up to $12.5 million under our license agreement for XACIATO and up to $8.0 million in additional funding for pre-clinical development of DARE-LARC1 under our June 2021 grant agreement, and we will continue to seek to raise capital through the sale of shares of our common stock under our ATM sales agreements, however, when we effect such sales and the amount of shares we can sell depends on a variety of factors including, among others, market conditions, the trading price of our common stock, our determination as to the appropriate sources of funding for our operations, and the number of authorized shares of common stock available for issuance, which is approximately 27 million as of the date hereof. For the foreseeable future, we will evaluate and may pursue a variety of capital raising options on an on-going basis, including equity and debt financings, government or other grant funding, collaborations and strategic alliances or other similar types of arrangements, to cover our operating expenses, and the cost of any license or other acquisition of new product candidates or technologies. The amount and timing of our capital needs have been and will continue to depend highly on many factors, including the product development programs we choose to pursue, the pace and results of our clinical development efforts, and the nature and extent of expansion of our product candidate portfolio, if any. If we raise capital through collaborations, strategic alliances or other similar types of arrangements, we may have to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates we would otherwise seek to develop or commercialize.

There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders, and debt financings may subject us to restrictive covenants, operational restrictions and security interests in our assets. If we cannot raise capital when needed, on favorable terms or at all, we will not be able to continue development of our product candidates, will need to reevaluate our planned operations and may need to delay, scale back or eliminate some or all of our development programs, reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. See the risk factor in Part I, Item 1A of our 2021 10-K titled *We will need to raise additional capital to continue our operations and execute our business strategy*.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Three months ended March 31,	
	2022	2021
Net cash used in operating activities	$ (12,343,473)	$ (8,377,015)
Net cash used in investing activities	(4,553)	—
Net cash provided by financing activities	—	11,374,540
Effect of exchange rate changes on cash and cash equivalents	(9,150)	(6,841)
Net increase (decrease) in cash and cash equivalents	$ (12,357,176)	$ 2,990,684

Net cash used in operating activities

Cash used in operating activities for the three months ended March 31, 2022 included the net loss of $8.4 million, decreased by non-cash stock-based compensation expense of approximately $0.5 million. Components providing operating cash were an increase in accrued expenses of approximately $0.4 million and an increase in accounts payable of approximately $0.7 million**.** Components reducing operating cash were an increase in prepaid expenses of approximately $4.3 million, a decrease in deferred grant funding of approximately $0.8 million, and an increase in other receivables of approximately $0.6 million.

Cash used in operating activities for the three months ended March 31, 2021 included the net loss of $7.3 million, decreased by non-cash stock-based compensation expense of approximately $0.4 million and increased by the non-cash gain on the extinguishment of the note payable and accrued interest of approximately $0.4 million related to our PPP loan. Components providing operating cash were an increase in accounts payable of approximately $0.5 million, a decrease in prepaid expenses of approximately $0.2 million, and a decrease in other receivables of approximately $0.2 million. Components reducing operating cash were a decrease in deferred grant funding of approximately $0.9 million and a decrease in accrued expenses of approximately $0.8 million, and an increase in other non-current assets of approximately $0.1 million.

Net cash used in investing activities

Cash used in investing activities for three months ended March 31, 2022 was approximately $4,600.

No cash was provided by or used in investing activities for the three months ended March 31, 2021.

Net cash provided by financing activities

No cash was provided by financing activities for the three months ended March 31, 2022.

Cash provided by financing activities for the three months ended March 31, 2021 consisted of approximately $11.4 million in the aggregate from sales of shares of our common stock under our ATM sales agreement and our equity line after fees and expenses and upon the exercise of warrants during the period.

License and Royalty Agreements

We agreed to make royalty and milestone payments under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream, 3.6%, and under other agreements related to our other clinical and preclinical candidates. For further discussion of these potential payments, see Note 3 to our unaudited condensed consolidated financial statements contained in this report.

Other Contracts

We enter into contracts in the normal course of business with various third parties for research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and we do not believe that our non-cancelable obligations under these agreements are material.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports 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 our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on an evaluation performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of March 31, 2022 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. As of the date of filing this report, there is no material pending legal proceeding to which we are a party or to which any of our property is subject, and management is not aware of any contemplated proceeding by any governmental authority against us.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described in our 2021 10-K, in addition to other information in this report, before investing in our common stock. The occurrence of any of these risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. There have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our 2021 10-K.

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

(a) None.
(b) None.
(c) None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.
(b) None.

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
10.1+	Exclusive license agreement by and between Organon International GmbH and Daré Bioscience, Inc., dated as of March 31, 2022					X
10.2+	Consent, Waiver and Stand-By License Agreement, dated March 30, 2022, by and among TriLogic Pharma, LLC, and MilanaPharm LLC, Dare Bioscience, Inc., and Organon International GmbH.					X
10.3*	Amended & Restated Non-Employee Director Compensation Policy (as amended through January 2022)					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					#
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

\+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and is the type that we treat as private or confidential.

* Management contract or compensatory plan or arrangement

Furnished herewith. This certification is being furnished solely to accompany this report pursuant to U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated herein by reference into any filing of the registrant whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Daré Bioscience, Inc.

Date: May 12, 2022

By: /s/ Sabrina Martucci Johnson
Sabrina Martucci Johnson
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2022

By: /s/ Lisa Walters-Hoffert
Lisa Walters-Hoffert
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

EXCLUSIVE LICENSE AGREEMENT

by and between

ORGANON INTERNATIONAL GMBH

and

DARÉ BIOSCIENCE, INC.

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "**Agreement**") is entered as of March 31, 2022 (the "**Execution Date**") by and between Organon International GmbH, a limited liability company organized and existing under the laws of Switzerland ("**Organon**") and Daré Bioscience, Inc., a corporation organized and existing under the laws of Delaware ("**Daré**").

RECITALS:

WHEREAS, Daré has developed or Controls Daré Know-How (as hereinafter defined) and Daré Patents (as hereinafter defined);

WHEREAS, Organon and Daré desire to enter into a collaboration to develop, manufacture, commercialize and otherwise exploit Licensed Products (as hereinafter defined) upon the terms and conditions set forth herein;

WHEREAS, Organon desires to obtain an exclusive license under the Daré Patents and Daré Know-How, and Daré desires to grant such a license, all upon the terms and conditions set forth herein; and

WHEREAS, until Organon establishes the capability to manufacture or have manufactured the Licensed Products, the Parties desire Daré to supply Licensed Products to Organon for its resale and distribution upon the terms and conditions of the Supply and Distribution Agreement (as hereinafter defined).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Daré and Organon hereby agree as follows:

ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

1.1 "**Act**" means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as amended from time to time.

1.2 "**Adverse Event**" means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered a Licensed Product, whether or not having a causal relationship with such Licensed Product, including, without limitation, any unfavorable and unintended sign (including, without limitation, abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.

1.3 "**Affiliate**" means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be equal to or less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity.

1.4 "**Agreement**" has the meaning given such term in the preamble to this document.

1.5 "**Alliance Manager**" has the meaning set forth in Section 2.4.1.

1.6 "**Antibiotic**" means the active pharmaceutical ingredient of a product that has received Marketing Authorization in the United States as of the Effective Date, that is indicated for use in bacterial vaginosis on its label, and that is within the [***] drug class.

1.7 "**Anti-Corruption Laws**" means any Applicable Laws regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to Public Officials or private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including the United States Foreign Corrupt Practices Act, 15 U.S.C. § 78-dd-1, et seq., the United Kingdom Bribery Act 2010, the Criminal Law and Anti-Unfair Competition Law of the People's Republic of China, and laws implementing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions; each as may be amended or supplemented from time to time.

1.8 "**Antitrust Clearance Date**" means the earliest date on which all applicable waiting periods and approvals required under Antitrust Laws with respect to the transactions contemplated under this Agreement have expired or have been terminated (in the case of waiting periods) or been received (in the case of approvals), in each case, without the imposition of any conditions.

1.9 "**Antitrust Filing**" means filings by the Parties with the United States Federal Trade Commission and the United States Department of Justice and any applicable Governmental Authority in each other country or jurisdiction where antitrust clearance is required under any Antitrust Laws with respect to the transactions contemplated under this Agreement, together with all required documentary attachments thereto.

1.10 "**Antitrust Laws**" means any and all Applicable Laws, including HSR Act, designed to prohibit, restrict, or regulate actions for the purpose or effect of monopolization or restraint of trade.

1.11 "**Applicable Laws**" means applicable laws, statutes, ordinances, rules, regulations, guidances and orders of any Governmental Authority (including court orders) having jurisdiction over or related to the subject item.

1.12 "**Assignment Date**" has the meaning set forth in Section 3.2.4.

1.13 "**Business Day**" means a day, other than a Saturday or a Sunday, on which banking institutions in New York, New York are open for business.

1.14 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.15 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.16 "**Change of Control**" means, with respect to a Party, the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

1.16.1 any Exchange Act Person becomes the Owner, directly or indirectly, of securities of such Party representing more than [***]% of the combined voting power of such Party's then outstanding securities, other than by virtue of a merger, consolidation or similar transaction;

1.16.2 there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) such Party or an Affiliate of such Party and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of such Party (or such Affiliate of such Party) immediately prior thereto do not Own,

directly or indirectly, outstanding voting securities representing more than [***]% of the combined outstanding voting power of the surviving Person in such merger, consolidation or similar transaction or more than [***]% of the combined outstanding voting power of a parent of the surviving Person in such merger, consolidation or similar transaction; or

1.16.3 there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of such Party (or the direct or indirect parent entity of such Party) to an Exchange Act Person.

1.17 "**Clinical Trial**" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or post-Marketing Authorization human clinical trial.

1.18 "**Closing Condition**" has the meaning set forth in Section 11.4.

1.19 "**Clindamycin Product**" means (a) a thermosetting vaginal gel formulated with clindamycin phosphate two percent (2%) that is the subject of the Daré Marketing Authorization, [***] and (b) any other product formulated with clindamycin [***].

1.20 "**Code**" has the meaning set forth in Section 10.6.10.

1.21 "**Combination Product**" means a Licensed Product that contains (a) clindamycin [***] together with (b) [***], an "**Other Product**").

1.22 "**Commercialization**" means with respect to a product in a country, any and all activities that are undertaken after receipt of Marketing Authorization for the product in such country and that relate to the pricing or reimbursement (including obtaining and maintaining the establishment of prices for such product that can be charged or reimbursed in regulatory jurisdictions where the applicable Regulatory Authorities approve or determine the price or reimbursement of pharmaceutical products but that are not necessary for obtaining Marketing Authorization), marketing, promoting, distributing, importing for sale, offering for sale, selling, or otherwise disposing of the product in such country, including post-Marketing Authorization human clinical trials that are voluntarily undertaken and are not mandated by a Regulatory Authority as a condition of receiving or maintaining Marketing Authorization. "**Commercialize**" has correlative meaning.

1.23 "**Commercially Reasonable Efforts**" means, (a) with respect to the efforts to be expended by Daré to accomplish a specified objective, such efforts to accomplish such objective that are substantially equivalent to that which [***] would normally use to accomplish that objective under similar circumstances (b) with respect to the efforts to be expended by Organon with respect to an objective relating to a Licensed Product, such efforts to accomplish such objective that are substantially equivalent to those efforts and resources commonly used by [***] for another pharmaceutical product that is at a similar stage in its development or product life and is of similar market potential as the Licensed Product, taking into account [***], and (c) with respect to the efforts to be expended by each Party under Section 11.2.3, each Party shall comply, as promptly as possible, with any reasonable requests for information by the applicable Governmental Authorities. Commercially Reasonable Efforts shall be determined, with regard to subparts (a) and (b) in this Section 1.23, on a country-by-country basis, and it is anticipated that the level of effort will be different for different countries. [***].

1.24 "**Competing Program**" has the meaning set forth in Section 3.8.1(c).

1.25 "**Competitive Product**" means, with respect to a particular Licensed Product in a country, a product sold by Daré, its Affiliate or any Third Party (other than a Sublicensee) in such country that (a) is [***], (b) contains clindamycin, (c) is for treatment or prevention of bacterial vaginosis, (d) is the subject of a Marketing Authorization granted in such country after the Effective Date, and (e) has a [***].

1.26 "**Control**", "**Controls**" or "**Controlled by**" means, with respect to any item of or right under Daré Patents or Daré Know-How, the tangible possession of such items, or the legal authority or right (whether by ownership or license, other than pursuant to this Agreement), or the ability of a Party to grant access to, or a license or sublicense of, or right to use, such items or right, in each case as provided for herein and as applicable, without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such right to use, access or license or sublicense, and without requiring consent from a Third Party.

1.27 "**Convicted Individual**" or "**Convicted Entity**" has the meaning set forth in Section 7.2.14.

1.28 **"Covered Recipient**" has the meaning set forth in Section 3.4.4.

1.29 "**Daré**" has the meaning given such term in the preamble to this Agreement.

1.30 "**Daré Indemnitee**" has the meaning set forth in Section 8.1.

1.31 "**Daré Know-How**" means all information and materials, including discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including Daré's rights in Joint Agreement Information and Inventions), know-how, Gel Know-How, and trade secrets, patentable or otherwise, which during the term of this Agreement (a) are Controlled by Daré or any of its Affiliates, subject to Section 3.8, (b) are not generally known in the public domain and (c) are necessary or reasonably useful to Organon for Exploitation of a Clindamycin Product in the Field; and in each case of (a) through (c), excluding information and materials, including discoveries, improvements, processes, methods, protocols, formulas, data, inventions, know-how, Gel Know-How, and trade secrets, patentable or otherwise, that is or are solely necessary or reasonably useful for the Exploitation of an active or therapeutic ingredient other than clindamycin.

1.32 "**Daré Marketing Authorizations**" means (a) NDA 215650 approved by the FDA to Daré on December 7, 2021 for XACIATO, and (b) [***].

1.33 "**Daré Patents**" means all Patents that are Controlled by Daré or any of its Affiliates at any time during the term of this Agreement, subject to Section 3.8, that are necessary or reasonably useful to Organon for Exploitation of a Clindamycin Product in the Field. Daré Patents include (a) the Patents set forth on Schedule 1.33, (b) all Patents that claim priority to, or claim to a common priority as, any such Patents, in whole or in part, as of the Effective Date or at any time hereafter, and (c) all Patents licensed to Daré under the DTM Upstream License Agreement; and in the case of (a) and (b), excluding any Patents that are Controlled by Daré or any of its Affiliates [***].

1.34 "**Daré Regulatory Materials**" means all Regulatory Materials Controlled by Daré and its Affiliates related to the Daré Marketing Authorizations.

1.35 "**Data Package**" has the meaning set forth in Section 3.7.1(a).

1.36 "**Debarred Entity**" has the meaning set forth in Section 7.2.14.

1.37 "**Debarred Individual**" has the meaning set forth in Section 7.2.14.

1.38 "**Development**" means (a) pre-clinical and clinical research and drug development activities, (b) formulation, protocol design, test method development and stability testing, toxicology, pharmacokinetic, qualification and validation, manufacturing scale-up and process development and manufacturing of products for use in Clinical Trials, (c) conducting Clinical Trials, statistical analysis and report writing using data generated from Clinical Trials, preparation and submission of Regulatory Materials, seeking, obtaining and maintaining Marketing Authorizations (excluding pricing or governmental reimbursement approvals not necessary to legally market, distribute,

offer for sale or sell a product in a country), regulatory affairs with respect to the foregoing, including communicating with Regulatory Authorities, and satisfying post-marketing approval commitments, and (d) all other activities necessary or useful or otherwise requested or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining any Marketing Authorization (excluding pricing or governmental reimbursement approvals not necessary to legally market, distribute, offer for sale or sell a product in a country). "**Develop**" has correlative meaning.

1.39 "**Dispute**" has the meaning set forth in Section 12.7.1.

1.40 "**DTM Upstream License Agreement**" means the *Exclusive License Agreement* effective as of January 9, 2017, among Hammock Pharmaceuticals, Inc. ("**Hammock**" now Daré by assignment to Daré effective as of December 5, 2018), TriLogic Pharma, LLC ("**TriLogic**") and MilanaPharm LLC ("**MilanaPharm**"), as amended by that *First Amendment to License Agreement* effective as of December 5, 2018, and that *Amendment No. 2 to License Agreement* effective December 3, 2019, and that *Second Amendment to License Agreement* effective as of September 21, 2021.

1.41 "**Effective Date**" has the meaning set forth in Section 11.1.

1.42 "**Excluded Claim**" has the meaning set forth in Section 12.7.2.

1.43 "**Excluded Individual**" or "**Excluded Entity**" has the meaning set forth in Section 7.2.14.

1.44 "**Exchange Act Person**" means any Person or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act of 1934, as amended), whether or not their securities are listed for trading on a securities exchange, except that "Exchange Act Person" shall not, with respect to a potential Change in Control of a Party include (a) such Party or any subsidiary of such Party, (b) any employee benefit plan of such Party or any subsidiary of such Party or any trustee or other fiduciary holding securities under an employee benefit plan of such Party or any subsidiary of such Party, (c) an underwriter temporarily holding securities pursuant to an offering of such securities, or (d) a Person Owned, directly or indirectly, by the stockholders of such Party in substantially the same proportions as their Ownership of stock of such Party.

1.45 "**Exploit**" means to use, research, Develop, Manufacture, Commercialize or otherwise exploit. "**Exploitation**" has correlative meaning.

1.46 "**Facility**" means the facility(s) where any Licensed Product or active pharmaceutical ingredient therein is approved to be Manufactured by Daré or its Affiliate or its contract manufacturer under the Daré Marketing Authorizations as applicable, including [***].

1.47 "**FDA**" means the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.48 "**Field**" means the treatment, prevention, or supportive care of any human diseases, disorders, conditions, symptoms, or state of health or wellness in or through any intravaginal or urological applications, pathways or routes of administration.

1.49 "**First Commercial Sale**" means, with respect to any Licensed Product in a country, the first sale, by a Related Party, for monetary value to a Third Party for use or consumption of such Licensed Product in such country after Marketing Authorization of the Licensed Product in such country, excluding, however, any sale or other distribution for use in a Clinical Trial, reasonable and customary promotional use (including samples), other Development purposes, early access programs (such as pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

1.50 "**Gel Know-How**" means all information and materials, including discoveries, improvements, processes, methods, protocols, formulas, data, inventions, know-how and trade secrets, patentable or otherwise, which are in the possession and Control of Daré relating to the exploitation of thermosetting gel.

1.51 "**Gel Product**" means any compound or product, including any drug or device, (a) that is or contains a gel component that is the same or substantially similar to the gel component of any Licensed Product or (b) for which any Regulatory Authority relies, in whole or in part, on the Marketing Authorization, or on safety or efficacy data submitted in support of the Marketing Authorization, of any Licensed Product.

1.52 "**GLP**" means the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, including 21 C.F.R. part 58, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.

1.53 "**GMP**" means the applicable then-current standards for Manufacturing activities for pharmaceuticals, biologicals, or devices, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good manufacturing practice as are required by any Regulatory Authority in the Territory.

1.54 "**Governmental Authority**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasigovernmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, representative, organization, unit, body or entity and any court or other tribunal); (d) multinational or supranational organization or body; or (e) individual, entity, or body, including any court, exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.55 "**GxP**" means, collectively, all applicable good practice quality guidelines and regulations, encompassing such internationally recognized standards as GMP, Good Clinical Practice (GCP), GLP, Good Distribution Practice (GDP), and Good Review Practice (GRP), in each case (a) as such terms are defined from time to time by the FDA and other applicable Governmental Authorities pursuant to its regulations, guidelines or otherwise and (b) applicable from time to time to the Development or Manufacturing of a Licensed Product or any intermediate thereof pursuant to Applicable Law.

1.56 "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any rules or regulations promulgated thereunder.

1.57 "**IND**" means an investigational new drug application filed with the FDA or the equivalent application or filing filed with any equivalent agency or Governmental Authority outside the United States (including any supra-national entity such as in the European Union) for approval to commence Clinical Trials in such jurisdiction such as a clinical trial application or a clinical trial notification, and including all regulations at Title 21 of the Code of Federal Regulations Part 312 et seq. and equivalent foreign regulations.

1.58 "**Indemnified Party**" has the meaning set forth in Section 8.3.1.

1.59 "**Indemnifying Party**" has the meaning set forth in Section 8.3.1.

1.60 "**Information**" means any and all information and data, including all Organon Know-How, all Daré Know-How, and all other scientific, Development, regulatory, Manufacturing, and

Commercialization information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement. Daré's Information includes information and data relating to TriLogic or MilanaPharm in the DTM Upstream License Agreement and the terms of the DTM Upstream License Agreement.

1.61 "**Invention**" means, whether or not patentable, any process, method, composition of matter, article of Manufacture, discovery or finding that is conceived or reduced to practice by or on behalf of at least one representative of Daré or at least one representative of Organon in performing Development activities pursuant to this Agreement.

1.62 "**Joint Agreement Information and Inventions**" means all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, that are developed, created, made, discovered, invented, conceived, reduced to practice or otherwise result from the activities conducted by or on behalf of at least one representative of Daré together with at least one representative of Organon in performing research or Development activities pursuant to this Agreement.

1.63 "**Joint Patents**" means Patents that claim or cover Joint Agreement Information and Inventions.

1.64 "**Knowledge**" means, with respect to a Party, the actual knowledge of the officers of such Party after reasonable investigation, including through direct or indirect reports of any such officer, except in such cases indicated in this Agreement where no investigation is required.

1.65 "**Licensed Product**" means (a) the thermosetting vaginal gel formulated with clindamycin phosphate two percent (2%) that is the subject of the Daré Marketing Authorization, [***] and (b) any other product formulated with clindamycin [***], including any Combination Product, and (ii) that is Developed, Manufactured, Commercialized or otherwise Exploited using any Daré Know-How or the Development, Manufacture, Commercialization or Exploitation of which would, but for the rights granted under this Agreement, infringe a Daré Patent.

1.66 "**Legacy Data**" has the meaning set forth in Section 2.2.2.

1.67 "**Losses**" has the meaning set forth in Section 8.1.

1.68 "**Manufacture**" means all activities related to the synthesis, making, having made, production, processing, purifying, formulating, filling, finishing, packaging, labelling, shipping, and holding of a product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, supply chain, stability testing, quality assurance testing and release, investigations, risk assessments, corrective actions, and quality control. "**Manufactured**" or "**Manufacturing**" has a correlative meaning.

1.69 "**Manufacturing Process**" has the meaning set forth in Section 4.2.

1.70 "**Manufacturing Technology Transfer**" has the meaning set forth in Section 4.2.

1.71 "**Marketing Authorization**" means (a) approval or other authorization of an NDA in the United States, and in any other jurisdiction, all approvals from the relevant Regulatory Authority necessary to legally market, distribute, offer for sale or sell a product in the Field in the Territory, including all applicable pricing and governmental reimbursement approvals in regulatory jurisdiction where the applicable Regulatory Authorities must approve or determine the price or reimbursement of all of the product in a country and (b) any other required approvals or authorizations from the relevant Regulatory Authority related to marketing, promoting, distributing, importing for sale, offering for sale, selling, or otherwise disposing of the product in such country (including any required pricing and governmental reimbursement approvals).

1.72 "**MilanaPharm**" has the meaning set forth in Section 1.40.

1.73 "**NDA**" means a New Drug Application, Biologics License Application, any other Marketing Authorization, filing pursuant to Section 510(k) of the Act or a Premarket Approval (PMA) premarketing authorization, or similar application or submission for Marketing Authorization filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or medical device product in that country or in that group of countries.

1.74 "**Negotiation Period**" has the meaning set forth in Section 3.7.1(a).

1.75 "**Net Sales**" means the gross invoice price ([***]) of a Licensed Product sold by a Related Party to the first Third Party in a country after the First Commercial Sale of Licensed Product in such country, after deducting:

1.75.1 [***];

1.75.2 [***];

1.75.3 [***];

1.75.4 [***]; and

1.75.5 [***].

Deductions shall be calculated in accordance with the Related Party's standard accounting standards consistently applied by the Related Party for the country(ies) in which the sales occur. Deductions for a single sale that includes Licensed Products with products that are not Licensed Products shall be [***].

Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in any Clinical Trial, non-clinical development activities with respect to Licensed Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate or other similar use or for reasonable and customary quantities of Licensed Product samples.

The following provisions (a) through (c) regarding Combination Products apply only to any given Combination Product where [***].

(a) If (i) a Licensed Product is sold by a Related Party in a country in the form of a Combination Product, (ii) the Licensed Product is sold by such Related Party in such country in a form [***] and (iii) the Other Product is also sold in such country [***], then Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where "**A**" is [***], and "**B**" is [***].

(b) If (i) a Licensed Product is sold by a Related Party in a country in the form of a Combination Product, (ii) the Licensed Product is sold by such Related Party in such country in a form [***], and (iii) such Other Products in the Combination Product are not sold as a separate product in such country [***], then Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/C where "**A**" is [***], and "**C**" is [***].

(c) If a Licensed Product is sold by a Related Party in a country only in the form of a Combination Product, then Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction D/E where "**D**" is [***] and "**E**" is [***]. If a Licensed Product [***].

If a Related Party sells a Licensed Product to a customer who also purchases other products or services from such Related Party, the Related Party shall not manipulate the discount or price of any Licensed Product solely to increase sales or prices of such other products or services.

1.76 "**Non-compete Product**" means a product, including any drug or device, that [***].

1.77 "**Non-Identifiable Data**" has the meaning set forth in Section 2.6.1.

1.78 "**Organon**" has the meaning given such term in the preamble to this Agreement.

1.79 "**Organon Indemnitee**" has the meaning set forth in Section 8.2.

1.80 "**Organon Know-How**" means all information and materials, including discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including Organon's rights in Joint Agreement Information and Inventions), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement are owned by Organon or any of its Affiliates.

1.81 "**Organon Marketing Authorizations**" has the meaning set forth in Section 10.6.7(a).

1.82 "**Organon Patents**" means Patents that are Controlled by Organon or any of its Affiliates and that claim or cover a Licensed Product.

1.83 "**Own**," to have "**Owned**," to be the "**Owner**" of, and "**Ownership**" of securities by a Person means such Person has acquired, directly or indirectly (including through ownership of securities or any contract, arrangement, understanding, relationship or otherwise), or such Person, directly or indirectly, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

1.84 "**Party**" means Organon or Daré, individually, and "**Parties**" means Organon and Daré, collectively.

1.85 "**Patent**" means any patent, utility model, or certificate of invention, or other indicia of ownership of an invention recognized by any Governmental Authority of competent jurisdiction, any application for any of the foregoing, and any and all pre-grant and post-grant forms of any of the foregoing, including all continuations, continuations-in-part, divisionals, provisionals, and extensions, and including any counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.

1.86 "**Patent Challenge**" has the meaning given to it in Section 10.3.3.

1.87 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or agency, or any other entity not specifically listed herein.

1.88 "**Personal Data**" has the meaning set forth in Section 2.6.1.

1.89 "**Phase I Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a).

1.90 "**Phase II Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(b).

1.91 "**Phase III Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(c).

1.92 "**Privacy Laws**" means any Applicable Laws regarding the collection, use, transfer, storage, protection, deletion, processing (both by computer and manually), combination, or other use of Clinical Trial subject or patient data (sometimes referred to as protected health information) or other personal data.

1.93 "**Product Data**" has the meaning set forth in Section 2.5.

1.94 "**Product-Specific Patents**" has the meaning set forth in Section 9.1.1.

1.95 "**Product Trademark**" means any of the Trademarks XACIATO or BIVVIE, in any and all words, stylizations, or design formats, and all transliterations or local language character adaptations thereof, alone or in combination with other words or elements, whether or not registered with a Governmental Authority. Product Trademarks include the Trademark registrations and applications for Trademark registration set forth on Schedule 1.95.

1.96 "**Public Official**" means (a) any elected or appointed officer, employee or representative of any regional, federal, state, provincial, county or municipal Governmental Authority, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a Governmental Authority, including any state-owned or controlled veterinary, laboratory research or medical facility; (c) any political party officer, candidate for public office, or political party employees or individuals acting for or on behalf of a political party or candidate for public office; (d) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (e) any person acting in an official capacity for any Governmental Authority, enterprise or organization identified above. For clarity, healthcare providers employed by government-owned or -controlled hospitals, or a person serving on a healthcare committee that advises a Governmental Authority, will be considered Public Officials.

1.97 "**Regulatory Authority**" means any applicable regulatory Governmental Authority involved in granting approvals for the Manufacturing, Commercialization, reimbursement or pricing of a Licensed Product in the Territory, including, in the United States, the FDA.

1.98 "**Regulatory Exclusivity**" means, with respect to a particular Licensed Product in a country in the Territory, any exclusivity (including for clarity new biologic exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity) conferred by the Regulatory Authority in such country which confers an exclusive commercialization period during which any Related Party has the exclusive right to market and sell the Licensed Product in such country, excluding any rights conferred by or based on any Patents.

1.99 "**Regulatory Materials**" means applications, submissions, notifications (or waivers), registrations, copies of licenses, approvals and permits, or other filings or documents that are made to or with a Regulatory Authority and that are necessary or reasonably desirable in order to develop, seek, obtain or maintain a Marketing Authorization for, Exploiting a product or maintaining a Marketing Authorization for a product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, NDAs, copies of applications for Marketing Authorization and all materials that support a Marketing Authorization (but not the Marketing Authorization itself), including all correspondence and reports to or received from Regulatory Authorities (including official minutes and official contact reports relating to any communication with Regulatory Authorities), specifications of INDs, labelling requirements, specifications for animal studies and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and all data relied on in connection with the foregoing and related to a product.

1.100 "**Regulatory Milestone**" has the meaning set forth in Section 6.2.3.

1.101 "**Related Party**" means each of Organon, its Affiliates, and their respective Sublicensees, as applicable.

1.102 "**Required Filings**" has the meaning set forth in Section 11.2.

1.103 "**Released Product**" has the meaning set forth in Section 3.7.1(b).

1.104 "**Research Data Sets**" has the meaning set forth in Section 2.6.2.

1.105 "**Restricted Product**" means any product [***].

1.106 "**Reversion License**" has the meaning set forth in Section 10.6.6(a).

1.107 "**Reversion Royalty Dispute**" has the meaning set forth in Section 10.6.6(b).

1.108 "**ROFN Exercise Notice**" has the meaning set forth in Section 3.7.1.

1.109 "**ROFR Activity**" has the meaning set forth in Section 3.7.

1.110 "**ROFR Product**" means any product, including any drug or device, that (1) (a) includes [***] and (b) [***]; or (2) is [***]; or (3) includes [***].

1.111 "**Royalties**" has the meaning set forth in Section 6.3.1(a).

1.112 "**Royalty Period**" has the meaning set forth in Section 6.3.1(d).

1.113 "**Safety Reason**" has the meaning set forth in Section 10.5.

1.114 "**Sales Milestone Event**" has the meaning set forth in Section 6.2.2.

1.115 "**Sales Milestone Payment**" has the meaning set forth in Section 6.2.2.

1.116 "**Serious Adverse Event**" means an Adverse Event occurring at any dose of a drug that (a) results in death or poses a threat to life; (b) requires or prolongs hospitalization; (c) results in persistent or significant disability or incapacity; (d) is medically significant; or (e) results in a congenital anomaly or birth defect.

1.117 "**Standby Agreement**" means a *Consent, Waiver and Stand-by License Agreement* executed as of the Execution Date among Daré, Organon, Trilogic and MilanaPharm.

1.118 "**Statement of Use**" has the meaning set forth in Section 3.2.4.

1.119 "**Sublicensee**" means any Person to which Organon or any of its Affiliates grants a sublicense under any of the rights licensed/sublicensed to Organon under Section 3.1; except for contract manufacturers and distributors of the Licensed Products.

1.120 [***]

1.121 "**Supply and Distribution Agreement**" has the meaning set forth in Section 4.1.

1.122 "**Taxes**" has the meaning set forth in Section 6.7.

1.123 "**Territory**" means all of the countries in the world, and their territories and possessions.

1.124 "**Third-Party Claim**" has the meaning set forth in Section 8.1.

1.125 "**Third Party**" means an entity other than Organon and its Affiliates, and Daré and its Affiliates.

1.126 "**Third Party Licenses**" has the meaning set forth in Section 6.3.2(a).

1.127 "**Trademark**" means trademarks, service marks, assumed business names, trade names, commercial names, certification marks, collective marks, and other proprietary rights to any words, names, slogans, symbols, logos, devices or combinations thereof used to identify, distinguish and indicate the source or origin of goods or services, including without limitation the associated registrations, renewals, applications for registration, equivalents and counterparts of the foregoing.

1.128 "**Transition Plan**" has the meaning ascribed to it in Section 10.6.14.

1.129 "**TriLogic**" has the meaning set forth in Section 1.40.

1.130 "**United States**" or "**U.S.**" means the United States of America, excluding its territories and possessions.

1.131 [***]

1.132 "**USPTO**" has the meaning set forth in Section 3.2.4.

1.133 "**Valid Patent Claim**" means a claim in an issued, unexpired Patent within the Daré Patents that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any Governmental Authority of competent jurisdiction, (b) has not been revoked, held invalid, or declared unpatentable or unenforceable [***], (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding.

ARTICLE 2 REGULATORY, PHARMACOVIGILANCE, EXCLUSIVITY GOVERNANCE, AND DATA.

2.1 Assignment and Disclosure of Regulatory Materials.

2.1.1 **Assignment**. Upon request by Organon, Daré hereby assigns all right, title and interest in the Daré Marketing Authorizations and Daré Regulatory Materials to Organon. Promptly after requested by Organon, Daré will cooperate with Organon as reasonably requested to effect an orderly transition of Control of the Daré Marketing Authorizations, and will use Commercially Reasonable Efforts to assist Organon in all interactions with the applicable Regulatory Authorities and other Development activities related to the Licensed Products from Daré to Organon. Upon and after such request by Organon, Organon shall be the holder of all Marketing Authorizations for Licensed Products in the Field in the Territory and shall have the sole right to maintain such Marketing Authorizations and responsibility for interactions with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory; provided that Daré will hold the Daré Marketing Authorizations after such request until they are officially transferred to Organon by the applicable Regulatory Authority. Upon and after the Execution Date, Daré will not assign or otherwise grant to any Person other than Organon any rights, title or interest in or to any of the Daré Marketing Authorizations and Daré Regulatory Materials.

2.1.2 **Disclosure**. Within [***] after the Effective Date, Daré will provide to Organon the Daré Marketing Authorizations and original and electronic copies of the Daré Regulatory Materials. Thereafter, Daré will provide to Organon the original and an electronic copy of all updates to the Daré Marketing Authorizations and Daré Regulatory Materials within [***] after receipt or filing, as applicable.

2.2 Adverse Event Reporting; Global Safety Database; Transition to Organon; Pharmacovigilance Agreement.

2.2.1 Adverse Event Reporting. On and after the assignment and transfer of the Daré Marketing Authorizations to Organon hereunder, Organon shall be solely responsible for the collection, review, assessment, tracking, submission, and filing of information related to Adverse Events and Serious Adverse Events associated with all Licensed Products, in accordance with 21 C.F.R. §§ 312.32 and 314.80 and comparable regulations, guidance, and directives governing such events associated with Licensed Products.

2.2.2 Legacy Adverse Events. No later than [***] after the Effective Date, Daré and its Affiliates shall provide Organon an electronic copy of the CIOMS I form or XML files, or an agreeable format, for all legacy data of Adverse Events and Serious Adverse Events for all Licensed Products, and for all Gel Products Exploited by or on behalf of Daré, its Affiliates or their respective licensee/sublicensee, in the Territory ("**Legacy Data**") that is within Daré or its Affiliate's possession and Control, for inclusion in Organon's safety database for the Licensed Products. Daré and its Affiliates shall keep Legacy Data up-to-date until the completion of transfer and processing of all Legacy Data by the Parties.

2.2.3 Global Database Holder. Upon completion of processing of all Legacy Data, Organon will assume the role of global safety database holder for the Licensed Products (even if before transfer of the Daré Marketing Authorizations). Between the Execution Date and such time as Organon assumes such role, Daré shall continue to be the global safety database holder for the Licensed Products and shall continue to maintain such global safety database and, subject to Section 2.2.1, shall be responsible for the collection, review, assessment, tracking, submission, and filing of information related to Adverse Events and Serious Adverse Events associated with all Licensed Products, in accordance with 21 C.F.R. §§ 312.32 and 314.80 and comparable regulations, guidance, and directives governing such events associated with Licensed Products.

2.2.4 Transition to Organon. Subject to Section 2.2.5, as applicable, starting with the Execution Date and until completion of assignment and transfer to Organon of all Daré Marketing Authorizations and Daré Regulatory Materials with respect to Licensed Products, Daré shall, at its own cost:

(a) promptly notify Organon of any information of which Daré becomes aware concerning any newly known Adverse Events or Serious Adverse Events with respect to any Licensed Product and any such notice will: (i) be provided in English in the form of a processed CIOMS I; and (ii) be provided within [***] of such Adverse Event where such Adverse Event is a Serious Adverse Event and within [***] otherwise;

(b) be responsible for documenting and reporting any newly known Adverse Events or Serious Adverse Events in the Territory with respect to each Licensed Product in conformance with all Applicable Laws, and responding to safety issues and to all requests of Regulatory Authorities related to each Licensed Product in the Territory;

(c) be responsible for submission or filing of any other information or reports to Regulatory Authorities with respect to each Licensed Product in conformance with all Applicable Laws;

(d) promptly notify Organon of any information of which Daré becomes aware concerning any Adverse Events or Serious Adverse Events with respect to any Gel Product Exploited by or on behalf of Daré, its Affiliate or their respective licensee/sublicensee where the Adverse Event is not attributed to the active ingredient in such Gel Product, and any such notice will: (i) be provided in

English in the form of a processed CIOMS I; and (ii) be provided within [***] of such Adverse Event where such Adverse Event is a Serious Adverse Event and within [***] otherwise; and

(e) be responsible for documenting and reporting any Adverse Events and Serious Adverse Events in the Territory with respect to each Gel Product Exploited by or on behalf of Daré, its Affiliate or their respective licensee/sublicensee that is not attributed to the active ingredient in the Gel Product, in conformance with all Applicable Laws, and responding to safety issues and to all requests of Regulatory Authorities related to each such Gel Product in the Territory.

2.2.5 **Agency Correspondence**. Notwithstanding anything in this Agreement to the contrary and to the extent permitted in accordance with Applicable Law,

(a) Between the Execution Date and the Effective Date, Organon shall have the right to review and comment on, prior to submission, any correspondence between Daré and any Regulatory Authority that affects or relates to any Licensed Product or Gel Product Exploited by or on behalf of Daré, its Affiliate or their respective licensee/sublicensee. Daré shall consider in good faith Organon's comments and not refuse to implement any proposed comments to the correspondence for submission reasonably requested by Organon provided, however, that if Daré objects to implementation of any revisions required by Organon, then the [***] of each Party shall promptly meet, at mutually convenient time, to discuss and address the refusal, and to consider a revised correspondence for submission by Daré to the Regulatory Authority; *provided, however, that* Daré shall have the final decision authority with respect to the proposed correspondence so discussed.

(b) After the Effective Date and until the completion of transfer of all Daré Marketing Authorizations to Organon, Organon shall have the right to review and approve, prior to submission, such approval not to be unreasonably withheld, any correspondence between Daré and any Regulatory Authority that affects or relates to any Licensed Product, or to any or Gel Product Exploited by or on behalf of Daré, its Affiliate or their respective licensee/sublicensee. If Organon notifies Daré that Organon does not approve any correspondence promptly after receiving the proposed correspondence, the Parties' [***] shall promptly meet, at mutually convenient time, to discuss and address the objection, and to consider a revised correspondence for submission by Daré to the Regulatory Authority. As between the Parties, Daré shall have the final decision authority with respect to the proposed correspondence so discussed *provided, however, that*, upon and after [***] assumes the role of global safety database holder for the Licensed Products pursuant to Section 2.2.3, Organon shall have the final decision authority on the data, reports, and submissions related to Adverse Events and Serious Adverse Events for Licensed Products to be included in any such correspondence.

(c) Organon shall have the right to perform any audit or investigation, in each case, with respect to any Licensed Product sold anywhere in the Territory prior to the date upon which all Daré Marketing Authorizations have been transferred to Organon.

2.2.6 **Pharmacovigilance Agreement**. No later than [***] before Daré, its Affiliates or any of its or their sublicensees, [***] Daré will provide notice of such to Organon. Upon Organon's request, the Parties shall promptly, but no later than the date that any Clinical Trial relating to a Gel Product commences, negotiate and enter into a pharmacovigilance agreement for the Licensed Product and such Gel Product that sets forth the responsibilities of each Party with respect to pharmacovigilance matters relating to the

Licensed Products and the Gel Products in the Territory until the termination or expiration of this Agreement.

2.3 Development and Commercialization Exclusivity. Subject to the terms and conditions of this Agreement, including Section 3.4:

2.3.1 Development Exclusivity. As between the Parties, subject to Section 2.1 and Section 2.2 and the other terms of this Agreement, Organon shall have the exclusive right, but not the obligation, to conduct all Development involving any Licensed Product after the Effective Date. Without limiting the foregoing, upon and after the Execution Date, except as provided in Sections 2.1 and 2.2, Daré shall not, and shall cause its Affiliates not to, without the advance, written consent or request of Organon, anywhere in the world: (a) conduct any Clinical Trials involving a Licensed Product, (b) seek, obtain or maintain any Marketing Authorization involving a Licensed Product, (c) generate any new Regulatory Materials involving a Licensed Product, (d) except to the extent required by Applicable Law and with notice to Organon, communicate with any Regulatory Authority regarding any Licensed Product, Daré Marketing Authorizations or Daré Regulatory Materials, or (e) assign, license, sublicense or otherwise grant or convey any rights under any of the Product Trademarks, Daré Know-How or Daré Patents for any Licensed Product for Exploitation in the Field.

2.3.2 Commercialization Exclusivity. Upon and after the Execution Date, and subject to the terms of this Agreement, as between the Parties, Organon shall have the sole right and responsibility, but not the obligation (other than Organon's diligence obligation under Section 3.4.1), at its sole cost and expense, to Commercialize Licensed Products or Restricted Products [***] in the Territory and to conduct market access activities relating to the Licensed Products or Restricted Products that are not Non-compete Products, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating reimbursement approvals with Governmental Authorities, (c) marketing, advertising and promoting, (d) distributing and performing related services, (e) handling order processing, invoicing and collecting inventory and receivables, (f) determining pricing and terms of sale of Licensed Products or Restricted Products that are not Non-compete Products, (g) providing customer support, and (h) assign, license, sublicense or otherwise grant or convey any rights under any of the Product Trademarks, Daré Know-How or Daré Patents for any Licensed Product or Restricted Product that are not Non-compete Products for Exploitation in the Field.

2.3.3 Medical Affairs Exclusivity. Subject to the terms of this Agreement, including Section 3.8, as between the Parties, Organon shall have the exclusive right to conduct medical affairs relating to Licensed Products or Restricted Products that are not Non-compete Products.

2.3.4 [***], *provided, however, that* upon termination of this Agreement in any country within the Territory, the Parties' obligation under this Section 2.3.4 also terminates with respect to such country.

2.4 Alliance Managers.

2.4.1 Appointment. Each Party shall appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement (each an "**Alliance Manager**"). Such persons shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as the day-to-day primary point of contact for any matters arising under this Agreement (but communications between them are not substitutes for notices required to be provided in accordance with Section 12.5). The Alliance Managers shall have such other responsibilities as the Parties may mutually agree in writing. Unless designated by a Party otherwise before the Effective Date, the Alliance Manager for Organon shall be

[***] and for Daré shall be [***]. Each Party may designate different Alliance Managers by notice in writing to the other Party.

2.4.2 **Responsibilities of the Alliance Managers**. The Alliance Managers shall have the responsibility of creating and maintaining a constructive and amicable work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:

(a) [***];

(b) [***];

(c) [***];

(d) [***]; and

(e) [***].

2.5 **Transfer of Data**. Within [***] after the Effective Date and within [***] from Organon's reasonable written request at any time thereafter throughout the term of this Agreement, Daré shall transfer to Organon a copy of all preclinical and clinical data in Daré's Control that relates to (a) [***] and (b) [***] (the "**Product Data**"). During the term of this Agreement, [***]

2.6 **Personal Data**.

2.6.1 **Responsibilities**. Daré shall not provide to Organon any data that identifies or could be used to identify an individual natural person within the Daré Know-How and Product Data ("**Personal Data**"), except to the limited extent required by Applicable Law. If Daré is required to provide to Organon any Personal Data, then each Party will abide by all Applicable Laws with respect to its disclosure and use of such Personal Data.

2.6.2 **Organon Rights**. Organon and its Affiliates may use Non-Identifiable Data received from Daré to create data sets ("**Research Data Sets**") for Organon's and its Affiliates' internal research purposes, and may use and disclose the Research Data Sets for medical research, including research unrelated to the Licensed Products, and any filings of medical research study results with regulatory Governmental Authorities worldwide. For purposes of this section, "**Non-Identifiable Data**" means Personal Data that has been de-identified such that it meets the Health Insurance Portability and Accountability Act safe harbor for de-identification of protected health information set forth at 45 C.F.R. § 164.514. Organon will: (a) [***]; (b) use appropriate safeguards to prevent [***]; (c) not use the Research Data Sets to identify any study subject or contact any study subject; and (d) use and disclose Research Data Sets in compliance with Applicable Laws.

ARTICLE 3 LICENSES AND OWNERSHIP OF IP.

3.1 **License Grant**.

3.1.1 **Patents.** Subject to the terms of this Agreement, Daré hereby grants to Organon an exclusive license (even as to Daré) in the Territory under all rights in the Daré Patents and all of Daré's rights in Joint Patents, with the right to grant and authorize sublicenses, to Exploit Licensed Products in the Field.

3.1.2 **Know-How.** Subject to the terms of this Agreement, Daré hereby grants to Organon an exclusive license (even as to Daré) in the Territory under all rights in the Daré Know-How and all of Daré's rights in Joint Agreement Information and Inventions, with the right to grant and authorize sublicenses, to Exploit Licensed Products in the Field.

3.1.3 **Sublicenses**. The foregoing licenses include the right to further sublicense, provided that such further sublicenses (a) are in writing, (b) shall refer to and be subject and subordinate to the applicable terms of this Agreement, and are consistent with the terms and requirements of this Agreement, and (c) disclaim any representations or warranties of Daré and licensors under the DTM Upstream License Agreement. Organon will promptly notify Daré upon execution of each sublicense, in each case within [***] and shall furnish Daré with a true copy of each sublicense and of any amendment thereto, each of which may be redacted by Organon for competitively sensitive or financial information or information unrelated to the obligations of Organon to Daré hereunder. Organon shall remain liable to Daré for the performance of all of Organon's obligations under this Agreement, and will be liable for any act or failure to act by any Sublicensee that if committed (or not committed) by such Sublicensee would be a breach of any of Organon's obligations under this Agreement as though the same were a breach by Organon itself.

3.1.4 **Marking**. Organon will use Commercially Reasonable Efforts to mark or virtually mark (including by listing applicable Patents on a website for Licensed Products) and require all Sublicensees to mark or virtually mark all Licensed Products with appropriate patent numbers. This Section 3.1.4 shall expire, on a Daré Patent-by-Daré Patent basis, upon expiration or cancellation of such Daré Patent.

3.2 **Trademarks**.

3.2.1 **License Grant**.

(a) Daré hereby grants to Organon an exclusive license (even as to Daré) in the Territory to the Product Trademarks, with the right to grant and authorize sublicenses (pursuant to Section 3.1.3), for purposes of using the Product Trademarks in connection with the Development and Commercialization of any Licensed Product.

(b) Daré hereby grants to Organon a non-exclusive license in the Territory to use Daré's corporate name and corporate logo ("**Corporate Trademarks**") to the extent that Organon is required to use Corporate Trademarks under Applicable Laws in connection with the Exploitation of the Licensed Products. Organon will [***], and Organon will not [***].

3.2.2 **Use of Trademarks**.

(a) Organon will use the Corporate Trademarks as permitted under Section 3.2.1, and Daré shall have the right to reasonably verify that such use is, in accordance with all applicable Marketing Authorizations and Applicable Law. In the case of Product Trademarks, until the Assignment Date as defined in accordance with Section 3.2.4, (a) Organon will use the Product Trademarks, and Daré shall have the right to reasonably verify that such use is, in accordance with all applicable Marketing Authorizations and Applicable Law; and (b) Daré will exclusively own and retain all rights to such Product Trademark together with all goodwill associated therewith throughout the Territory.

(b) Daré will not use any Product Trademark, or any other Trademark selected by Organon for use in connection with the sale of any Licensed Product, to Develop or Commercialize any product or service other than Licensed Products.

3.2.3 **Domain Names**. Within [***] after the Effective Date, Daré will transfer to Organon the Control of any and all (a) Internet domain names registered to Daré that include any Product Trademark in the domain and (b) social media account identifiers that include any Product Trademark in its handle. Other than such Internet domain names and social

media account handles, Daré will not register or maintain any Internet domain name that includes any Product Trademark in the domain or social media account that includes any Product Trademark in its handle.

3.2.4 **Assignment of Trademarks**. As of the date of Notice of Acceptance of Statement of Use issued from the United States Patent and Trademark Office ("**USPTO**") for a Product Trademark having an application for registration filed with the USPTO, Daré agrees to assign to Organon, effective as of the filing date of the accepted Statement of Use under 37 C.F.R. § 2.88 ("**Statement of Use**;" each such Statement of Use filing date, an "**Assignment Date**") all right, title and interest in and to each such Product Trademark throughout the Territory, including all applications and registrations therefor, and the goodwill of the business symbolized by each such Product Trademark or associated with the use of each such Product Trademark.

3.2.5 **Selection and Registrations of Trademarks**.

(a) Subject to Section 3.2.5(b), as between the Parties, Organon shall have the sole right and responsibility to select, file, prosecute, register and maintain any Product Trademark or any other Trademark for use in connection with the Exploitation of any Licensed Product or Restricted Product using counsel of Organon's choice.

(b) Until the Assignment Date for a Product Trademark, Daré will prosecute, register, maintain and enforce, as applicable, all Product Trademarks; *provided that*, within [***] after the Effective Date, Daré will instruct its legal representatives to take instruction from Organon with respect to the filing, prosecution, registration (including the defense against any and all oppositions) and maintenance of all Product Trademarks still owned in the name of Daré. Organon shall keep Daré advised of the status of such registrations and applications for registration of the Product Trademarks that are still owned in Daré's name and, upon Daré's request, shall provide advance copies of any papers related to such filing, prosecution (including the defense against any and all oppositions), registration and maintenance of such Product Trademarks.

3.2.6 **Enforcement**. Daré shall give notice to Organon promptly upon becoming aware of any infringement of any Product Trademark or any other use of any Product Trademark, whether or not such use is as a Trademark. As between the Parties, following the Assignment Date for a Product Trademark, Organon shall have the sole right to enforce such Product Trademark. Organon shall have the sole right to enforce any other Trademark selected by Organon for use in connection with the sale of any Licensed Product, anywhere in the world.

3.2.7 **Cooperation**.

(a) In case at any time after the Effective Date, as applicable, any further action is necessary or desirable to carry out the purposes of this Section 3.2, Daré will take such further action as Organon may reasonably request as will be deemed necessary to (i) transfer, convey and assign to Organon all of the rights, titles, interests, remedies, powers and privileges in the Product Trademarks, and (ii) otherwise effect the transactions contemplated by this Section 3.2, including (1) obtaining all necessary actions or non-actions, consents, and the making of all necessary registrations and filings and the taking of all steps as may be necessary to obtain an approval or waiver from, or to avoid an action or proceeding by, any Governmental Authority or Third Party and (2) executing and delivering any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purpose of, this Section 3.2. In case at any time after the Assignment Date with respect to a Product Trademark any further action

is necessary or desirable to carry out the purposes of this Section 3.2, Organon will fully record or otherwise further document the assignment of such Product Trademark in the name of Organon.

(b) After the Effective Date, Daré will, without further compensation to Daré, but at the expense of Organon, and upon request of Organon, cooperate in all lawful acts as may be necessary to (i) file, prosecute, register (including with respect to filing any statement of use), maintain, abandon, or renew in any country any Trademark registration with respect to any Product Trademark, or (ii) enforce Organon's rights in or defend against challenges to the validity or enforceability of any Product Trademark in the name under which it is registered in the respective jurisdiction. Without limiting the generality of the foregoing, after the first use in commerce of any Product Trademark, Daré will take all actions necessary to file, or facilitate the filing of, a Statement of Use with the USPTO in connection with such Product Trademark.

3.3 Information Transfer.

3.3.1 Daré Know-How. Within [***] after the Effective Date, Daré will deliver to Organon a complete and accurate copy of all of the items of Daré Know-How that were made available to Organon through the electronic data room during the due diligence leading to the execution of this Agreement, and disclose and deliver to Organon any additional Daré Know-How, including all of the Gel Know-How, requested by Organon within [***] after the Effective Date. Thereafter, Daré shall use Commercially Reasonable Efforts on an ongoing basis during the term of this Agreement to disclose to Organon in English and in writing or in an electronic format all Daré Know-How not previously disclosed promptly after such Daré Know-How first arises.

3.3.2 Assistance. In connection the disclosure of Daré Know-How hereunder, Daré shall, in a timely manner, use Commercially Reasonable Efforts to assist Organon in the use and understanding of such Daré Know-How, [***]. Without limiting the generality of the foregoing, if [***] Organon shall reimburse Daré for its documented and verifiable out-of-pocket costs and expenses charged by a Third Party for providing the assistance described in this Section 3.3.2, provided such costs are pre-approved by Organon. [***].

3.4 Development and Commercialization.

3.4.1 Diligence. Organon shall use Commercially Reasonable Efforts to (a) upon and after completion of the assignment and transfer of the Daré Marketing Authorizations to Organon, maintain a Marketing Authorization for [***] Licensed Product in the United States, (b) effect a First Commercial Sale of a Licensed Product within [***], (c) after the First Commercial Sale of a Licensed Product within the United States, Commercialize [***] Licensed Product on an ongoing basis within the United States, (d) evaluate in good faith whether to seek and obtain Marketing Authorization for [***] Licensed Product [***], and (e) Commercialize [***] Licensed Product on an ongoing basis in each of [***]. In the event that Organon is unable to effect a First Commercial Sale of a Licensed Product within the time frame of foregoing subpart (b), the Parties' [***] shall promptly meet, at mutually convenient time, to discuss and address the circumstances leading to the delay, and agree to a reasonable extension of time for effecting the First Commercial Sale by mutual agreement.

3.4.2 Subcontracting. Organon will have the right to engage any Third Party subcontractor to perform any or all of its obligations hereunder, including contract research organizations, contract manufacturing organizations and similar service providers. The applicable provisions of each agreement between Organon and a Third Party subcontractor shall be materially consistent with the corresponding provisions of this Agreement and shall include confidentiality and non-use provisions at least as stringent as those set forth in

Article 5. Organon's engagement of any subcontractor pursuant to this Section 3.4.2 shall not relieve Organon of its obligations under this Agreement and Organon shall be fully responsible for any acts or omissions of its subcontractors, including compliance by such subcontractors with Anti-Corruption Laws, Privacy Laws and GxP standards, as applicable, and for compliance with all provisions of this Agreement.

3.4.3 **Reports**. With respect to each Licensed Product, Organon shall provide to Daré [***] a summary report, which shall summarize the results of the development work and regulatory activities performed during the preceding [***] and summarize the activities planned for the [***]. Such reports shall be prepared by Organon and provided to Daré between [***] and shall include status or results of any Clinical Trials conducted in the preceding year, when applicable.

3.4.4 **Sunshine Act**. The Parties acknowledge and agree that any direct or indirect payment or transfer of value, as defined in the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h) and its implementing regulations (42 C.F.R. § 403.900 et seq.), including any compensation, reimbursement for expenses, meals, travel, and medical journal reprints to any teaching hospital in the United States or any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife who is not a bona fide employee of a Party that is licensed to practice in the United States (each, a "**Covered Recipient**") is subject to transparency reporting requirements, including disclosure on the federal Open Payments website. The Parties shall comply with such law in their performance of this Agreement.

3.5 **Excused Performance**. In addition to the provisions of Article 7, the obligations of Organon with respect to any Licensed Product under Section 3.4 are expressly conditioned upon (a) the absence of any Serious Adverse Event demonstrated, through pharmacovigilance surveillance, where such Serious Adverse Event was not known at the time of Marketing Authorization, and (b) the ability to have the Licensed Product Manufactured and delivered to Organon in sufficient quantities; *provided that* in each case Organon notifies Daré promptly upon becoming aware of any such condition and uses Commercially Reasonable Efforts to overcome such condition as promptly as possible. The obligations of Organon under Section 3.4 with respect to any Licensed Product shall be delayed or suspended so long as any such condition or event exists. If the obligations of Organon with respect to any Licensed Product under Section 3.4 are suspended or delayed pursuant to this Section 3.5 for [***], then the Parties' [***] shall promptly meet, at a mutually convenient time, to discuss and address the circumstances leading to the delay.

3.6 **New Information and Inventions**.

3.6.1 **Ownership**. The ownership of the entire right, title and interest in any new inventions or discoveries conceived or works created by the Parties during the term of this Agreement shall be allocated consistent with inventorship.

3.6.2 **Standards**. For the purposes of determining ownership under this Section 3.6, (a) inventorship shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred and whether or not any subject matter is patentable or patented) and (b) authorship shall be determined in accordance with United States copyright laws (regardless of where the applicable activities occurred).

3.6.3 **Disclosure.**

(a) Each Party shall promptly disclose in writing to the other Party the development, creation, making, conception or reduction to practice of any Joint Agreement Information and Inventions.

(b) Upon Daré becoming aware of the existence of any Other Technology Patent (as defined in the DTM Upstream License Agreement), or upon Control by Daré

after the Effective Date of any information, materials, discoveries, improvements, processes, methods, protocols, formulas, data, inventions, know-how, or trade secrets not generally known in the public domain and not already disclosed to Organon, in each case that could reasonably be deemed necessary or reasonably useful for Exploitation of Licensed Products in the Field, Daré will promptly disclose in writing to Organon such Other Technology Patent or such other information, materials, discoveries, improvements, processes, methods, protocols, formulas, data, inventions, know-how, or trade secrets, as applicable.

3.6.4 **Exploitation of Joint Agreement Information and Inventions and Joint Patents**. Subject to the licenses granted under this Agreement and the other terms and conditions of this Agreement, each Party shall have the non-exclusive right to exploit its interest in Joint Agreement Information and Inventions and Joint Patents, and to grant licenses under its interest in Joint Agreement Information and Inventions and Joint Patents, as it deems appropriate, without the consent of, and without accounting to, the other Party; provided, however, that for clarity, the foregoing joint ownership rights shall not be construed as granting, conveying or creating any license or other rights to the other Party's intellectual property. Each Party will grant and hereby does grant to the other Party all further permissions, consents, and waivers with respect to, and all licenses under, the Joint Agreement Information and Inventions and Joint Patents, throughout the world, necessary to provide the other Party with full rights of use and Exploitation of the Joint Agreement Information and Inventions and Joint Patents.

3.7 **Right of First Refusal**. Daré hereby grants to Organon the exclusive right of first refusal in the event that either (a) Daré or any of its Affiliates [***], or (b) Daré or its Affiliate [***] (any of the foregoing, a "**ROFR Activity**"), as follows.

3.7.1 **First Negotiation**. Upon determining to engage in a ROFR Activity, Daré will notify Organon in writing of such determination and identify [***] and [***]. Organon will have an exclusive right, exercisable [***] after receipt of any such written notice from Daré [***], to notify Daré in writing as to whether Organon desires to negotiate exclusively for the rights to such ROFR Product in such jurisdictions (each, a "**ROFN Exercise Notice**").

(a) If Organon provides a ROFN Exercise Notice to Daré [***], then (i) upon Organon's request, Daré will (A) within [***] after Organon's request, provide Organon with [***]; and (ii) Organon will have the exclusive right for [***] to request, by notice, to enter into an agreement or an amendment to this Agreement, as applicable, with respect to the exploitation by Organon of such ROFR Product in such jurisdiction(s). If Organon notifies Daré within [***] that Organon wishes to enter into such agreement or amendment, then the Parties will [***] for [***] to execute such agreement or amendment ("**Negotiation Period**").

(b) If, with respect to a ROFR Product in the applicable jurisdiction(s), [***], such ROFR Product shall [***] and, subject to Section 3.7.2, Daré shall [***].

3.7.2 **Most Favorable Terms**. Daré may not, during [***], transfer, license, sublicense, assign, grant, or otherwise dispose of any rights to a Third Party with respect to the ROFR Product in the applicable jurisdiction(s) that were the subject of the ROFR Activity that triggered the Negotiation Period (other than the grant of express or implied licenses/sublicenses to an agent or a consultant, contract manufacturing organization, contract research organization, distributors, or other similar type contractor acting for or on behalf of Daré or its Affiliates) upon terms that on the whole are more favorable to such Third Party than the most favorable terms on the whole offered by Daré in writing to Organon during the Negotiation Period.

3.8 Effects of Change of Control.

3.8.1 Acquisition by Daré. If Daré acquires a Third Party that becomes an Affiliate through merger, acquisition, consolidation or similar transaction or series of related transactions, and any such transaction(s) do/does not result in a Change of Control of Daré, then:

(a) all know-how, patent rights, technology, information, materials, intellectual property rights or other items that are owned or in-licensed or controlled by the new Affiliate when such Person becomes an Affiliate of Daré constitute Daré Know-How or Daré Patents (to the extent otherwise falling within either of such definitions).

(b) if the new Affiliate is engaged in Commercialization of any ROFR Product, or is engaged in Development of [***], when such Person becomes an Affiliate of Daré, then, [***], each product that is the subject of such Development or Commercialization [***] for purposes of Section 3.7 [***].

(c) if the new Affiliate is engaged in Development, Manufacture, Commercialization or other Exploitation of [***] or Commercialization of any [***] when such Person becomes an Affiliate of Daré, then Daré and its new Affiliate will have [***] to wind down or divest to a Third Party all rights, title, and interests in and to such [***], and during such [***] period, such new Affiliate's conduct of such [***].

3.8.2 Acquisition of Daré. If a Third Party becomes an Affiliate of Daré through merger, acquisition, consolidation, or other similar transaction or series of related transactions, and any such transaction(s) do/does result in a Change of Control of Daré, then:

(a) notwithstanding the definitions of Daré Know-How or Daré Patents, none of the know-how, patent rights, technology, information, materials, intellectual property rights or other items that are owned or in-licensed or controlled by such new Affiliate when such Person becomes an Affiliate of Daré constitute Daré Know-How or Daré Patents.

(b) if (i) such new Affiliate is engaged in any Development, Manufacturing, Commercialization or other Exploitation of a product that would constitute [***] when such Person becomes an Affiliate of Daré and (ii) Daré is not engaged in any of such activities for such product at or before such time, then, [***].

(c) if such new Affiliate is engaged in [***] when such Person becomes an Affiliate of Daré, then (i) [***], subject to Section 6.3.1(c), and (ii) [***].

3.8.3 Acquisition by Organon. If Organon acquires a Third Party that becomes an Affiliate through merger, acquisition, consolidation or similar transaction or series of related transactions, and any such transaction(s) do/does not result in a Change of Control of Organon, and if the new Affiliate is engaged in Commercialization of a Non-compete Product, then Organon will notify Daré thereof within [***], and can elect to either (a) wind down or divest to a Third Party all rights, title, and interest in and to such Commercialization activities within [***], and during such [***] period, such new Affiliate's conduct of such Commercialization activities will not constitute a breach of Organon's obligations under Section 2.3.4; or (b) treat such Non-compete Product as a Licensed Product for purposes of the calculation of Net Sales and Section 6.3 of this Agreement (in which case for the avoidance of doubt such Net Sales shall be calculated from the time of the closing of the transaction). Organon will notify Daré of Organon's election prior to expiration of the foregoing [***] period. Organon's failure to notify Daré of a Change of Control transaction within the foregoing [***] period [***] shall not be deemed a material breach of this Agreement.

3.8.4 **Acquisition of Organon**. If (a) a Third Party becomes an Affiliate of Organon through merger, acquisition, consolidation, or other similar transactions or series of related transactions, and any such transaction(s) do/does result in a Change of Control of Organon and (b) the new Affiliate is engaged in Commercialization of a Non-compete Product when such Person becomes an Affiliate of Organon, then the new Affiliate may continue with Commercialization of the Non-compete Product without such Affiliate's conduct of such activities constituting a breach of Organon's obligations under Section 2.3.4.

3.9 **No Implied Rights**. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other right, title or interest, by implication, estoppel or otherwise, in any Information or Inventions or other information disclosed to it under this Agreement or under any Patents or other intellectual property rights Controlled by the other Party or any of its Affiliates, and each Party reserves all such other right, title and interest in and to such Information, Inventions, other information, Patents or other intellectual property rights.

ARTICLE 4 MANUFACTURING.

4.1 **Interim Supply**. Prior to the completion of the Manufacturing Technology Transfer pursuant to Section 4.2, Daré will, either by itself or through a contract manufacturer(s), Manufacture and supply the Licensed Products to Organon and its Affiliates and Sublicensees until [***]. During such time, Daré appoints Organon as Daré's exclusive distributor of the Licensed Products, and Organon or its Affiliate(s) will purchase all of Organon and its Affiliates' requirements of such Licensed Products from Daré for use by Organon and its Affiliates and Sublicensees pursuant to a supply and distribution agreement (the "**Supply and Distribution Agreement**"). The Parties will use Commercially Reasonable Efforts to enter into the Supply and Distribution Agreement promptly after the Effective Date and prior to [***]. The terms of the Supply and Distribution Agreement will be consistent with the terms for it specified in this Agreement, including those in this Section 4.1 and the terms set forth on Schedule 4.1 (as applicable to Manufacture and supply of the Licensed Product), and other terms customary for supply arrangements between Persons in a similar relationship as the Parties**.**

4.1.1 **Form of Product and Price**. Neither Daré nor its contract manufacture(s) may initiate any changes with respect to the Manufacture of any Licensed Product that could reasonably be expected to affect the quality, performance, or requirements of the FDA in the Daré Marketing Authorization, in each case, of such Licensed Product as Manufactured by Daré or its contract manufacturer(s), without the prior written consent of Organon or as otherwise set forth in the Quality Agreement (as referenced in Schedule 4.1). Daré will Manufacture and supply the Licensed Products [***] in the Daré Marketing Authorization and Change Being Effected Day Zero (CBE0), in each case, pursuant to this Section 4.1 at a transfer price equal to Daré's Manufacturing costs plus [***] percent ([***]%). All Manufacturing activities by or on behalf of Daré and its contract manufacturer(s) will at all times be in compliance with GMP and in compliance with Applicable Laws, and Facilities in which Licensed Product are Manufactured will at all times be in compliance with Applicable Laws. Organon hereby grants back to Daré a nonexclusive, royalty-free license to Manufacture the Licensed Products solely for supply to Organon under the terms of the Supply and Distribution Agreement.

4.1.2 **Inventory Transfer**. At Organon's request, Daré shall, after the Effective Date, transfer, assign and deliver to Organon all Licensed Products in Daré's (or its Affiliates' or its contract manufacturers') inventory. Daré hereby represents to Organon that Schedule 4.1.2 sets forth a complete and accurate list of the total quantities of such inventory as of the Execution Date (and indicating whether such inventory is GMP or non-GMP). On the Effective Date, Daré shall deliver to Organon an update of Schedule 4.1.2 reflecting the information therein as of the Effective Date. Daré shall make available to Organon documentation demonstrating that all such inventory to be provided to Organon was Manufactured in accordance with GMPs. Daré shall and hereby does, represent to

Organon that, to Daré's Knowledge, such inventory was Manufactured in accordance with GMPs, Applicable Laws and the specifications therefor. In furtherance of and without limiting the foregoing, Daré shall provide to Organon, [***], supporting documentation within its Control with respect to such inventory and the Certificates of Analysis with respect to such inventory. Organon may, within [***] of receipt of the Certificates of Analysis, notify Daré if Organon elects to take possession of less than the inventory remaining because Organon or its Affiliates reasonably believes that any such inventory was not (and at all times up until delivery of such inventory to Organon hereunder did not remain) Manufactured or stored in accordance with all Applicable Laws (including, as applicable, GMPs), and the specifications therefor, or that such inventory were adulterated or misbranded or could not be introduced into interstate commerce. If Organon elects to take possession of less than the remaining inventory, Organon shall so notify Daré and Daré shall transfer, assign and deliver to Organon only such inventory as requested by Organon. Except as otherwise set forth in this Section 4.1.2, Organon shall accept all such inventory transferred, assigned and delivered to Organon on an as-is basis. Deliveries shall be made at Organon's expense Ex Works (Incoterms 2020).

4.1.3 **Governmental Authority Action**. Daré shall promptly notify Organon of any information Daré receives regarding any threatened or pending action by any Governmental Authority, including any Governmental Authority non-approval or regulatory action, that may impact the Manufacture of Licensed Product by Daré or its Affiliate or its contract manufacturer. Upon receipt of such information, Daré shall consult with Organon in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

4.1.4 **Governmental Authority Inspection**. Daré shall promptly notify Organon of any proposed visit or inspection of a Facility directly related to, and/or which could potentially impact, Manufacture of Licensed Product by any Governmental Authority, and agrees to use Commercially Reasonable Efforts to permit one or more qualified representatives of Organon to be present if requested by Organon. Daré shall notify Organon of any unannounced visits or inspections of a Facility as soon as reasonably practical upon becoming aware of the same. If Organon is not present during such a visit or inspection, Daré shall, [***]. Daré shall, [***]. Organon will [***].

4.1.5 **Audit and Inspection**. [***]. Organon shall have access to Daré's contract manufacturer's Facilities [***] to observe the Licensed Product and its components manufacturing services and to audit its compliance with cGMP and Applicable Laws in the manufacture of Licensed Products and components of Licensed Products. Organon's access and audits shall in no way give Organon the right to any of the contract manufacturer's confidential or proprietary information. Furthermore, such audits shall normally be limited in frequency to [***] and limited to a maximum number of [***] of Organon, each of which are deemed representatives of Organon, but [***].

4.2 **Manufacturing Technology Transfer**. Without limiting Daré's obligations under Section 3.3, [***], Daré will, [***], transfer to Organon or its designated contract manufacturer, all Daré Know-How relating to the Manufacture of Licensed Product (the "**Manufacturing Process**") necessary or useful to allow Organon or its designated contract manufacturer to implement the Manufacturing Process at facilities designated by Organon (such transfer and implementation, as more fully described in this Section 4.2, the "**Manufacturing Technology Transfer**"). Daré shall provide [***], all assistance reasonably requested by Organon to enable Organon (or its Affiliate(s) or designated contract manufacturer(s), as applicable) to implement the Manufacturing Process at the facilities designated by Organon. If requested by Organon, such assistance shall include [***]. Without limitation to the foregoing, in connection with the Manufacturing Technology Transfer:

(a) [***];

(b) [***];

(c) [***]; and

(d) [***].

ARTICLE 5 CONFIDENTIALITY AND PUBLICITY.

5.1 **Nondisclosure Obligation**. All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

(b) is in the public domain by use or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;

(c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;

(d) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;

(e) is deemed necessary by the receiving Party to be disclosed to its Affiliates, licensees and sublicensees, agent(s), consultant(s), or other Third Parties for any and all purposes such Party and its Affiliates deem necessary or advisable in the ordinary course of business in accordance with this Agreement on the condition that such Third Parties have a need to know such Information so that the receiving Party may exercise its rights and perform its obligations hereunder and agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, however, that the term of confidentiality for such Third Parties shall be no less than [***], and the receiving Party shall be liable and responsible for such Persons' compliance with the terms of this Article 5; or

(f) is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, insurers, independent accountants or financial advisors for the sole purpose of enabling such attorneys, insurers, independent accountants or financial advisors to provide advice and services to the receiving Party, on the condition that such attorneys, insurers, independent accountants and financial advisors agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, however, that the term of confidentiality for such attorneys, insurers, independent accountants and financial advisors shall be no less than [***], and the receiving Party shall be liable and responsible for such Persons' compliance with the terms of this Article.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

5.2 **Mandatory and Permitted Disclosures**. Section 5.1 shall not apply to Information that the receiving Party is required by Applicable Law, or similar requirements to disclose, provided that the receiving Party provides the disclosing Party with prompt notice thereof such that the disclosing Party may seek a protective order or other appropriate remedy with respect to such Information, including, without limitation, confidential treatment to the extent available under any Applicable Law, and the receiving Party shall provide the disclosing Party with reasonable cooperation in order to obtain such a protective order or other remedy, including confidential treatment, and discloses only that portion of the confidential Information that it is legally compelled to disclose.

Additionally, notwithstanding Section 5.1, Organon may disclose the information of Daré as is deemed necessary by Organon to be disclosed to a Governmental Authority to exercise Organon's or its Affiliate's rights or perform its obligations with respect to Patents under Article 9 or to seek, obtain or maintain Marketing Authorizations for Licensed Products.

Information that is disclosed pursuant to this Section 5.2 shall remain otherwise subject to the confidentiality and non-use provisions of Section 5.1.

5.3 **Daré Know-How**. Daré will use Commercially Reasonable Efforts to keep all Daré Know-How confidential as if the Daré Know-How were first disclosed by Organon to Daré. For the avoidance of doubt, Daré may disclose Daré Know-How as permitted in this Article 5, and otherwise to Third Parties as if Daré were a receiving Party of the Daré Know-How.

5.4 **Disclosure to DTM Upstream Licensors**. Organon acknowledges and agrees that Daré may disclose Information of Organon, and the terms of this Agreement, to MilanaPharm or TriLogic as necessary to comply with the DTM Upstream License Agreement.

5.5 **Publicity/Use of Names.** No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, Trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s), and Organon may not use the name, trade name or logo of any Daré licensor, in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law.

5.6 **Announcements**. Promptly following the Execution Date, the Parties shall issue an initial press release having the content specified in Schedule 5.6. Following such initial press release, Daré agrees [***]. Organon will have the right without obtaining Daré's consent to make public announcements concerning the Development, Commercialization or other Exploitation of Licensed Products under this Agreement. The Parties agree that after a press release (including the initial press release or any subsequent press release, such as on or after the Effective Date) or other public announcement has been issued in accordance with this Section 5.6, each Party may make subsequent public disclosures of the information contained in such press release or other public announcement without the further approval of the other Party, so long as the information in such press release or other public announcement remains true and correct. Notwithstanding anything to the contrary set forth in this Agreement, each Party may issue a press release or public announcement as required, in the reasonable judgment of such Party, by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

5.7 **Required Disclosures**. If either Party is required to disclose the terms of this Agreement in submissions to the U.S. Securities and Exchange Commission or other equivalent Governmental Authority, it will [***]. The requirements of this Section 5.7 shall not apply if the substance of the description of or reference to this Agreement contained in the proposed filing or disclosure has been included in any previous filing or disclosure made by either Party or otherwise approved by the other Party and such information remains accurate as of such time.

5.8 **Publications**. Subject to Organon's obligations under Section 2.6, and notwithstanding anything to the contrary in this Article 5, Organon shall have the right to disclose, publish or present all Information, including preclinical and clinical data, relating to the Licensed Products. Daré shall not disclose, publish or present any preclinical and clinical data relating to the Licensed Products to any Third Party without first submitting such disclosure, publication or presentation to Organon for review. Organon shall have [***] to review such disclosure, publication or presentation to determine whether the Information proposed to be disclosed contains any of Organon's confidential Information or confidential Daré Know-How and issue notice of such to Daré. If notification is not received by Daré within such [***] period, Daré will be free to proceed with such disclosure, publication or presentation. If due to a valid business reason or a reasonable belief by Organon that the disclosure, publication or presentation contains (a) confidential Information of Organon or confidential Daré Know-How, or (b) subject matter for which a patentable invention should be sought, then prior to the expiration of the [***], Organon will so notify Daré, and the Daré will then (x) at the request of Organon delete any confidential Information of Organon or confidential Daré Know-How, or (y) delay public disclosure, publication or presentation of such Information for [***] to permit the preparation and filing of a patent application on the subject matter to be disclosed, published, or presented or other protective action to be taken. The determination of authorship for any paper will be in accordance with accepted scientific practice.

ARTICLE 6 PAYMENTS; ROYALTIES AND REPORTS.

6.1 **License Fee and Development Milestone.** In partial consideration for the licenses and other rights granted to Organon herein under the Daré Patents and Daré Know-How, upon the terms and conditions contained herein, Organon shall pay to Daré $10,000,000 ("**Upfront Payment**") within [***] after the Effective Date, and such amount is non-refundable and non-creditable.

6.2 **Milestone Payments.** Organon shall pay to Daré the following milestone payments corresponding to the following milestone events during the term of this Agreement:

6.2.1 **First Commercial Sale Milestone.** Organon shall pay to Daré $2,500,000 for the First Commercial Sale in the United States of a Licensed Product.

6.2.2 **Sales Milestones.** Organon shall pay to Daré each of the following amounts in Table 6.2.2 below (each, a "**Sales Milestone Payment**") [***] as a result of the [***] of the corresponding event (each, a "**Sales Milestone Event**").

Table 6.2.2 Sales Milestone Events and Payments

Milestone Event No.	One Time Milestone Event Description	One Time Milestone Payment
1	[***]	$[***]
2	[***]	$[***]
3	[***]	$[***]
4	[***]	$[***]
5	[***]	$[***]
[***]		$[***]

6.2.3 **Regulatory Milestones**. Organon shall pay to Daré $[***] upon [***] (any such event described by foregoing clauses (a) and (b), a "**Regulatory Milestone**"), *provided, however, that* [***].

6.2.4 **Notifications of Sales Milestones and Regulatory Milestones**.

(a) Organon shall notify Daré in writing within [***] after the end of a Calendar Quarter in which the Sales Milestone Event first occurs. The Sales Milestone Payment for each such event shall be due and payable [***].

(b) Organon shall notify Daré in writing within [***] following the achievement of each Regulatory Milestone, and shall make the appropriate milestone payment within [***].

(c) Each milestone payment shall be payable only upon the initial achievement of the applicable corresponding milestone and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone.

6.3 Royalties.

6.3.1 **Royalties Payable By Organon.** Subject to the terms and conditions of this Agreement, Organon shall pay Daré royalties, calculated on all Licensed Products and on a tiered basis, as set forth in this Section 6.3.

(a) **Patent Royalties**. Subject to the provisions of Section 6.3.1(b) through Section 6.3.1(e), Organon shall pay Daré royalties ("**Royalties**") in an amount equal to the following percentage of Net Sales during a Royalty Period:

(i) [***] of the aggregate of such Net Sales in each Calendar Year up to and including [***] of such Net Sales;

(ii) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales up to and including [***] of such Net Sales; and

(iii) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales up to and including [***] of such Net Sales; and

(iv) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales up to and including [***] of such Net Sales; and

(v) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales.

(b) **Know-How Royalty**. On a Licensed Product-by-Licensed Product and country-by-country basis, if during any Calendar Quarter within the applicable Royalty Period for such Licensed Product in such country, no Valid Patent Claim exists that would be infringed, in the absence of the license granted under Section 3.1, by the sale of such Licensed Product in such country, [***], then, commencing the first Calendar Quarter thereafter and for all Calendar Quarters thereafter, Organon shall pay royalties at rates equal to [***] of the applicable royalty rate determined according to Section 6.3.1(a). Such royalties shall be calculated after first calculating royalties under Section 6.3.1(a).

(c) **Competition**. On a Licensed Product-by-Licensed Product and country-by-country basis during the Royalty Period, if (i) [***] in such country and Regulatory Exclusivity for such Licensed Product has expired (or otherwise does not exist) and (ii) if [***] during [***] (the "**Competition Analysis Period**") is [***] during such Competition Analysis Period and (iii) aggregate Net Sales of such Licensed Product in such Competition Analysis Period is [***] during the [***], then commencing [***] after the Competition Analysis Period and each Calendar Quarter thereafter, the royalty rates set forth in Section 6.3.1(a) for such Licensed Product in such country during such next Calendar Quarter shall be reduced in such country by [***]. For purposes of the foregoing, [***].

(d) **Royalty Period and Application to Tiers and Sales Milestone Events**. Royalties due pursuant to Section 6.3.1(a) through Section 6.3.1(c) and Sales Milestone Events shall be calculated based on Net Sales of all Licensed Products during a Royalty Period throughout the Territory, provided that the determination of whether the royalty rate shall be reduced under Section 6.3.1(b) or Section 6.3.1(c) shall be determined on a country-by-country and Licensed Product-by-Licensed Product basis. Royalties on each Licensed Product at the applicable rates set forth above shall continue on a country-by-country and Licensed Product-by-Licensed Product basis from the First Commercial Sale of such Licensed Product in such country until the expiration of the later of: (i) the date that no Valid Patent Claim would be infringed, in the absence of the license granted hereunder, by the sale of such Licensed Product in such country occurred; (ii) for a period of ten (10) years after the end of the month in which the First Commercial Sale of such Licensed Product in such country occurred; and (iii) expiration of Regulatory Exclusivity (the "**Royalty Period**").

(e) **Net Sales and Royalty Conditions**. All Net Sales calculations and associated royalties are subject to the following conditions:

(i) that only one royalty shall be due with respect to the same unit of Licensed Product; and

(ii) that no Net Sales calculations will be performed for the purposes of Sales Milestone Events and no royalties shall be due upon the sale or other transfer among Related Parties where the Licensed Product will not be used or consumed by such Related Party(ies), but in such cases the Net Sales calculation and associated royalty shall be due and calculated upon Organon's or its Related Party's Net Sales to the first independent Third Party that is not a Related Party.

6.3.2 Third Party Licenses.

(a) In the event that Organon obtains (after the Effective Date) a license under, or other rights to, Patents or know-how or other intellectual property from any Third Party(ies) that Organon reasonably determines add value, are strategically important or are useful, or are reasonably necessary or required, in order to Exploit Licensed Product(s) ("**Third Party Licenses**"), [***] of the amounts actually paid (including milestone payments, royalties or other license fees) under such Third Party Licenses by Organon or its Related Parties as consideration for the acquisition or exploitation of such Third Party License in connection with the Exploiting of Licensed Product(s) for a Calendar Quarter shall be creditable against the royalty payments due Daré by Organon with respect to the sale of such Licensed Product in such Calendar Quarter. Amounts payable by Organon to TriLogic or MilanaPharm pursuant to the Standby Agreement shall not be subject to offset pursuant to this Section 6.3.2.

(b) Notwithstanding the foregoing provisions of this Section 6.3.2, in no event shall the royalties owed by Organon to Daré for any Calendar Quarter be reduced by more than [***] pursuant to this Section 6.3.2 (*provided, however, that* if Organon is not able to fully recover the amounts paid by Organon or its Related Parties under any Third Party License as a result of the foregoing restriction, then Organon shall be entitled to carry forward such right of offset to one or more future Calendar Quarter(s) with respect to such excess amount until the amounts have been fully offset). At the reasonable request of Organon, Daré shall provide reasonable assistance to Organon (or its Related Parties) in obtaining any such Third Party Licenses or otherwise taking reasonable action with respect Patents or know-how or other intellectual property of any Third Party(ies) that may be necessary or useful in order to Exploit Licensed Product(s) or any components of Licensed Product(s).

6.3.3 **Floor**. Notwithstanding anything to the contrary, in no event will the royalty rate that otherwise would be applicable under Section 6.3.1(a) to a Licensed Product in a country in a Calendar Quarter be reduced by more than [***].

6.4 **Reports; Payment of Royalty.** During the term of this Agreement, on a country-by-country and Licensed Product-by-Licensed Product basis, following the month in which the First Commercial Sale of a Licensed Product occurs in a country, Organon shall furnish to Daré a [***] written report for such and each subsequent [***] showing (a) [***]. Reports shall be due [***]. Royalties shall be due and payable on the date such royalty report is due. Each Related Party shall keep complete and accurate books and records pertaining to Net Sales in sufficient detail to calculate all amounts payable hereunder with respect thereto and to verify compliance with its obligations under this Agreement. Such books and records shall be retained until [***] after the end of the Calendar Year to which such books and records pertain.

6.5 **Audits**.

6.5.1 **Generally**. Upon the written request of Daré and not more than [***], Organon shall permit an independent certified public accounting firm of nationally recognized standing selected by Daré and reasonably acceptable to Organon to have access during normal business hours to such of the records of Organon and its Affiliates as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than [***] prior to the date of such request. Any records or accounting information received from Organon shall be Organon's confidential Information, and the accounting firm will sign a confidentiality agreement in form and substance that is reasonably satisfactory to Organon prior to beginning any audit. The accounting firm shall disclose to Daré only whether the royalty reports are correct or incorrect and the amount of any discrepancy. Such disclosure by the accounting firm will be deemed confidential Information hereunder. No other Information of Organon or its Affiliate shall be provided to Daré by the accounting firm without Organon's prior written consent.

6.5.2 **Discrepancy**. If such accounting firm correctly identifies an underpayment made during such period, Organon shall pay Daré the amount of the underpayment within [***] after the date Daré delivers to Organon such accounting firm's written report that correctly identifies such discrepancy, or as otherwise agreed upon by the Parties. If such accounting firm identifies an overpayment made during an audited period, such overpayment will be creditable towards Organon's future payments hereunder. The fees charged by such accounting firm shall be paid by Daré; provided, however, that if such audit uncovers an underpayment of royalties by Organon that exceeds [***], then the fees of such accounting firm shall be paid by Organon.

6.5.3 **Sublicensee Compliance**. Organon shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to make reports to

Organon, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Daré's independent accountant to the same extent required of Organon under this Agreement.

6.5.4 **Confidentiality**. Daré shall treat all financial information subject to review under this Section 6.5 or under any sublicense agreement as the confidential Information of Organon in accordance with Article 5.

6.6 **Payment; Currency Exchange**. All payments to be made by Organon to Daré under this Agreement shall be made in United States dollars and may be paid by check made to the order of Daré or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by Daré from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due Daré shall be made at the rate of exchange utilized by Organon in its worldwide accounting system from time to time, consistently applied.

6.7 **Income Tax Withholding**. Daré shall be liable for all income and other taxes (including interest) ("**Taxes**") imposed upon its income. If Applicable Laws, rules or regulations require the withholding of Taxes, Organon shall make such withholding payments and shall subtract the amount thereof from the payments due hereunder. Organon shall submit to Daré appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. Organon shall provide Daré reasonable assistance in order to allow Daré to obtain the benefit of any present or future treaty against double taxation which may apply to the payments due hereunder. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

6.8 **Late Payment**. Organon may not offset, deduct or withhold any amounts payable hereunder except pursuant to Section 6.7, Section 10.3.2 and as permitted under the Standby Agreement. Any payments or portions thereof due hereunder that are not paid when due (including any underpayment of Royalties) will accrue interest under this Agreement at a rate of [***] per annum or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.

ARTICLE 7 REPRESENTATIONS AND WARRANTIES; COVENANTS.

7.1 **Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party that as of the Execution Date, and unless also limited to just the Execution Date, then again as of the Effective Date:

7.1.1 such Party is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate right, power and authority to enter into this Agreement and to perform its obligations hereunder;

7.1.2 the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement has been duly executed by such Party. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and

7.1.3 the execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not (a) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any Governmental

Authority to which such Party is subject, (b) violate any provision of the corporate charter, by-laws or other organizational documents of such Party, or (c) constitute a material violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party is otherwise bound.

7.2 **Daré Representations and Warranties**. Daré represents and warrants to Organon that as of the Execution Date, and unless also limited to just the Execution Date, then again as of the Effective Date:

7.2.1 (a) Schedule 1.33 sets forth a true, correct and complete list of Daré Patents, and Schedule 1.95 sets forth a true, correct and complete list of all Product Trademarks, existing as of the Execution Date; and (b) the Daré Patents, Product Trademarks, and Daré Know-How constitute all intellectual property owned by or licensed to Daré (or any of its Affiliates) that are necessary or useful for Exploitation of the Licensed Products in the Field;

7.2.2 all Patents within the Daré Patents and Trademarks within the Product Trademarks are subsisting and in full force and effect, and, to Daré's Knowledge, the issued Daré Patents are not invalid or unenforceable, in whole or in part;

7.2.3 it has the full right, power and authority and sufficient resources to perform the activities hereunder and to grant the licenses granted hereunder (including under Article 3);

7.2.4 it has not (a) assigned, transferred, conveyed, licensed or otherwise encumbered its right, title and interest in or to Daré Patents, Daré Know-How or Product Trademarks or (b) otherwise granted any rights, covenant not to sue, or immunity from suit to any Person; in each case of (a) and (b) that would conflict with the rights granted to Organon hereunder;

7.2.5 Daré's right, title and interest in the Daré Patents, Daré Know-How and Product Trademarks is free and clear of any liens, charges, restrictions and encumbrances (other than restrictions and encumbrances of the DTM Upstream License Agreement and other than Joint Agreement Information and Inventions and Joint Patents), and no Third Party (including any Governmental Authority or subdivision thereof), has or shall have any claim of ownership whatsoever with respect to the Daré Patents and Daré Know-How (other than ownership by the licensors under the DTM Upstream License Agreement) and Product Trademarks;

7.2.6 to Daré's Knowledge, but without any further inquiry or investigation, the Manufacture, use, sale, offer for sale, or importation of the Licensed Product in the form that is the subject of the Daré Marketing Authorization as of the Execution Date, does not and will not infringe, misappropriate, or otherwise violate any intellectual property rights that exist as of the Execution Date (and again as of the Effective Date) of any Person;

7.2.7 neither it nor any of its Affiliates has received any written notification from a Third Party that the Exploitation of any Licensed Product or component thereof, or the use of any Product Trademark, infringes or misappropriates or will infringe or misappropriate the Patents or other intellectual property rights of any Person, and Daré has no Knowledge that any Person has any basis for any such claim;

7.2.8 there are no claims, judgments or settlements against or owed by Daré (or any of its Affiliates) or, to Daré's Knowledge, threatened claims or litigation, in each case relating to the Daré Patents, Product Trademarks, or Daré Know-How;

7.2.9 Daré has disclosed to Organon all reasonably relevant information Controlled by Daré regarding (a) the Licensed Products, including the Facilities at which the Licensed Products may be Manufactured by Daré or its contract manufacturer(s), and (b) the Daré

Patents and Daré Know-How licensed under this Agreement, including (i) any licenses and binding agreements related to the Daré Patents, Product Trademarks, and Daré Know-How to which Daré is a party, and (ii) and safety or efficacy information related to the Licensed Products or any component thereof of which Daré has Knowledge, and none of the foregoing information disclosed by Daré to Organon is not Controlled by Daré;

7.2.10 Daré has disclosed to Organon the existence of any patent opinions or results of freedom to operate or patentability searches of which Daré is aware that are related to the Daré Patents and Daré Know-How licensed under this Agreement;

7.2.11 Daré has disclosed to Organon all material information and data and all material correspondences to/from any Regulatory Authority related to Licensed Products and Facilities at which Licensed Products may be Manufactured by Daré or its contract manufacturer(s) Controlled by Daré, regardless of whether such data and information would have a positive, negative or neutral impact on the potential commercial, scientific or strategic value or attractiveness of the Licensed Products;

7.2.12 Daré has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;

7.2.13 except for the Regulatory Materials and Marketing Authorizations assigned by Daré to Organon pursuant to Section 2.1, neither Daré nor any of its Affiliates has obtained, or filed for, any Marketing Authorizations, pricing or reimbursement approvals from any Governmental Authority (whether or not required to legally market, distribute, offer for sale or sell a product), INDs or NDAs for any Licensed Products, ROFR Products, Restricted Products, Competitive Products or Non-Compete Products;

7.2.14 Daré and its Affiliates have not ever been, nor are they currently, the subject of a proceeding that could lead to Daré or its Affiliates becoming a Debarred Entity, Excluded Entity or Convicted Entity and it and its Affiliates will not, to its Knowledge, use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual, where for purposes of this provision, the following definitions shall apply: (a) a "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application, (b) a "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity, (c) an "**Excluded Individual**" or "**Excluded Entity**" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in U.S. federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA), and (d) a "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a-7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible;

7.2.15 all research and development (including non-clinical studies and Clinical Trials) performed by Daré, and, to Daré's Knowledge, on behalf of Daré, related to the Licensed Products prior to the Effective Date has been conducted in accordance with all Applicable Laws;

7.2.16 all information, data and statements provided by Daré, and, to Daré's Knowledge, on behalf of Daré, to each Regulatory Authority in connection with the Licensed Product were, and remain, true and accurate and complete in all material respects and there have been no material omissions from such information, data or statements, and Daré has not disclosed, failed to disclose, or cause to be disclosed, any information, data or statements that would reasonably be expected to cause the information, data and statements that has been disclosed to any Regulatory Authority to be misleading in any material respect; and

7.2.17 all information and data provided by or on behalf of Daré to Organon on or before the Effective Date in contemplation of this Agreement was and is, to Daré's Knowledge, true and accurate and complete in all material respects, and Daré has not knowingly disclosed, failed to disclose, or cause to be disclosed, any information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect.

7.3 **Daré Upstream License Agreements Representations and Warranties**. Daré represents and warrants to Organon that as of the Execution Date, and unless also limited to just the Execution Date, then again as of the Effective Date:

7.3.1 except for the DTM Upstream License Agreement, there are no agreements (including any licenses), written or oral, granting any licenses or other rights to (or from) Daré (or any of its Affiliates) relating to the Licensed Products or the Daré Know-How or Daré Patents;

7.3.2 with respect to the DTM Upstream License Agreement, (a) it is in full force and effect; (b) neither Daré nor any of its Affiliates is in breach thereof; (c) neither Daré nor any of its Affiliates has received any notice of breach or notice of threatened breach thereof; and (d) neither Daré nor any of its Affiliates has received any notice from the counterparty to such DTM Upstream License Agreement of intent to reduce the scope of the field thereof or render any of the licenses thereunder non-exclusive;

7.3.3 Daré has provided to Organon as of the Effective date a true, correct and complete (but with commercial information redacted) copy of each of the DTM Upstream License Agreement, including any and all amendments, restatements, side letters, and other modifications thereto, as such DTM Upstream License Agreement is in effect as of the Effective Date;

7.3.4 that the payments required to be paid by Organon pursuant to this Agreement are sufficient to satisfy Daré's obligation under Section 2.1.3(ii) of the DTM Upstream License Agreement; and

7.3.5 to Daré's Knowledge, Hammock has retained no right, title or interest in or to any intellectual property rights or Information under the DTM Upstream License Agreement relating to any (a) product that would constitute at any time Licensed Product, ROFR Product or Competitive Product, (b) Daré Patents, Joint Patents, or Daré Know-How, (c) Daré Marketing Authorizations or Daré Regulatory Materials, (d) any intellectual property rights licensed under the DTM Upstream License Agreement, and (e) any Technology and Data (as defined in the Assignment Agreement between Daré and Hammock, effective December 5, 2018); and to Daré's Knowledge, there is no Hammock Data (as defined in the DTM Upstream License Agreement).

7.4 **Covenants**. Each of the following provisions are effective as of the Execution Date and remain in effect during the term of this Agreement unless otherwise noted.

7.4.1 **Compliance with Laws**. Each Party hereby covenants to the other Party that, in the performance of its obligations under this Agreement, such covenanting Party shall comply, and shall cause its and its Affiliates' and sublicensees' and its and their

employees and subcontractors to comply, with all Applicable Laws, including (a) all Anti-Corruption Laws, (b) all Privacy Laws, (c) all current governmental regulations concerning GxP, as applicable, and (d) national and international pharmaceutical industry codes of practice.

7.4.2 **No Kickback**. Each Party hereby covenants to the other Party that such covenanting Party and its Affiliates' employees and contractors shall not, in connection with the performance of its 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 other person for purpose of obtaining or retaining business for or with, or directing business to, any person, and shall not directly or indirectly promise, offer, or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or any other person in connection with the performance of its obligations under this Agreement.

7.4.3 **Notice of Violation**. Each Party hereby covenants to the other Party that such covenanting Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of any Anti-Corruption Laws, any Privacy Laws, or any other Applicable Laws in connection with its performance of this Agreement or its or its Affiliates' or sublicensees' Exploitation of any Licensed Product.

7.4.4 **Organon Policies**. Organon hereby covenants to Daré that (a) Organon and its Affiliates shall maintain and enforce a compliance and ethics program containing adequate systems, policies and procedures for the detection, investigation, documentation, and remediation of any allegations, reports or findings related to a potential violation of Applicable Laws, including Anti-Corruption Laws, with respect to the Licensed Products and payments and activities under this Agreement, (b) such policies and procedures will set out rules governing interactions with healthcare providers, Public Officials, the engagement of Third Parties, and where appropriate, conducting due diligence, and the investigation, documentation and remediation of any allegations, reports or findings related to a potential violation of Applicable Laws, and (c) Organon shall comply and shall cause its and its Affiliates' employees and contractors to comply with all such policies and procedures in connection with the performance of its obligations under this Agreement.

7.4.5 **Daré Policies**. Daré hereby covenants to Organon that Daré shall maintain a "Code of Business Conduct and Ethics" approved by its Board of Directors of a scope substantially equivalent to, and in any event no less stringent than, Daré's Code of Business Conduct and Ethics that is in effect as of the Execution Date and, in the performance of its obligations under this Agreement, Daré shall comply and shall require its and its Affiliates' employees and contractors to comply with such Code of Business Conduct and Ethics.

7.4.6 **No Encumbrances**. Daré will not enter into any assignment, transfer, license, conveyance or encumbrance of, or otherwise assign, transfer, license, convey or encumber, its right, title, or interest in or to the Daré Patents, Joint Patents or Daré Know-How or grant to any Person any such right, title, or interest, in each case that conflicts with the rights and licenses granted, or to be granted, to Organon under this Agreement.

7.4.7 **Upstream Licenses**. Daré further covenants and agrees that Daré (a) shall satisfy all of its obligations under (including making all payments), and take all reasonable and lawful steps to maintain in full force and effect, the DTM Upstream License Agreement in all manner necessary to prevent any adverse effect on the rights of Organon under this Agreement; (b) will not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 12.2), amend, restate, amend and restate, terminate in whole or in part, or otherwise modify the DTM Upstream License Agreement without the prior written consent of Organon, in all manner necessary to

prevent an adverse effect on the rights of Organon under this Agreement; and (c) will provide Organon with prompt notice of any claim of a breach under the DTM Upstream License Agreement or notice of termination of the DTM Upstream License Agreement, made by either Daré or the counterparty to such DTM Upstream License Agreements (or any party acting on behalf of such counterparty). For the purposes of clarity, Daré (and not Organon) shall be responsible for all of the financial and other obligations of Daré (or any of its Affiliates) under the DTM Upstream License Agreement, including any and all financial obligations thereunder with respect to Net Sales of the Related Parties or other payments due or made by Organon under this Agreement.

7.4.8 **Patent Maintenance**. Between the Execution Date and the Effective Date Daré will (a) diligently prepare, file, prosecute and maintain the Daré Patents licensed to Organon under this Agreement, (b) keep Organon informed of all material actions taken or intended to be taken in connection with the preparation, filing, prosecution and maintenance of such Daré Patents and (c) consult with Organon and reasonably consider Organon's reasonable requests with respect to the preparation, filing, prosecution and maintenance of such Daré Patents.

7.4.9 **Trademark Maintenance**. Between the Execution Date and the Assignment Date, Daré will (a) diligently prepare, file, prosecute, register and maintain the Product Trademarks, (b) keep Organon informed of all material actions taken or intended to be taken in connection with the preparation, filing, prosecution, registration, and maintenance of Product Trademark, and (c) consult with Organon and reasonably consider Organon's reasonable requests with respect to the preparation, filing, prosecution, registration, and maintenance of Product Trademarks.

7.4.10 **[***]**

7.5 **Disclaimers**. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS, PATENT APPLICATIONS, KNOW-HOW, PRODUCTS AND MATERIALS, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS OR THAT PATENTS WILL ISSUE UPON APPLICATIONS, OR THE TITLE, QUALITY, COMPLETENESS, ACCURACY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 8 INDEMNIFICATION.

8.1 **Indemnification by Organon**. Organon shall indemnify Daré and its Affiliates and their respective licensors (including TriLogic and MilanaPharm), directors, officers, employees, and agents (each, a "**Daré Indemnitee**") and defend each of them (subject to Section 9.5) and hold each of them harmless from and against any and all liabilities, damages, expenses, fines, penalties, costs and losses, including reasonable legal expenses and attorneys' fees (and excluding any multiplier of attorneys' fees or similar penalty payable to Daré Indemnitees based upon a contingency fee arrangement with their attorneys) (collectively, "**Losses**"), to which any Daré Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party (each, a "**Third-Party Claim**") to the extent such Losses arise out of or relate to:

(a) the Exploitation of any Licensed Product by or on behalf of Organon or its Affiliates or Sublicensees;

(b) the negligence or willful misconduct of any Organon Indemnitee;

(c) use or disclosure of Research Data Sets and Non-Identifiable Data; or

(d) the breach by Organon of any warranty, representation, covenant, or agreement made by Organon in this Agreement,

except, in each case (a) thru (d), to the extent such Losses arise out of any activities set forth in Section 8.2 for which Daré is obligated to indemnify any Organon Indemnitee under Section 8.2.

8.2 Indemnification by Daré. Daré shall indemnify Organon and its Affiliates and their respective directors, officers, employees, and agents (each, an "**Organon Indemnitee**") and defend each of them (subject to Section 9.5) and hold each of them harmless from and against any and all Losses (and excluding any multiplier of attorneys' fees or similar penalty payable to Organon Indemnitees based upon a contingency fee arrangement with their attorneys) to which any Organon Indemnitee may become subject as a result of any Third-Party Claim to the extent such Losses arise out of or relate to:

(a) the Exploitation of any Licensed Product by or on behalf of, or for, Daré, its Affiliates, or its or their sublicensees anywhere in the world;

(b) the negligence or willful misconduct of any Daré Indemnitee; or

(c) the breach by Daré of any warranty, representation, covenant, or agreement made by Daré in this Agreement,

except, in each case (a) thru (c), to the extent such Losses arise out of any activities set forth in Section 8.1 for which Organon is obligated to indemnify any Daré Indemnitee under Section 8.1.

8.3 Indemnification Procedure.

8.3.1 Defense. The Party claiming indemnity under this Article 8 (the "**Indemnified Party**") from a Third-Party Claim shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Third-Party Claim; provided, however, that failure to promptly notify the Indemnifying Party shall not relieve it of its obligations under this Article 8, unless such failure materially prejudices the Indemnifying Party's ability to defend the Third-Party Claim.

8.3.2 Cooperation. Subject to Section 9.5, the Indemnified Party: (a) shall allow the Indemnifying Party to control the defense and settlement of the Third-Party Claim; (b) shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's request and expense, in connection with the defense of the Third-Party Claim for which indemnity is being sought; and (c) may participate in and monitor such defense with counsel of its own choice at its own expense.

8.3.3 Settlement. The Indemnifying Party shall not settle any Third-Party Claim without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed, provided, however, that no consent is necessary if the settlement involves only the payment of money (which will be paid by the Indemnifying Party), no admission of wrong-doing or fault by the Indemnified Party, and no restriction on the future actions or activities of the Indemnified Party. Subject to Section 9.5, so long as the Indemnifying Party is actively defending the Third-Party Claim in good faith, the Indemnified Party shall not settle such Third-Party Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed.

8.3.4 Control by Indemnified Party. If the Indemnifying Party does not assume and conduct the defense of the Third-Party Claim as provided in Section 8.3.1 or if the Indemnified

Party has the right to control such defense under Section 9.5, (a) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Third-Party Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify and hold harmless the Indemnified Party as provided in this Article 8.

8.4 **Insurance**. Each Party, at its own expense, shall maintain insurance (or self-insurance), including commercial general liability insurance, product liability insurance and other appropriate insurance, in amounts [***]. Each Party shall maintain such insurance for the period commencing on the Effective Date until [***] after expiration or termination of this Agreement. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations under this Agreement.

8.5 **Limitation of Liability**. EXCEPT FOR (A) DAMAGES THAT ARE CAUSED BY (I) A PARTY'S WILLFUL MISCONDUCT OR FRAUD, (II) A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 5, (III) DARÉ'S FAILURE TO ASSIGN THE DARÉ MARKETING AUTHORIZATIONS AND DARÉ REGULATORY MATERIALS TO ORGANON AND FAILURE TO COOPERATE WITH ORGANON FOR PURPOSES OF EFFECTING AN ORDERLY TRANSITION OF CONTROL OF DARÉ MARKETING AUTHORIZATIONS IN BREACH OF SECTION 2.1, OR (IV) DARÉ'S BREACH OF SECTION 2.3, THE FIRST SENTENCE OF SECTION 2.5, THE FIRST SENTENCE OF SECTION 3.3.1, OR THE FIRST SENTENCE OF SECTION 4.2 (AND IN EACH CASE WHERE SUCH BREACH IS NOT CURED WITHIN [***] OF RECEIPT OF NOTICE FROM ORGANON DESCRIBING THE BREACH), AND (B) AMOUNTS PAYABLE PURSUANT TO INDEMNIFICATION UNDER SECTION 8.1 OR SECTION 8.2, NEITHER PARTY SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR [***] SUFFERED BY THE OTHER PARTY (OR ITS AFFILIATES OR (SUB)LICENSEES), [***]. DAMAGES CAUSED BY A PARTY'S INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS ARE NOT LIMITED BY THIS SECTION 8.5.

ARTICLE 9 PATENT PROVISIONS.

9.1 Filing, Prosecution and Maintenance of Patents.

9.1.1 **Product-Specific Patents**. As between the Parties, after the Effective Date, [***] shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain (a) the Daré Patents that are set forth on Schedule 9.1.1 and all Patents that claim priority thereto, whether existing as of the Effective Date or first existing thereafter, (b) Daré Patents first Controlled by Daré or its Affiliates after the Effective Date that [***], (c) Daré Patents first Controlled by Daré or its Affiliates after the Effective Date that [***], and (d) Daré Patents first Controlled by Daré or its Affiliates after the Effective Date that [***]; and in each of foregoing clauses (b) through (e), within the Field and to the extent not otherwise the subject of foregoing clause (a) (each of the Daré Patents described in foregoing clauses (a)–(d), collectively, the "**Product-Specific Patents**"), [***]. Product-Specific Patents include the Patents set forth on Schedule 9.1.1 and all Patents that claim priority to or have common priority with any such Patents, in whole or in part, as of the Effective Date or at any time hereafter. [***] shall give [***] at least [***] to review the text of any new patent application filed within the Product-Specific Patents [***], and shall supply [***] with a copy of the application and other material filings as filed, together with notice of its filing date and serial number. [***] shall keep [***] regularly advised of the status of the Product-Specific Patents, including upon [***] request. [***] shall promptly give notice to [***] of the grant, lapse, or invalidation of any Product-

Specific Patents. [***] shall give notice to [***] of any desire to cease prosecution or maintenance, or abandonment, of Product-Specific Patents [***] in the Territory, and shall permit [***] to continue prosecution or maintenance of such Product-Specific Patents [***]. If [***] elects to continue prosecution or maintenance of such Product-Specific Patents, [***] shall execute documents in a timely manner as may be reasonably necessary to allow [***] to continue such prosecution or maintenance.

9.1.2 **Joint Patents.** [***] shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain patents and patent applications claiming Joint Agreement Information and Inventions. [***] shall give [***] at least [***] to review the text of any patent application and a reasonable opportunity to review any other material filing before submission, [***], and shall supply [***] with a copy of the application and other material filings as filed, together with notice of its filing date and serial number. [***] shall keep [***] regularly advised of the status of the Joint Patents[***]. [***] shall promptly give notice to [***] of the grant, lapse, or invalidation of any Joint Patents. [***] shall give notice to Daré of any desire to cease prosecution or maintenance, or abandonment, of Joint Patents [***] in the Territory, and shall permit [***] to continue prosecution or maintenance of such Joint Patents [***]. If [***] elects to continue prosecution or maintenance of such Joint Patents, [***] shall execute documents in a timely manner as may be reasonably necessary to allow [***] to continue such prosecution or maintenance.

9.1.3 **Patent Term Extension.** The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Product-Specific Patents and Joint Patents. [***]

9.1.4 **Other Cooperation.** The Parties agree to cooperate fully and provide any information and assistance that either may reasonably request for the filing, prosecution and maintenance of Daré Patents and Joint Patents. The Parties will, and will cause their Affiliates to, cooperate and implement reasonable patent filing and prosecution strategies (including filing divisionals, continuations, or otherwise) so that, to the extent reasonably feasible, Daré Patents and Joint Patents are pursued in mutually exclusive patent applications of the other Party's Patents. Such prosecution strategies will include the obligation of each Party to refrain from the use of statements that disparage the other Party's Patents. The Parties further agree to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. § 102(c) for U.S. patents and patent applications.

9.1.5 **Filing, Prosecution and Maintenance** [***]**.** With respect to all filing, prosecution and maintenance activities under this Section 9.1, the filing or prosecuting Party shall be responsible [***].

9.1.6 **Inventor Remuneration.** Daré shall comply with all applicable country-specific inventor remuneration laws and regulations associated with Daré Owned Patents when inventor remuneration obligations are triggered by an employee of Daré or its Affiliates, or a Third Party acting on behalf of Daré or its Affiliates.

9.1.7 [***] **Patents.** As between the Parties, [***] shall have the exclusive right to file Patent applications [***] and to prosecute, maintain, seek patent term extensions and abandon such Patents, and to conduct or defend against any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review or similar contested administrative proceeding involving a Third Party relating to any of the foregoing[***].

9.1.8 [***] **Patents.** As between the Parties, with respect to [***] shall have the exclusive right to file Patent applications and to prosecute, maintain, seek patent term extensions and abandon Patents, and to conduct or defend against any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review or similar contested administrative proceeding relating to any of the foregoing[***].

9.1.9 **Decision Not to Prosecute.** In the event that [***] decides not to prepare, file, prosecute, or maintain any Product-Specific Patent in any country or jurisdiction, [***] shall provide reasonable prior written notice to [***] of such intention (which notice shall, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such Product-Specific Patent in such country or jurisdiction). [***] shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Product-Specific Patent at its expense in such country or jurisdiction. If [***] exercises this option, it shall promptly notify [***] thereof, and provide written instructions to [***] to transfer control of such Product-Specific Patent to counsel instructed by [***].

9.2 Interference, Derivation, Opposition, Reexamination, Reissue, Supplemental Examination, *Inter Partes* Review and Post-Grant Review Proceedings.

9.2.1 **Third Party Initiated Proceedings.** Each Party shall, within [***] after learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review or similar contested administrative proceeding involving a Third Party relating to Daré Patents or Joint Patents. [***] shall have the first right, but not the obligation, to control such proceedings with respect to Product-Specific Patents, and Joint Patents, [***].

9.2.2 **Party Initiated Proceedings.** [***] shall have the first right, but not the obligation, to initiate a reexamination, supplemental examination, reissue or similar administrative proceeding relating to Product-Specific Patents or Joint Patents [***].

9.2.3 **Cooperation.** In connection with any administrative proceeding under Sections 9.2.1 or 9.2.2, Organon and Daré shall cooperate fully and provide each other with any information or assistance that either may reasonably request. [***]

9.2.4 [***].

9.3 Enforcement and Defense.

9.3.1 **Notice; [***] First Right.** The Parties shall give notice to each other promptly upon becoming aware of either (a) any infringement of Daré Patents or Joint Patents, or (b) any misappropriation or misuse of Daré Know-How. With respect to Product-Specific Patents and Joint Patents, [***]. After the Effective Date, [***] shall have the first right, but not the obligation, to initiate and prosecute such legal action within the Field at its own expense and in the name of [***] and to control the defense of any declaratory judgment action relating to Product-Specific Patents or Joint Patents[***].

9.3.2 [***] **Backup Right.** [***] shall promptly inform [***] if [***] elects not to exercise its first right under Section 9.3.1 to initiate and prosecute legal action, and [***] shall thereafter have the right, at its own cost and expense, to either initiate and prosecute such action or to control the defense of such declaratory judgment action [***]. [***] shall have the right to be represented by counsel of its own choice [***].

9.3.3 **Joinder.** For any action to enforce any infringement of Product-Specific Patents or Joint Patents against a Third Party, in the event that a Party is unable, as a matter of law, to

initiate or prosecute such action solely in its own name, the other Party will [***] join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the Party to initiate litigation to prosecute and maintain such action under this Section 9.3. In connection with any action or potential action, Organon and Daré will cooperate fully and will provide each other with any information or assistance that either may reasonably request[***]. Each Party shall keep the other informed of developments in any action or proceeding. In connection with any defense pursuant to this Section 9.3.3, the controlling Party shall (a) [***], (b) keep the other Party reasonably informed of material steps taken in the course of such defense, and (c) provide copies of all documents filed in connection with such defense.

9.3.4 **Recoveries.** Any recovery obtained by either or both Organon and Daré in connection with or as a result of any action contemplated by this Section 9.3, whether by settlement or otherwise, shall be shared in order as follows:

(a) [***];

(b) [***];

(c) the amount of any recovery remaining shall then [***].

9.3.5 **Generic Certification.** Each Party shall inform the other Party of any notice of certification regarding any Daré Patents or Joint Patents it has received pursuant to either 21 U.S.C. §§ 355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV), or its successor provisions or any similar provisions in a country in the Territory other than the United States, and shall provide a copy of such notice of certification within [***] after its receipt. [***] has the first right, but not the obligation, to initiate and prosecute any legal action as a result of such notice of certification with respect to Product-Specific Patents or Joint Patents; provided, however, that [***] shall inform [***] of such decision to initiate such action within [***]after its receipt of the notice of certification, after which time, [***]. Regardless of which Party has the right to initiate and prosecute such action, both Parties shall, as soon as practicable after receiving notice of such notice of certification, convene and consult with each other regarding the appropriate course of conduct for such action. The non-initiating Party shall [***]. Daré's and Organon's rights and obligations with respect to the prosecution of any legal action as a result of such notice of certification and any recovery obtained as a result of such legal action shall be as defined in Sections 9.3.3 and 9.3.4.

9.3.6 **Organon Patents.** As between the Parties, Organon shall have the exclusive right to enforce any of the rights in the Organon Patents and Organon Know-How, in each case in its sole discretion.

9.3.7 **Other Daré Patents.** As between the Parties, Daré shall have the exclusive right to enforce any of the rights in the Daré Patents that are not Product-Specific Patents or Joint Patents, in each case in its sole discretion.

9.4 **Orange Book Listings**. After the Effective Date, [***] will [***] determine which, if any, of the Product-Specific Patents should be listed in any governmental registers in any country requiring or permitting a listing of patents covering a Licensed Product which has received Marketing Authorization in such country, including, but not limited to, the Orange Book and the Canadian Patent Register. [***]make any such filings and listings, and will have [***].

9.5 **Infringement of Third Party Patents**.

9.5.1 **Notice**. If any claim, suit, or proceeding is brought by a Third Party against either Party, its Affiliates, Sublicensees or its or its Affiliates' sublicensees, as applicable, alleging patent infringement by such Party, its Affiliates, Sublicensees or its or its Affiliates'

sublicensees caused by the Exploitation of a Licensed Product, such Party shall promptly notify the other Party in writing.

9.5.2 **Control and Cooperation**. As between the Parties, each Party shall have the right to defend itself against any such claim, suit, or proceeding that names such Party, its Affiliates, Sublicensees or its or its Affiliates' sublicensees as a defendant. The other Party shall provide such defendant Party with such reasonable assistance in such defense, at the defendant Party's expense, as the defendant Party may request. The defendant Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding. However, if such claim, suit or proceeding is subject to a Party's obligation to indemnify and hold harmless the other Party in accordance with Sections 8.1 or 8.2, then this Section 9.5.2 shall not apply to such claim, suit or proceeding, and the provisions of Sections 8.1 or 8.2 shall apply. [***].

9.6 [***]

ARTICLE 10 TERM AND TERMINATION.

10.1 **Term and Expiration.** This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Section 10.2, Section 10.3, Section 10.4 or Section 10.5, this Agreement shall expire on a Licensed Product-by-Licensed Product and country-by-country basis, upon the expiration of the Royalty Period for such Licensed Product in such country, at which point Organon's license to the applicable Daré Patents and Daré Know-How in the applicable country pursuant to Section 3.1 shall become fully paid-up, irrevocable, perpetual, and survive termination for any reason.

10.2 **Termination by Organon for Convenience.** Following the first (1st) anniversary of the Effective Date, Organon shall have the right to terminate this Agreement in its entirety or on a country-by-country basis at any time in its sole discretion by giving one hundred twenty (120) days' advance written[1] notice to Daré. Any termination by Organon under this Section 10.2 can be effected only through a written notice specifically referring to this Section 10.2.

10.3 **Material Breach; Patent Challenge**.

10.3.1 **Termination for Material Breach**. This Agreement may be terminated at any time during the term of this Agreement upon written notice by either Party if the other Party is in material breach of this Agreement and has not cured such breach within [***] after notice requesting cure of the breach; provided, however, [***].

10.3.2 **Organon's Alternative Remedy**. If Organon has the right to terminate this Agreement under Section 10.3.1 (either as a result of resolution of a Dispute pursuant to Section 12.7, or because Daré does not dispute Organon's ability to do so), then in lieu of Organon terminating this Agreement pursuant to Section 10.3.1 [***], Organon may, upon notice to Daré, [***] have this Agreement continue in full force as modified by this Section 10.3.2, in which case, effective as of the date Organon delivers such waiver notice to Daré to exercise this alternative remedy: (i) any milestone payments payable by Organon to Daré shall be reduced by [***]%; (ii) the royalty rates payable by Organon to Daré pursuant to Section 6.3.1 shall be replaced with the royalty rates set forth in clauses (a) through (d) below; (iii) Organon shall be entitled [***], and (iv) all other provisions of this Agreement shall remain in full force and effect without change.

(a) [***] of the aggregate of such Net Sales in each Calendar Year up to and including [***] of such Net Sales;

[1] NTD: This time period has been publicly disclosed, including in Daré's 8-K filed 3/31/2022.

(b) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales up to and including $50,000,000 of such Net Sales;

(c) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***] of such Net Sales up to and including [***] of such Net Sales; and

(d) [***] of the aggregate of such Net Sales in each Calendar Year greater than [***].

If Organon notifies Daré that Organon believes it has the right to terminate this Agreement under Section 10.3.1 (whether or not it is at such time electing to do so), then, upon and after such notice, Organon may [***]. If such right to terminate is confirmed, then [***]. If such right to terminate is determined to be incorrect, then [***].

10.3.3 Termination for Patent Challenge. Daré may terminate this Agreement [***] if Organon or its Affiliate individually or in association with any other Person, asserts[***] a Patent Challenge with respect to [***] other than (a) as permitted in accordance with Section 9.2.2 or (b) as part of a defense or counterclaim to any action brought or threatened by Daré against Organon or any of its Affiliates. If a Sublicensee individually or in association with any other Person, asserts, voluntarily assists or directs a Patent Challenge with respect to [***] and either (i) Organon does not [***] or (ii) such Patent Challenge with respect to such [***] is not stopped and withdrawn within [***] of commencement, then Daré may terminate this Agreement with respect to [***]. "**Patent Challenge**" means [***].

10.4 Termination for Insolvency. This Agreement may be terminated at any time during the term of this Agreement immediately upon written notice by either Party, in the event the other Party files for protection under bankruptcy Applicable Laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within [***] of the filing thereof.

10.5 Termination for Safety. This Agreement may be terminated on a Licensed Product-by-Licensed Product basis at any time during the term of this Agreement immediately upon written notice by Organon, if Organon reasonably believes in good faith, after due inquiry and in a manner consistent with Organon's then-current decision-making process with respect to such a determination (where a reasonable summary of such inquiry and Organon's conclusions are included in such notice), that Development or commercialization of such Licensed Product should be terminated due to there being a Serious Adverse Event related to such Licensed Product (where such adverse effect was not included in the FDA-approved label for such Licensed Product at the time the Marketing Authorization was obtained for such Licensed Product) that is based upon and demonstrated by (a) preclinical safety data, including data from animal toxicology studies, (b) the observation of one or more Serious Adverse Events in humans after such Licensed Product has been administered to humans, such as during a Clinical Trial of such Licensed Product, or (c) with respect to such Licensed Product, (i) any other safety concern required to be reported under 21 C.F.R. § 312.32(c)(1)(iii) or the equivalent in any non U.S. jurisdiction, or (ii) a material toxicity or material drug safety issue or any other evidence of a Serious Adverse Event reasonably related to a Licensed Product (any of the foregoing reasons, a "**Safety Reason**"). If the Parties reasonably disagree as to the existence of a Safety Reason, the Parties' [***] shall promptly meet, at a mutually convenient time, to discuss and address the disagreement and possible resolution.

10.6 Effects of Termination.

10.6.1 General Consequences. Upon termination of this Agreement in its entirety, or upon termination for a specific country pursuant to Section 10.2, except for the licenses that are fully paid-up and except for the surviving provisions set forth in this Section 10.6 or

Section 10.7, the provisions of this Agreement are of no further force or effect as of the effective date of such termination and the terms of this Section 10.6 shall apply.

10.6.2 Confidential Information. Upon termination of this Agreement in its entirety, either Party may request in writing, and the other Party shall either promptly return to the requesting Party, or as soon as reasonably practicable delete or destroy, all of the requesting Party's Information in such other Party's Control to which such other Party does not retain rights under the surviving provisions of this Agreement; *provided that* such other Party may keep one copy of such materials for legal archival purposes subject to continuing confidentiality obligations, and *further provided that*, if any license to Organon is deemed fully paid up at the time of such termination, then Organon shall be entitled to retain Daré's Information necessary or reasonably useful for the Exploitation of such license. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such confidential Information that (a) it is required by Applicable Law to retain (the disclosure of which shall continue to be governed by the provisions of Article 5), or (b) have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

10.6.3 Sublicenses. In the event of termination of this Agreement under Section 10.2 or by Daré under Section 10.3 or Section 10.4, at the request of Organon received by Daré by notice within [***] after the effective date of such termination, *provided* such Sublicensee is not then in default of its obligations under its sublicense agreement with Organon, Daré shall consider in good faith whether or not to enter into a license with such Sublicensee granting such Sublicensee rights under the Daré Know-How and Daré Patents (or the subset of the Daré Know-How and Daré Patents that were sublicensed to such Sublicensee), that do not conflict with the remaining rights granted to Organon hereunder, on commercially reasonable terms, and subject to the requirements of the DTM Upstream License Agreement.

10.6.4 Commercial Inventory. In the event of termination of this Agreement for a specific country or termination of this Agreement in its entirety, Organon, its Affiliates and its and their Sublicensees and distributors shall be entitled, during the [***] period immediately following the effective date of such termination, to finish work-in-progress and to sell any Licensed Product remaining in inventory in accordance with the terms of this Agreement; *provided that*, for a period of [***] ending on the last day of such [***] period, Organon will offer to sell to Daré inventories of any Licensed Products that are not Combination Products and that can be sold legally and solely in such terminated country(ies) and that remain in Organon's and its Affiliates' and their contract manufacturers' inventory at the end of such [***] period at [***]); *provided further that*, if the Parties cannot agree upon a price or Daré elects not to purchase the entire remaining inventory of such Licensed Product, Organon and its Affiliates can continue selling such inventories of Licensed Product that can be sold legally solely in such terminated country for [***] period. For the avoidance of doubt, such sales constitute Net Sales and are subject to Royalties if the sales are not to Daré or its Affiliates.

10.6.5 License to Organon. In the event of termination of this Agreement for any reason in a particular country, effective as of the date of such termination, the licenses granted by Daré to Organon under Section 3.1 and Section 3.2 shall automatically terminate in such country if not fully paid up before the date of such termination, except that Daré grants to Organon, its Affiliates and Sublicensees (as the case may be) nonexclusive licenses or rights of reference to any Daré Know-How, Daré Patents and Product Trademarks in such country that are reasonably necessary for Organon, its Affiliates or Sublicensees to exercise its rights or fulfill its obligations set forth in this Section 10.6.

10.6.6 Reversion License.

(a) In the event of termination of this Agreement under Section 10.2 or by Daré under Section 10.3, Organon shall, and hereby does, grant to Daré, effective on the effective date of termination, an exclusive (even as to Organon and its Affiliates), royalty-bearing license, with the right to sublicense through multiple tiers, under the Organon Patents that claim inventions conceived or reduced to practice during the term of this Agreement, Joint Patents and Organon Know-How created or conceived during the term of this Agreement to Exploit Licensed Products in the Field in the portion of the Territory terminated, which Licensed Products are or have been made or sold in the portion of the Territory terminated during the term of this Agreement, as such Licensed Products exist as of the effective date of termination (the "**Reversion License**"). In all cases, the Reversion License excludes any Organon Patents to the extent that such Patent claims or covers the composition of any Other Product in a Combination Product.

(b) The royalty(ies) to be paid by Daré to Organon under the Reversion License shall [***] ("**Reversion Royalty Dispute**"), the Reversion Royalty Dispute shall be resolved in accordance with Section 12.7.

(c) In connection with the negotiation and execution of a Reversion License, with respect to any Organon Patent or Organon Know-How that is licensed by Organon from Third Parties and sublicensed to Daré, [***].

10.6.7 Assignment of Regulatory Materials; Trademarks. In the event of termination of this Agreement by Organon under Section 10.2, or by Daré under Sections 10.3.1 or 10.3.3, or by either Party under Section 10.4, or by Organon under Section 10.5 but where the Safety Reason does not result in either a recall of the Licensed Product or the withdrawal of Marketing Authorization of the Licensed Product, in each case as required by a Regulatory Authority, then Organon shall promptly:

(a) where permitted by Applicable Law, assign and transfer (or cause to be assigned and transferred) to Daré or its designee (and, if in Organon's possession or control, provide copies of) all (i) Daré Marketing Authorizations and Daré Regulatory Materials and (ii) Marketing Authorizations that are Controlled by Organon, and obtained during the term of this Agreement and solely relating to Licensed Products ("**Organon Marketing Authorizations**") and Regulatory Materials that are Controlled by Organon and solely relating to Organon Marketing Authorizations, in each case within this clause (a), solely relating to the Licensed Products in the Field and in the portion of the Territory terminated and that are the subject of the license granted in Section 10.6.6; and

(b) if this Agreement is terminated in its entirety, assign to Daré or its designee all of Organon's and its Affiliates' rights, title, and interest in and to all Product Trademarks that are in actual use in the portion of the Territory terminated at the time of such termination as a Trademark solely in connection with the sale of Licensed Products in the Field and all Internet domain names and social media accounts that incorporate any such Product Trademarks, in each case, that are solely used in connection with the sale of Licensed Products in the Field in the portion of the Territory terminated, including the goodwill symbolized by, or associated with the use of, such Product Trademarks.

10.6.8 Joint Patents. In the event of termination of this Agreement by Organon under Section 10.3 or Section 10.4, Daré will assign, and hereby does assign, to Organon all of Daré's right, title and interest in and to the Joint Patents. In the event of any other termination of this Agreement, the Parties shall confer to determine how ownership of the Joint Patents will be addressed, subject to Section 10.6.14.

10.6.9 Manufacturing. In the event of termination of this Agreement in its entirety under Section 10.2 or by Daré under Section 10.3 or Section 10.4, the Parties shall negotiate in good faith with respect to the transition of the then-current Manufacturing Process from Organon (or its Affiliates or designated contract manufacturer) to Daré.

10.6.10 Bankruptcy. If this Agreement is terminated by Organon under Section 10.4 due to the rejection of this Agreement by or on behalf of Daré under Section 365 of the United States Bankruptcy Code (the "**Code**"), all licenses and rights to licenses granted under or pursuant to this Agreement by Daré to Organon are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Organon, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against Daré under the Code, Organon shall be entitled to a complete duplicate of or complete access to (as Organon deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Organon (a) upon any such commencement of a bankruptcy proceeding upon written request therefore by Organon, unless Daré elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, upon the rejection of this Agreement by or on behalf of Daré upon written request therefore by Organon. Unless required by Applicable Law, Daré will not reject any license hereunder in bankruptcy proceedings outside of the United States.

10.6.11 Remedies. Except as otherwise expressly provided herein, termination of this Agreement as permitted herein shall not limit remedies that may otherwise be available in law or equity, all of which are cumulative.

10.6.12 [***]

10.6.13 Patent Matters. If [***] has assumed the prosecution or enforcement of any of the Product-Specific Patents, then upon termination of this Agreement for any reason, [***] shall ensure that the prosecution and enforcement of such Patents in each country of the Territory that was terminated is transferred to [***] in a prompt and orderly fashion such that no deadline is missed in respect of such prosecution or enforcement and that the scope of such Patents is not limited or restricted as a consequence of such transfer. [***] will cooperate with [***] and provide [***] with reasonable assistance in the transfer of all prosecution, maintenance, defense and enforcement activities, filings and documents with respect to such Patents. After any such transfer, if [***] has retained any right to prosecute or enforce any Product-Specific Patents anywhere in the Territory, [***] will keep [***] reasonably informed of any prosecution and enforcement conducted by or on behalf of [***] with respect to any Product-Specific Patents, including by: [***]. If this Agreement is terminated by Organon pursuant to Section 10.3 or Section 10.4, then [***].

10.6.14 Transition Plan. If this Agreement is terminated in its entirety or in a country by Organon under Section 10.2, or by Daré under Sections 10.3.1 or 10.3.3, or by either Party under Section 10.4, or by Organon under Section 10.5 but where the Safety Reason does not result in either a recall of the Licensed Product or the withdrawal of Marketing Authorization of the Licensed Product, in each case as required by a Regulatory Authority, then the Parties will promptly discuss in good faith the terms and conditions of a written plan ("**Transition Plan**") pursuant to which they will effectuate and coordinate an orderly transition of the relevant obligations and rights to Daré as reasonably necessary for Daré to Develop, Manufacture, Commercialize and otherwise Exploit Licensed Products that are not Combination Products after such termination in a manner consistent with Applicable Law and standards of ethical conduct and as promptly as

possible. The Transition Plan shall be subject to Section 10.6 and is expected to address at least:

(a) [***];

(b) [***]; and

(c) [***].

10.7 **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including the obligation to make payments under Article 6, which obligation accrued prior to such expiration or termination. Organon will provide a final royalty report and royalty payment in accordance with Section 6.4 within [***] after the end of the Calendar Quarter in which expiration or termination occurs, and the obligation of Related Parties to keep books and records under Section 6.4 shall survive termination for the period specified therein. The provisions of Article 5 shall survive the expiration or termination of this Agreement and shall continue in effect for [***]. In addition, the provisions of Article 1, Article 8, Article 9 (with respect to [***]) and Article 12, and Sections 2.6, 3.9, 6.5 through 6.8 (with respect to payment obligations accruing hereunder), 7.5, 10.6, and 10.7 shall survive any expiration or termination of this Agreement.

ARTICLE 11 EFFECTIVENESS.

11.1 **Effective Date**. Except for the Parties' obligations under Article 5 and this Article 11 or other provisions specified to occur, be effective or based on the Execution Date or "during the term of this Agreement", all of which will be effective as of the Execution Date, the other provisions of this Agreement will become effective on [***] after all of the Closing Conditions have been met or if Organon waives such Closing Conditions by notice to Daré (the "**Effective Date**"); *provided that* the Effective Date will not occur (a) if either Party exercises its termination right under Section 11.3 or under Article 10 prior to the Antitrust Clearance Date, (b) if and for so long as there is in force any Applicable Law (i) enjoining or prohibiting the consummation of the transactions contemplated by this Agreement or (ii) imposing any conditions in connection with such effectiveness, or (c) there is any action, proceeding, or investigation brought by a Governmental Authority pending that would reasonably be expected to lead to any of the foregoing that would be material in the context of the transactions contemplated by this Agreement.

11.2 **Filings.** Each Party will, unless otherwise agreed by the Parties, within [***] following the Execution Date, file those Antitrust Filings required under the applicable Antitrust Laws (the "**Required Filings**").

11.2.1 **Cooperation**. The Parties will reasonably cooperate with one another to the extent necessary in the preparation and execution of all such documents that are required to be filed pursuant to the Required Filings.

11.2.2 **Costs**. Each Party will be responsible for [***] associated with any such Required Filing, including premerger filing fees incurred by each Party associated with any such Required Filing.

11.2.3 **Waiting Period**. With respect to the Required Filings, the Parties will use Commercially Reasonable Efforts to obtain any necessary approvals or consents under such applicable Antitrust Law, [***].

11.2.4 **Communications**. To the extent permitted under Applicable Law and by the applicable Governmental Authorities, the Parties will (a) provide each other reasonable advance

written notice of any meetings or telephone conferences with a Governmental Authority under the HSR Act relating to the transactions contemplated by this Agreement, and (b) permit each other to attend and participate in those meetings and telephone conferences. Each Party will (i) provide the other with reasonable opportunity to review and comment on any written submissions, and will consider comments in good faith, and (ii) keep the other Party apprised of the status of any communications with, and any inquiries or requests for information from, any Governmental Authority under the HSR Act, regardless of whether such other Party declines to participate in any meetings or telephone conferences; *provided that* neither Party will be obligated to disclose any commercially sensitive or privileged information, and to the extent the Parties agree to share information of this nature, such exchange and review will be limited to the Parties' outside counsel only.

11.2.5 Not Required. Notwithstanding any provision to the contrary set forth in this Agreement, nothing in this Agreement (including this Section 11.2) will require either Party or any of its Affiliates to [***].

11.3 Outside Date. This Agreement will terminate at the election of either Party, immediately upon written notice to the other Party, (a) if any Governmental Authority [***] injunction under applicable Antitrust Laws against the Parties to enjoin the transactions contemplated by this Agreement; or (b) in the event that the Antitrust Clearance Date has not occurred on or prior to [***], and the Parties have not agreed in writing to extend the Antitrust Clearance Date. In the event of such termination, this Agreement will be of no further force and effect, except for the Parties' continued obligations under Article 5, which shall survive such termination.

11.4 Closing Conditions. Unless waived by Organon, this Agreement will not become effective until each of the following conditions (each a "**Closing Condition**") have been met:

11.4.1 Antitrust. the occurrence of the Antitrust Clearance Date;

11.4.2 [***];

11.4.3 [***]; and

11.4.4 Bring Down. all representations and warranties of Daré in this Agreement shall be true and correct as of the Effective Date, Daré will have, up through the Effective Date, complied with all of its obligations set forth in Section 7.4 and Daré will have delivered to Organon a certificate executed by an officer of Daré certifying the accuracy of the foregoing.

ARTICLE 12 MISCELLANEOUS.

12.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement, except for the obligation to make payment, to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

12.2 Assignment. Either Party may, without consent of the other Party, assign this Agreement in its entirety and all of its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its assets related to the subject matter of this Agreement. Except as provided in the preceding sentence, this Agreement may not be assigned,

nor may any right or obligation hereunder be assigned, by either Party without the consent of the other Party. Any attempted assignment not in accordance with this Section 12.2 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

12.3 **Use of Affiliates**. Each Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates, and each Party's Affiliates will have the benefit of all rights (including all licenses) of such Party under this Agreement. Accordingly, in this Agreement "Daré" will be interpreted to mean "Daré or its Affiliates" and "Organon" will be interpreted to mean "Organon or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to the applicable Party in this Agreement; provided, however, that in any event each Party will remain responsible hereunder for the acts and omissions of its respective Affiliates.

12.4 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

12.5 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if sent by internationally-recognized commercial courier, addressed as follows:

if to Daré, to:	Daré Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, CA 92122 Attention: Sabrina Johnson, CEO
With a copy to, which shall not constitute notice:	Mintz Levin 3580 Carmel Mountain Rd. #300 San Diego, CA 92130 Attention: Tali Tuchin
if to Organon, to:	Organon International GmBH Weystrasse 20, 6006 Lucerne, Switzerland Attention: General Counsel -and- Organon LLC 30 Hudson Street, Floor 33 New Jersey, NJ, USA 07302 Attention: SVP, Business Development -and- Via electronic mail to: [***] Organon LLC 30 Hudson Street, Floor 33 New Jersey, NJ, USA 07302 Attention: General Counsel
With a copy to, which shall not constitute notice:	Jones Day 4655 Executive Drive, Suite 1500 San Diego, CA 92121-3134 Attention: Thomas Briggs and Jonn Beeson

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given upon receipt. The Parties hereby agree that, to the extent permitted by Applicable Law, any notice provided in accordance with this Section 12.5 shall constitute due service of process with respect to any legal proceeding between the Parties arising hereunder and that compliance with the Hague Convention for the Service of Process, if otherwise applicable, shall not be required.

12.6 **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any rules of conflict of laws or venue.

12.7 **Dispute Resolution**.

12.7.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a "**Dispute**"). Any Party shall give the other Party written notice of any Dispute not resolved in the normal course of business. Within [***] from the date of delivery of such notice, the receiving Party shall submit to the other Party a written response. The notice and response shall include (a) a statement of that Party's position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within [***] from the date of delivery of the initial notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute and shall be at a higher level of management than the persons with direct responsibility for administration of this Agreement. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

12.7.2 If the Parties do not fully settle following the procedure in Section 12.7.1, and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof that is not an "**Excluded Claim**" shall be brought in the federal court for the District of Delaware, if federal jurisdiction is available, or, alternatively, in the state courts in Wilmington, Delaware. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. **Each party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.**

12.8 **DTM Upstream License Agreement Licensors**. Organon acknowledges that neither TriLogic nor MilanaPharm provides any representations, warranties, indemnities or has any liabilities to Organon pursuant to this Agreement.

12.9 **Entire Agreement; Amendments**. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the subject matter hereof and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof and the licenses granted hereunder are superseded by the terms of this Agreement. The

Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

12.10 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

12.11 **Independent Contractors**. It is expressly agreed that Daré and Organon shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Daré nor Organon shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.12 **Expenses**. Except as specifically provided in this Agreement, each Party will be responsible for its own costs and expenses associated with its negotiation, execution, delivery and performance of this Agreement.

12.13 **Waiver**. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

12.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

12.15 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Schedule shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause or Schedule, of or to, as the case may be, this Agreement, unless otherwise indicated. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Unless the context of this Agreement otherwise requires, (a) words of any gender include any other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) each use of the word “including” is not limiting and is deemed to be followed by the words “without limitation”, (e) the words “shall” and “will” have the same meaning unless the context dictates otherwise, (f) use of the words “or,” “either” or “any” will not be exclusive, and (g) the word “or” will be interpreted in the inclusive sense commonly associated with the term “and/or.”

12.16 **Counterparts**. This Agreement may be signed in any number of counterparts (including by facsimile or electronic transmission), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After facsimile or electronic transmission, the Parties agree to execute and exchange documents with original signatures.

12.17 **Further Assurances**. From time to time, each Party will execute, acknowledge and deliver to each other any further documents, assurances and other matters, and will take any other action consistent with the terms and conditions of this Agreement, that may reasonably be requested by a Party and necessary or desirable to carry out the purpose of this Agreement.

[SIGNATURES ON FOLLOWING PAGE]

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

ORGANON INTERNATIONAL GMBH	DARÉ BIOSCIENCE, INC.
BY: /s/ Thomas Morlet	BY: /s/ Sabrina Johnson
NAME: Thomas Morlet TITLE: Managing Officer	NAME: Sabrina Johnson TITLE: Chief Executive Officer

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. IN THIS EXHIBIT, "[***]" INDICATES WHERE SUCH INFORMATION HAS BEEN OMITTED.

CONSENT, WAIVER AND STAND-BY LICENSE AGREEMENT

This CONSENT, WAIVER AND STAND-BY LICENSE AGREEMENT (this "**Agreement**"), dated March 30, 2022 ("**Execution Date**"), is by and among TriLogic Pharma, LLC, a limited liability company organized under the laws of Delaware ("**TriLogic**"), MilanaPharm LCC, a limited liability company organized under the laws of Delaware ("**MilanaPharm**"), Daré Bioscience, Inc., a corporation organized and existing under the laws of Delaware ("**Daré**"), and Organon International GmbH, a limited liability company organized and existing under the laws of Switzerland ("**Organon**").

RECITALS:

A. TriLogic, MilanaPharm and Hammock Pharmaceuticals, Inc. ("**Hammock**") entered into that Exclusive License Agreement effective as of January 9, 2017 (the "**Original License Agreement**").

B. Hammock assigned to Daré Hammock's entire right, title and interest in the Original License Agreement pursuant to that Assignment Agreement between Hammock and Daré effective as of December 5, 2018.

C. Daré, TriLogic and MilanaPharm amended the Original License Agreement pursuant to that First Amendment to License Agreement effective as of December 5, 2018, that Amendment No. 2 to License Agreement effective as of December 3, 2019 and that Second Amendment to License Agreement effective as of September 21, 2021 (the Original License Agreement, as amended, the "**DTM Upstream License Agreement**").

D. Daré desires to sublicense to Organon, and Organon desires to receive a sublicense from Daré, under rights granted to Daré in the DTM Upstream License Agreement as set forth in the Exclusive License Agreement between Daré and Organon being entered as of the Execution Date (the "**Daré-Organon Sublicense Agreement**"), a redacted copy of which is attached as **Schedule A**.

E. As a condition to entering into the Daré-Organon Sublicense Agreement: (i) Organon requested Daré to obtain from TriLogic and MilanaPharm consent to the Daré-Organon Sublicense Agreement as a sublicense under the DTM Upstream License Agreement, including waivers of any requirements for such sublicensing to the extent not satisfied by the Daré-Organon Sublicense Agreement, (ii) Organon requested TriLogic and MilanaPharm to provide Organon certain assurances regarding Organon's rights and obligations should the DTM Upstream License Agreement be terminated, and (iii) Daré requested TriLogic and MilanaPharm to further amend the Original License Agreement.

F. TriLogic and MilanaPharm have agreed to provide such consent, waivers, assurances and amendments to the extent set forth below.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Daré, TriLogic, MilanaPharm and Organon hereby agree as follows:

ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

1.1 "**Affiliate**" means a Person or entity that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than 50% of the voting stock of such entity, or by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity.

1.2 "**Effective Date**" means the Effective Date of the Daré-Organon Sublicense Agreement.

1.3 "**Parties**" means, collectively, TriLogic, MilanaPharm, Daré and Organon.

1.4 "**Party**" means one of TriLogic, MilanaPharm, Daré and Organon.

1.5 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

ARTICLE 2 CONSENT TO SUBLICENSE, WAIVERS AND COOPERATION.

2.1 **Consent to Daré-Organon Sublicense Agreement**. TriLogic and MilanaPharm each consent to the Daré-Organon Sublicense Agreement as a sublicense under the DTM Upstream License Agreement and agree that, notwithstanding anything to the contrary in the DTM Upstream License Agreement, the terms of this Agreement together with the provisions of the Daré-Organon Sublicense Agreement satisfy all of the obligations of Daré related to sublicensing under the DTM Upstream License Agreement, including those specified in Section 2.1.3 (Sublicensing) of or elsewhere in the DTM Upstream License Agreement. To the extent that any provision of this Agreement or the Daré-Organon Sublicense Agreement conflicts with or otherwise could/would be deemed not to satisfy any right of TriLogic or MilanaPharm or any obligation of Daré regarding a grant of a sublicense under the DTM Upstream License Agreement, each of TriLogic and MilanaPharm hereby waives each such right or obligation, including any such right or obligation specified in Section 2.1.3 (Sublicensing) or elsewhere in the DTM Upstream License Agreement.

2.2 **Waivers Of Certain Obligations of Daré under DTM Upstream License Agreement.** To the extent that Organon's performance of its obligations under the Daré-Organon Sublicense Agreement would not otherwise satisfy any of Daré's obligations to TriLogic or MilanaPharm under the DTM Upstream License Agreement, then, effective as of the Effective Date, TriLogic and MilanaPharm each hereby waive such obligation(s) of Daré. Without limiting the foregoing, as of the Effective Date, TriLogic and MilanaPharm each hereby waive Daré's obligation under:

2.2.1 Section 2.1.3(iii)(b) of the DTM Upstream License Agreement to include copies of Sections 4.5 (Royalty Records), 4.6 (Review), 9.1 (Indemnification by Hammock) and Articles 5 (Confidentiality) and 11 (Insurance) of the DTM Upstream License Agreement in the Daré-Organon Sublicense Agreement and

waive Organon's, but not Daré's, obligation to comply with the provisions of such Section and Articles;

2.2.2 Section 2.1.3(vi)(b) of the DTM Upstream License Agreement to require that further sublicenses of rights granted to Organon under the Daré-Organon Sublicense Agreement be consistent with the terms and requirements of the DTM Upstream License Agreement and include all provisions that Daré is required to include in a sublicense*; provided that*, the Daré-Organon Sublicense Agreement will require that further sublicenses of the rights granted to Organon under the Daré-Organon Sublicense Agreement will be consistent with the license set forth in Section 2.3 (Further Sublicensing by Organon) of this Agreement.

2.2.3 Section 3.2 (Diligence) of the DTM Upstream License Agreement to use commercially reasonable efforts and resources to develop and commercialize and continue to commercialize a Licensed Product (as defined in the DTM Upstream License Agreement) in the Field (as defined in the DTM Upstream License Agreement) in at least one of Canada or any country in the EU Major Market (as defined in the DTM Upstream License Agreement);

2.2.4 Section 3.4 (Hammock Data) of the DTM Upstream License Agreement to disclose to TriLogic or MilanaPharm any Data (as defined in the DTM Upstream License Agreement) disclosed by Organon to Daré or obtained by Daré on behalf of Organon;

2.2.5 Section 3.6 (Reports) of the DTM Upstream License Agreement to provide MilanaPharm reports on the regulatory activities performed by Organon or by Daré on behalf of Organon in connection with the Daré-Organon Sublicense Agreement; *provided that*, Daré shall be required to deliver to MilanaPharm a copy of all such reports or other notifications relating to regulatory activities prepared by it or received by it from Organon or any other source relating to the Licensed Products within [***] of any such report becoming available to it; and

1.1.6 Section 12.5 (Discontinuation of Sales) of the DTM Upstream License Agreement to notify MilanaPharm in the event that the sale of a Licensed Product (as defined in the DTM Upstream License Agreement) is discontinued indefinitely in a country after being launched in such country and TriLogic and MilanaPharm each waive their right under Section 12.5 (Discontinuation of Sales) of the DTM Upstream License Agreement to terminate the license granted under Section 2.1.1 (Grant of License) of the DTM Upstream License Agreement.

2.3 **Further Sublicensing by Organon**. Without limiting the generality of Sections 2.1 (Consent to Daré-Organon Sublicense Agreement) and 2.2 (Waiver of Certain Obligations of Daré under DTM Upstream License Agreement) of this Agreement, as of the Effective Date, TriLogic and MilanaPharm hereby grant Daré the right to allow Organon to grant further sublicenses of Organon's rights under the Daré-Organon Sublicense Agreement where such sublicenses are consistent with the terms and conditions of the Daré-Organon Sublicense Agreement and with the terms and conditions of the DTM Upstream License as amended by and with the waivers provided in this Agreement with respect to such sublicenses to the same extent as to Organon.

2.4 **Patent Cooperation**. As of the Effective Date:

2.4.1 Organon, upon notice to TriLogic and MilanaPharm, shall have the first right, but not the obligation, to initiate and prosecute any legal action to terminate an infringement of the Licensed Patents (as defined in the DTM Upstream License Agreement) within the Field (as defined in the Daré-Organon Sublicense

Agreement), and to control the defense against challenges to the validity or enforceability of such Licensed Patents within such Field, at its own expense and in its own name, in which case Organon shall keep TriLogic and MilanaPharm updated with respect to any such action, including providing copies of all material documents received, prepared and filed in connection with any such action, and shall consult with TriLogic and MilanaPharm to determine a course of action with respect to any defense of the validity and/or enforceability of any such Licensed Patents in such Field and shall consider in good faith all reasonable comments, requests, and suggestions provided by TriLogic and MilanaPharm with respect thereto. Subject to Organon's obligations to Daré under the Daré-Organon Sublicense Agreement, Organon shall have the right to enter into a settlement of any matter under this Section 2.4.1 (Patent Control), without MilanaPharm's and TriLogic's consent, so long as (a) such settlement does not involve any express statement or admission of any fault of, breach of contract by, or violation of applicable law by, MilanaPharm, (b) MilanaPharm is not liable under such settlement agreement to pay any monetary damages or other payments, for which Organon shall agree not to seek any indemnification from MilanaPharm, and does not include any requirement that MilanaPharm take or refrain from taking any actions other than compliance with any nondisclosure obligations related to the terms of such settlement contained in the settlement agreement, (c) such settlement includes a release of MilanaPharm on the same terms as such release applies to Organon, (d) such settlement agreement includes a reasonable confidentiality obligation by the third party claimant or defendant of the terms of the settlement, and (e) to the extent MilanaPharm is not a direct signatory of such settlement agreement, MilanaPharm is designated as an express third party beneficiary of the settlement agreement, entitled to enforce the applicable terms of such settlement agreement; in any other event, TriLogic and MilanaPharm's consent shall be required (such consent not to be unreasonably withheld, conditioned or delayed).

2.4.2 Each of TriLogic and MilanaPharm will fully cooperate with Organon and provide any information and assistance that Organon may reasonably request for the filing, prosecution, maintenance and defense of, and in connection with all administrative proceedings contemplated by Sections 9.2.1 (Third Party Initiated Proceedings) and 9.2.2 (Party Initiated Proceedings) of the Daré-Organon Sublicense Agreement with respect to, all Patents (as defined in the Daré-Organon Sublicense Agreement) that Organon has the right to file, prosecute, maintain and defend under the Daré-Organon Sublicense Agreement.

2.4.3 In the event that Organon is unable, as a matter of law, to initiate, prosecute or maintain, in its own name, any action to enforce any intellectual property rights that are exclusively licensed to Organon pursuant to the Daré-Organon Sublicense Agreement and any of TriLogic or MilanaPharm have any right, title or interest in or to such intellectual property rights, then each of TriLogic and MilanaPharm will, at Organon's expense, join such action voluntarily and will execute and cause its Affiliates to execute all documents where necessary for Organon to initiate, prosecute or maintain such action. In connection with any such action or potential action, each of TriLogic and MilanaPharm that has any right, title or interest in or to the intellectual property rights that are the subject of, or otherwise involved in, such action or potential action, will, at Organon's expense, cooperate fully with Organon and will provide Organon with any information or assistance that Organon may reasonably request, including cooperating with regard to any pre-litigation review of such intellectual property rights.

2.4.4 All recoveries in connection with an enforcement contemplated by Section 2.4.1 (Patent Control) of this Agreement will be shared in the manner contemplated by Section 9.3.4 (Recoveries) of the Daré-Organon Sublicense Agreement.

2.5 **Proof of Insurance**. Upon MilanaPharm or TriLogic's request, Daré will exercise its rights under Sections 8.4 and 5.4 of the Daré-Organon Sublicense Agreement to obtain a copy of Organon's certificate of insurance evidencing insurance (or self-insurance) and Daré will provide such copy to MilanaPharm or TriLogic, respectively.

ARTICLE 3 AMENDMENTS.

3.1 **Net Sales, Royalties and Reporting**. Effective as of the Effective Date, and during the term of this Agreement and solely as applied to "Licensed Products" as defined in the Daré-Organon Sublicense Agreement:

3.1.1 **Net Sales**. Section 1.24 ("Net Sales") of the DTM Upstream License Agreement is deleted in its entirety and replaced with Section 1.75 ("Net Sales") of the Daré-Organon Sublicense Agreement.

All definitions of the Daré-Organon Sublicense Agreement on which Section 1.75 ("Net Sales") of the Daré-Organon Sublicense Agreement depends and that correspond to definitions of the DTM Upstream License Agreement, replace such definitions of the DTM Upstream License Agreement. All other definitions of the Daré-Organon Sublicense Agreement on which Section 1.75 ("Net Sales") of the Daré-Organon Sublicense Agreement depends are added in alphabetical order to Article 1 (Definitions) of the DTM Upstream License Agreement and all Section references in Article 1 (Definitions) of the DTM Upstream License Agreement are updated accordingly.

1.1.2 **Royalty Rate**. Section 4.3.1 (Royalty Rate) of the DTM Upstream License Agreement is hereby amended by [***] the Percentage of Annual Net Sales for each category of Annual Net Sales by [***] (*i.e.*, the Percentage of Annual Net Sales shall be [***] for Annual Net Sales [***]; the Percentage of Annual Net Sales shall be [***] for the portion of Annual Net Sales equal to or greater than [***] but less than [***], etc.).

1.1.3 **Royalty Payments**. Section 4.4.1 (Payment of Royalties) of the DTM Upstream License Agreement is deleted in its entirety and replaced as follows: "Daré shall make royalty payments owed to MilanaPharm hereunder in arrears, [***] after receipt of the corresponding payment(s) from Daré's Sublicensee(s). Each royalty payment shall be accompanied by a report for each country in which sales of Licensed Products occurred in the Calendar Quarter covered by such statement, containing information sufficient to calculate the royalty payable on a country-by-country basis, including all amounts included in the calculation of Net Sales, the aggregate of deductions taken in such calculation, amounts from all Affiliates and Sublicensees."

3.2 **Competition; Third Party Payments**. Effective as of the Effective Date, and during the term of this Agreement and solely as applied to "Licensed Products" as defined in the Daré-Organon Sublicense Agreement:

3.2.1 Section 6.3.1(c) (Competition) of the Daré-Organon Sublicense Agreement is added after Section 4.3.3(iii) (Generic Competition) of the DTM Upstream License Agreement as new Section 4.3.3(iv) (Generic Competition) of the DTM Upstream License Agreement.

All definitions of the Daré-Organon Sublicense Agreement on which Section 6.3.1(c) (Competition) of the Daré-Organon Sublicense Agreement depends and that correspond to definitions of the DTM Upstream License Agreement, replace such definitions of the DTM Upstream License Agreement. All other definitions of the Daré-Organon Sublicense Agreement on which Section 6.3.1(c)

(Competition) of the Daré-Organon Sublicense Agreement depends are added in alphabetical order to Article 1 (Definitions) of the DTM Upstream License Agreement and all Section references in Article 1 (Definitions) of the DTM Upstream License Agreement are updated accordingly.

3.2.2 Section 4.3.4(ii) (Third Party Offset) of the DTM Upstream License Agreement is deleted in its entirety and replaced with Section 6.3.2 (Third Party Licenses) from the Daré-Organon Sublicense Agreement.

All definitions of the Daré-Organon Sublicense Agreement on which Section 6.3.2 (Third Party Licenses) of the Daré-Organon Sublicense Agreement depends and that correspond to definitions of the DTM Upstream License Agreement, replace such definitions of the DTM Upstream License Agreement. All other definitions of the Daré-Organon Sublicense Agreement on which Section 6.3.2 (Third Party Licenses) of the Daré-Organon Sublicense Agreement depends are added in alphabetical order to Article 1 (Definitions) of the DTM Upstream License Agreement and all Section references in Article 1 (Definitions) of the DTM Upstream License Agreement are updated accordingly.

3.2.3 The following is added immediately after Section 4.3.4 (Third Party Payments) of the DTM Upstream License Agreement as new Section 4.3.5 (Floor) of the DTM Upstream License Agreement: "Notwithstanding anything to the contrary in this Agreement: (a) in no event will the royalty rate that otherwise would be applicable under Section 4.3.1 (Royalty Rate) of this Agreement be [***] through application of the provisions of Section 4.3.3(vi) (Generic Competition), or Section 4.3.4 (Third Party Payments) of this Agreement; and (b) the application of clauses (a) through (c) of Section 1.24 ("Net Sales") of this Agreement will not [***] the royalty rate payable on Licensed Products [***] of Net Sales of Licensed Products if clauses (a) through (c) of Section 1.24 ("Net Sales") of this Agreement were not applied."

3.3 **Termination**. Any right that TriLogic or MilanaPharm have to terminate the DTM Upstream License Agreement with respect to "Licensed Products" as defined in the Daré-Organon Sublicense Agreement must be exercised jointly by TriLogic and MilanaPharm.

1.4 **Termination for Breach**. Section 12.2 (Termination for Breach) of the DTM Upstream License Agreement as applied to "Licensed Products" as defined in the Daré-Organon Sublicense Agreement is hereby amended to replace all references therein to "sixty (60)" days with [***]. All other provisions of such Section 12.2 shall remain as written.

ARTICLE 4 ACKNOWLEDGEMENT OF RIGHTS OF DARÉ UNDER AND MAINTENANCE OF DTM UPSTREAM LICENSE AGREEMENT; COMMERCIALIZATION DISCUSSION

4.1 **Representations**. Each of TriLogic and MilanaPharm represent to Organon that, as of the Execution Date:

4.1.1 the DTM Upstream License Agreement, inclusive of the amendments described in Recital C of this Agreement, and that License Agreement between TriLogic and MilanaPharm dated April 5, 2013 (the "**TriLogic-MilanaPharm Agreement**") constitute the entire agreement between any two or more of TriLogic, MilanaPharm and Daré related to the rights licensed to Daré thereunder, and no other amendments or agreements have been entered into in connection with the DTM Upstream License Agreement or the rights licensed thereunder;

4.1.2 the DTM Upstream License Agreement is in full force and effect and, to the best of their knowledge, Daré is not in breach of any of its provisions and there are no facts or circumstances that would result in Daré being in breach of the DTM Upstream License Agreement;

4.1.3 the TriLogic-MilanaPharm Agreement is in full force and effect and neither TriLogic nor MilanaPharm is in breach of any of its provisions;

4.1.4 neither TriLogic nor MilanaPharm, and, to the best of their knowledge, Daré or any other Person has granted to any Person any rights that are inconsistent with or affect the rights granted to Daré under the DTM Upstream License Agreement; and.

4.1.5 **Schedule 4.1.5** to this Agreement sets forth a complete and accurate list of all Licensed Patents (as defined in the DTM Upstream License Agreement).

4.2 **Maintain DTM Upstream License Agreement**. Each of TriLogic, MilanaPharm and Daré agree not to waive or amend the DTM Upstream License Agreement, without the prior written consent of Organon (which shall not be unreasonably withheld, conditioned or delayed), in any manner that would have a materially adverse effect upon the rights that are granted to Organon under the Daré-Organon Sublicense Agreement, including Organon's rights under the Licensed Intellectual Property (as defined in the DTM Upstream License Agreement).

4.3 **Assignment of DTM Upstream License Agreement**. Each of TriLogic, MilanaPharm and Daré agree not to provide consent to any other Party to the DTM Upstream License Agreement to assign such agreement in those cases where any such consent is required. If TriLogic, MilanaPharm or Daré assign any right title or interest in and to any of the Licensed Intellectual Property (as defined in the DTM Upstream License Agreement) or any right or obligation under the DTM Upstream License Agreement to any Person, the assigning Party will cause such Person to be bound in writing to the terms and conditions of this Agreement and take assignment thereof subject to all of the rights and obligations of Organon under this Agreement and the Daré-Organon Sublicense Agreement.

4.4 **Commercialization Discussion**. If Organon's and Daré's Chief Executive Officers meet in accordance with the last sentence of Section 3.4.1 (Diligence) of the Daré-Organon Sublicense Agreement to discuss a delay in the Commercialization (as defined in the Daré-Organon Sublicense Agreement) of a Licensed Product(s), then Organon and Dare will permit MilanaPharm's Chief Executive Officer to meet with them, at a mutually convenient time, to discuss and address the circumstances leading to such delay.

ARTICLE 5 GRANT OF STAND-BY LICENSE TO ORGANON.

5.1 **License Grant**. Effective as of the Stand-by License Time, immediately, automatically, and without any need for further action by any Party, TriLogic and MilanaPharm hereby grant to Organon all rights and licenses granted by TriLogic and MilanaPharm to Daré under the DTM Upstream License Agreement that were the subject of termination of the DTM Upstream License Agreement, on the same terms and conditions as such rights and licenses were granted to Daré under the DTM Upstream License Agreement immediately prior to the Stand-by License Time as modified by Section 5.2 (Amendments) of this Agreement, including all obligations of Daré thereunder going forward from the Stand-by License Time (such license, "**TMO License**"). For the avoidance of doubt: (a) the foregoing does not waive any obligation of (i) Daré to MilanaPharm or TriLogic or (ii) Organon to Daré, in each case of (i) and (ii), that has accrued prior to the Stand-by License Time; and (b) Organon will have no obligation to pay any amount to MilanaPharm or TriLogic arising from Daré's breach of the DTM Upstream License Agreement nor cure such breach. "**Stand-by License Time**" means the termination of the

DTM Upstream License Agreement, or part thereof, for any reason, including in connection with any laws governing an insolvency, reorganization, bankruptcy, liquidation or winding up of TriLogic, MilanaPharm or Daré or any breach of the DTM Upstream License Agreement.

5.2 **Amendments**. The TMO License is granted upon the terms and conditions of the DTM Upstream License Agreement except as stated below or as otherwise mutually agreed in writing by TriLogic, MilanaPharm and Organon:

5.2.1 Sections 3.4 (Hammock Data), 3.6 (Reports), 4.2.2 (Out-License Milestone Payment), 4.2.3 (Foreign Sublicense Income), 11 (Insurance) and 12.5 (Discontinuation of Sales) from the DTM Upstream License Agreement are not included as part of terms and conditions of the TMO License.

5.2.2 The obligations of Daré that are waived under Section 2.2 (Waiver of Certain Obligations of Daré under DTM Upstream License Agreement) of this Agreement shall continue to be irrevocably waived under the TMO License to the extent of such waiver.

5.2.3 The terms and conditions of the DTM Upstream License Agreement that are amended by Article 3 (Amendments) of this Agreement are amended in the TMO License *mutatis mutandis; provided that*, the first sentence of Section 4.4.1 (Payment of Royalties) of the DTM Upstream License Agreement will be replaced with the following: "Organon shall make royalty payments owed to MilanaPharm hereunder in arrears, within [***] after the end of the Calendar Quarter in which they become due."

5.2.4 To the extent there is any other inconsistency between a right or obligation of Organon under the Daré-Organon Sublicense Agreement and the corresponding right or obligation of Daré under the DTM Upstream License Agreement, the right or obligation of Organon in the Daré-Organon Sublicense Agreement is included in the TMO License in substitution for the corresponding right or obligation under the DTM Upstream License Agreement.

5.3 **Restatement of TMO License**. Upon request of any of TriLogic, MilanaPharm or Organon, such Parties will use commercially reasonable efforts to promptly restate the TMO License in a separate agreement that further documents the TMO License with the terms and conditions contemplated by Sections 5.1 (License Grant) and 5.2 (Amendments) of this Agreement or as may be otherwise mutually agreed by such Parties.

5.4 **Offset of Payments by Organon Under a TMO License**.

5.4.1 Organon can offset from any payments that Organon is obligated to pay Daré under the Daré-Organon Sublicense Agreement any and all payments that Organon is obligated to make to MilanaPharm or TriLogic under the TMO License against.

5.4.2 If any amount owed by Organon under the TMO License for any particular period or milestone event is less than the amount that Organon owes to Daré for the same period or event under the Daré-Organon Sublicense Agreement, then Organon may pay to Daré [***] otherwise in accordance with the applicable terms of the Daré-Organon Sublicense Agreement.

5.4.3 If any amount owed by Organon under the TMO License for any particular period or milestone event is more than the amount that Organon owes to Daré for

the same period or milestone event under the Daré-Organon Sublicense Agreement, then Organon [***].

ARTICLE 6 TERMINATION.

6.1 **Termination**. This Agreement automatically terminates upon termination of the Daré-Organon Sublicense Agreement for any reason, including if the Effective Date does not occur within the time specified under Article 11 therein, or upon expiration of the Daré-Organon Sublicense Agreement. Except as provided in the preceding sentence, this Agreement may not be terminated for any reason other than mutual written agreement of all of the Parties.

6.2 **Survival**. The provisions of Articles 7 (Confidentiality) – 9 (Miscellaneous) of this Agreement and this Section 6.2 (Survival) survive termination of this Agreement for any reason and remain in effect if and as applicable.

ARTICLE 7 CONFIDENTIALITY.

7.1 **Terms of this Agreement**. The existence and the terms and conditions of this Agreement will be considered the confidential information of each Party. Any confidential information of Organon provided by Daré to MilanaPharm or TriLogic in accordance with the Daré-Organon Sublicense Agreement will remain the confidential information of Organon. No disclosure of (a) the existence, or the terms or conditions, of this Agreement may be made by any Party, without the prior express written permission of all of the other Parties, or (b) the confidential information of Organon provided by Daré to MilanaPharm or TriLogic in accordance with the Daré-Organon Sublicense Agreement may be made without the prior express written permission of Organon, except, in each case of (a) and (b), as may be required by applicable laws. Without limiting the generality of the foregoing, no Party shall use the name, trademark, trade name or logo of any other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the express written permission of such Party.

7.2 **Required Disclosure**. If any Party is required to disclose the terms of this Agreement or other confidential information of another Party in submissions to the U.S. Securities and Exchange Commission or other equivalent governmental authority, it will (a) consult with the Party(ies) whose confidential information is required to be disclosed as to which information to redact from such confidential information; and (b) to the extent permitted under all applicable laws, redact all sensitive, material and non-public information, from such confidential information. The requirements of this Section 7.2 (Required Disclosure) shall not apply if the substance of the description of or reference to the applicable confidential information contained in the proposed filing or disclosure has been included in any previous filing or disclosure made by any Party or otherwise approved by all of the other Parties and such information remains accurate as of such time.

ARTICLE 8 NOTICES.

All notices which are required or permitted hereunder shall be in writing and sufficient if sent by internationally-recognized commercial courier, addressed as follows:

if to TriLogic, to:	TriLogic Pharma, LLC 219 S 8th Street Opelika, AL 36801 Attention: James A.H. Harwick
With a copy to, which shall not constitute notice:	Dentons Sirote PC 2311 Highland Avenue South Birmingham, Alabama 35205 Attention: Peter J. Hardin Facsimile No.: 205-212-3805
if to MilanaPharm, to:	MilanaPharm LLC 219 S 8th Street Opelika, AL 36801 Attention: James A.H. Harwick
With a copy to, which shall not constitute notice:	Dentons Sirote PC 2311 Highland Avenue South Birmingham, Alabama 35205 Attention: Peter J. Hardin
if to Daré, to:	Daré Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, CA 92122 Attention: Sabrina Johnson, CEO
With a copy to, which shall not constitute notice:	Mintz Levin 3580 Carmel Mountain Rd. #300 San Diego, CA 92130 Attention: Tali Tuchin

if to Organon, to:	Organon International GmBH Weystrasse 20, 6006 Lucerne, Switzerland Attention: General Counsel -and- Organon LLC 30 Hudson Street, Floor 33 New Jersey, NJ, USA 07302 Attention: SVP, Business Development -and- Via electronic mail to: [***] Organon LLC 30 Hudson Street, Floor 33 New Jersey, NJ, USA 07302 Attention: General Counsel
With a copy to, which shall not constitute notice:	Jones Day 4655 Executive Drive, Suite 1500 San Diego, CA 92121-3134 Attention: Thomas Briggs and Jonn Beeson

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party(ies) in writing in accordance herewith. Any such notice shall be deemed to have been given upon receipt. The Parties hereby agree that, to the extent permitted by applicable law, any notice provided in accordance with this Article 8 (Notices) shall constitute due service of process with respect to any legal proceeding between the Parties arising hereunder and that compliance with the Hague Convention for the Service of Process, if otherwise applicable, shall not be required.

ARTICLE 9 MISCELLANEOUS.

9.1 **Assignment**. No Party can assign this Agreement, in whole or in part, without the prior written consent of each other Party hereto, except that, without such consent (a) any Party may assign its respective interest under this Agreement to its Affiliate in a transaction or series of transactions in which such Affiliates is also the assignee of the assigning Party's interest in (i) the Licensed Intellectual Property and the DTM Upstream License Agreement, in the case of TriLogic or MilanaPharm, (ii) the DTM Upstream License Agreement and the Daré-Organon Sublicense Agreement in the case of Daré, or (iii) the Daré-Organon Sublicense Agreement in the case of Organon, and (b) any Party may assign its respective interest under this Agreement to the successors or assignees of at least substantially all of the assets of its business to which this Agreement relates.

9.2 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

9.3 **Relationship of the Parties**. This Agreement shall not constitute any Party as the joint venturer, legal representative or agent of any other Party hereto. No Party hereto shall have the right or authority to assume or create any obligation on the part of any among the Parties with respect to their collective subject matter.

9.4 **Specific Performance**. The Parties agree that if any of the terms and conditions of this Agreement were not performed in accordance with the terms and conditions herein and, accordingly, each Party [***] entitled to obtain an injunction to prevent any breaches and to obtain specific performance of the terms and conditions herein in addition to any other remedy available at law or in equity.

9.5 **Conflicts**. In the event of any conflict between this Agreement, on the hand, and the DTM Upstream License Agreement or the Daré-Organon Sublicense Agreement, on the other hand, the terms and conditions of this Agreement shall prevail.

9.6 **Entire Agreement; Amendments**. This Agreement, the DTM Upstream License Agreement and the Daré-Organon Sublicense Agreement, contain the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof and the licenses granted hereunder are superseded by the terms of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of all Parties hereto.

9.7 **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any rules of conflict of laws or venue.

9.8 **Dispute Resolution**.

9.8.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a "**Dispute**"). Any Party shall give the other Party(ies) to the Dispute written notice of any Dispute not resolved in the normal course of business. Within [***], the receiving Party shall submit to the other Party(ies) a written response. The notice and response shall include (A) a statement of [***], and (B) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within [***], the executives of the disputing Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute and shall be at a higher level of management than the persons with direct responsibility for administration of this Agreement. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

9.8.2 If the Parties do not fully settle following the procedure in Section 9.8.1, and a Party wishes to pursue the matter, each dispute, controversy or claim arising from

or related to this Agreement or the breach thereof shall be brought in the federal court for the District of Delaware, if federal jurisdiction is available, or, alternatively, in the state courts in Wilmington, Delaware. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. **Each Party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.**

9.9 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

9.10 **Waiver**. The waiver by any Party hereto of any right hereunder, or of any failure of any other Party to perform, or of any breach by any other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such any other Party whether of a similar nature or otherwise.

9.11 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party(ies) shall not apply.

9.12 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Schedule shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause or Schedule, of or to, as the case may be, this Agreement, unless otherwise indicated. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Unless the context of this Agreement otherwise requires, (a) words of any gender include any other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) each use of the word “including” is not limiting and is deemed to be followed by the words “without limitation”, (e) the words “shall” and “will” have the same meaning unless the context dictates otherwise, and (f) use of the words “or,” “either” or “any” will not be exclusive.

9.13 **Counterparts**. This Agreement may be executed in any number of counterparts (including by facsimile or electronic transmission) each of which shall be deemed and original but all of which together shall constitute one and the same instrument.

<signature page follows>

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

TRILOGIC PHARMA, LLC

BY: /s/ James A. H. Harwick
NAME: James A. H. Harwick
TITLE: Chief Executive Officer

MILANAPHARM, LLC

BY: /s/ James A. H. Harwick
NAME: James A. H. Harwick
TITLE: Chief Executive Officer

DARÉ BIOSCIENCE, INC.

BY: /s/ Sabrina Johnson
NAME: SABRINA JOHNSON
TITLE: Chief Executive Officer

ORGANON INTERNATIONAL GMBH

BY: /s/ Thomas Morlet
NAME: Thomas Morlet
TITLE: Managing Officer

DARÉ BIOSCIENCE, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY[1]

The board of directors (the "Board") of Daré Bioscience, Inc. (the "Company") has approved this amended and restated non-employee director compensation policy (this "Policy").

Cash Compensation

Under this Policy, the Company will pay its non-employee directors retainers in cash, unless a director elects to receive his or her retainer for a given calendar year in the form of awards of unrestricted shares of the Company's common stock, as described below. Each non-employee director will receive a retainer for service on the Board and for service on each committee of which the director is a member. The chairmen of the Board and of each committee will receive higher retainers for such service. The amounts of the retainers are as follows:

		Annual Retainer ($)
Board of Directors		
Chairman		65,000
Member		40,000
Committees of the Board of Directors		
Audit	Chair	20,000
	Member	7,500
Compensation	Chair	15,000
	Member	5,500
Nominating and Corporate Governance	Chair	10,000
	Member	4,000
Clinical Advisory	Chair	20,000
	Member	10,000

These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment shall be prorated for any portion of such quarter during which the director was not serving. The Company will also reimburse its non-employee directors for reasonable travel and other expenses incurred in connection with attending Board and committee meetings.

Each non-employee director may elect to receive up to 100% of these retainers in the form of awards of unrestricted shares of the Company's common stock, issued on the first trading day of the quarter following the quarter to which the retainer relates, for a number of shares of the Company's common stock equal to (x) the amount of the cash retainer that would otherwise have been payable to such director on the date of grant divided by (y) the fair market value of the Company's common stock on the date of grant. Directors wishing to make this election for a given calendar year must make the election on or before the last day of the prior calendar year, except that the election with respect to calendar year 2016 and in any year in which a director is newly elected must be made on or before June 30th of such year or such other date as determined by the Board.

Equity Compensation

[1] As amended through January 2022.

Initial Grants. Each director elected to the Board at the Company's annual meeting of stockholders in fiscal year 2022 will receive an option to purchase 57,000 shares of the Company's common stock (each, an "Initial Grant"). Each director newly elected to the Board thereafter will receive an Initial Grant. Each Initial Grant will vest as to one-third of the shares of the Company's common stock underlying such option on each anniversary of the grant date until the third anniversary of the grant date, subject to the director's continued service as a director, and will become exercisable in full upon a Change in Control (as defined below).

Annual Grants. On the date of each annual meeting of stockholders, beginning with the annual meeting of stockholders held in 2022, each director who has served on the Board for at least six months will receive an option to purchase 38,000 shares of the Company's common stock (each, an "Annual Grant"); provided, however, that if a director is up for election at such annual meeting of stockholders, such director will receive the Annual Grant only if such director is elected at such annual meeting. Each Annual Grant will vest in full on the earlier of the first anniversary of the date of grant or immediately prior to the Company's first annual meeting of stockholders occurring after the date of grant, subject to the director's continued service as a director, and will become exercisable in full upon a Change in Control.

Exercise Price. The exercise price of each option granted under this Policy will equal the fair market value of the Company's common stock on the date of grant.

Change in Control. For purposes of this Policy, "Change in Control" means the occurrence, in a single transaction or in a series of related transactions occurring after the date of grant of the applicable equity award, of any one or more of the following events: (1) any person or persons acting together becomes the owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction; (2) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such transaction; or (3) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company during any twelve month period, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition. Notwithstanding the above, to the extent that any interpretation of this definition would otherwise cause the option on or following a Change in Control to constitute deferred compensation that is subject to Section 409A of the Internal Revenue Code, and not otherwise exempt from complying with the provisions of the statute, then a Change in Control shall only be deemed to occur if the Change in Control also qualifies as a change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of a corporation's assets as defined in Treasury Regulation Section 1.409A-3(i)(5). No Change in Control will be deemed to occur because of a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

Exhibit 31.1

CERTIFICATIONS

I, Sabrina Martucci Johnson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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: May 12, 2022

/s/ Sabrina Martucci Johnson

Sabrina Martucci Johnson
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Lisa Walters-Hoffert, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Daré Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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: May 12, 2022

/s/ Lisa Walters-Hoffert
Lisa Walters-Hoffert
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 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 on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sabrina Martucci Johnson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 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: May 12, 2022

/s/ Sabrina Martucci Johnson

Sabrina Martucci Johnson
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 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 on Form 10-Q of Daré Bioscience, Inc. (the "Company") for the fiscal quarter ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lisa Walters-Hoffert, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 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: May 12, 2022

/s/ Lisa Walters-Hoffert

Lisa Walters-Hoffert
Chief Financial Officer
(principal financial officer)