UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 13, 2024, 8,700,389 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, to fund our operating needs and continue as a going concern;*
- *The number and scope of product development programs we pursue;*
- *Difficulties or delays in commencement or completion, or the termination or suspension, of our current or planned clinical or preclinical studies;*
- *Clinical trial outcomes and results of preclinical development;*
- *Failure to complete development of our product candidates or submit and obtain United States Food and Drug Administration, or FDA, or foreign regulatory authority approval for our product candidates on projected timelines or budgets, or at all;*
- *Challenges and delays in obtaining timely supplies of our product candidates, 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;*
- *Our failure, or a failure of a strategic collaborator, to successfully commercialize our product candidates, if approved, or our failure to otherwise monetize our portfolio programs and assets;*
- *Termination by a collaborator of our respective out-license agreements for commercialization of XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO, and Ovaprene®, or, in the case of Ovaprene, a decision by the collaborator not to make the license grant fully effective following its review of the results of the ongoing pivotal clinical trial of Ovaprene;*
- *The timing and amount of future royalty, milestone or other payments to us, if any, under our out-license agreement for Ovaprene, and of upside-sharing milestone payments from XOMA under our traditional and synthetic royalty purchase agreements, if any;*
- *The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;*
- *Difficulties with maintaining existing collaborations relating to the development and/or commercialization of our product candidates, or establishing new ones on a timely basis or on acceptable terms, or at all;*
- *The terms and conditions of any future strategic collaborations relating to our product candidates;*
- *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;*

- *Our loss of, or inability to attract, key personnel;*
- *A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket approval 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;*
- *Unfavorable 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 such agency 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 such agency 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 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;*
- *The timing and amount of 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 we develop, less competitive or obsolete;*
- *Unfavorable or unanticipated macroeconomic factors, geopolitical events or conflicts, public health emergencies, or natural disasters;*
- *Weak interest in women's health relative to other healthcare sectors from the investment community or from pharmaceutical companies and other potential development and commercialization collaborators;*
- *Cyber-attacks, security breaches or similar events compromising our technology systems and data, our financial resources and other assets, or the technology systems and data 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 them to competition from other formulations using the same active ingredients;*
- *Higher risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;*
- *Dependence on grants and other financial awards from governmental entities and private foundations to advance the development of several of our product candidates;*
- *Disputes or other developments concerning our intellectual property rights;*
- *Actual and anticipated fluctuations in our quarterly or annual operating results or results 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 safety, efficacy or quality concerns related to our product or product candidates (or third-party products or product candidates that share similar characteristics or drug substances), whether or not scientifically justified, leading to delays in or discontinuation of product development, product recalls or withdrawals, diminished sales, and/or other significant negative consequences;*
- *Product liability claims or governmental investigations;*
- *Changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, pricing and/or marketing of our products, product candidates and related intellectual property, health care information and data privacy and security laws, transparency laws and fraud and abuse laws, and the enforcement thereof affecting our business; 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

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 11,232,609	$ 10,476,056
Other receivables	518,886	949,211
Prepaid expenses	3,194,776	6,118,272
Total current assets	14,946,271	17,543,539
Property and equipment, net	706,256	655,975
Deposits	544,499	1,163,477
Operating lease right-of-use assets	1,327,833	1,319,630
Other non-current assets	533,942	599,594
Total assets	$ 18,058,801	$ 21,282,215
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable	$ 1,048,679	$ 3,385,551
Accrued expenses	1,850,862	2,889,005
Deferred grant funding	9,750,360	13,737,154
Current portion of lease liabilities	505,824	468,726
Total current liabilities	13,155,725	20,480,436
Deferred revenue, non-current	1,000,000	1,000,000
Liability related to the sale of future royalties, net	4,489,769	3,913,676
Lease liabilities long-term	897,790	935,743
Total liabilities	19,543,284	26,329,855
Commitments and contingencies (Note 9)		
Stockholders' deficit		
Preferred stock, $0.01 par value, 5,000,000 shares authorized; None issued and outstanding	—	—
Common stock, $0.0001 par value; 240,000,000 shares authorized; 8,546,364 and 8,331,161 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	854	833
Accumulated other comprehensive loss	(362,625)	(360,896)
Additional paid-in capital	168,660,520	166,548,454
Accumulated deficit	(169,783,232)	(171,236,031)
Total stockholders' deficit	(1,484,483)	(5,047,640)
Total liabilities and stockholders' deficit	$ 18,058,801	$ 21,282,215

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue				
License fee revenue	$ —	$ 1,000,000	$ —	$ 1,000,000
Royalty revenue	41,691	—	73,431	—
Total revenue	41,691	1,000,000	73,431	1,000,000
Operating expenses				
General and administrative expenses	2,041,268	2,696,779	7,159,979	8,954,877
Research and development expenses	2,656,772	6,674,636	10,894,066	17,738,543
Royalty expenses	—	—	7,674	—
License fee expenses	25,000	25,000	75,000	75,000
Total operating expenses	4,723,040	9,396,415	18,136,719	26,768,420
Loss from operations	(4,681,349)	(8,396,415)	(18,063,288)	(25,768,420)
Other income (expense)				
Sale of royalty and milestone rights, net	—	—	20,379,376	—
Other income (expense), net	(21,152)	97,319	(863,289)	664,591
Net income (loss)	$ (4,702,501)	$ (8,299,096)	$ 1,452,799	$ (25,103,829)
Foreign currency translation adjustments	22,935	(15,030)	(1,729)	(68,186)
Comprehensive income (loss)	$ (4,679,566)	$ (8,314,126)	$ 1,451,070	$ (25,172,015)
Income (loss) per common share:				
Basic	$ (0.55)	$ (1.09)	$ 0.17	$ (3.45)
Diluted	$ (0.55)	$ (1.09)	$ 0.17	$ (3.45)
Weighted average number of shares outstanding:				
Basic	8,534,433	7,587,637	8,656,856	7,268,465
Diluted	8,534,433	7,587,637	8,683,610	7,268,465

See accompanying notes.

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

Nine Months Ended September 30, 2024

	Common stock		Accumulated other comprehensive	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	loss	capital	deficit	equity (deficit)
Balance at December 31, 2023	**8,331,161**	**$ 833**	**$ (360,896)**	**$ 166,548,454**	**$ (171,236,031)**	**$ (5,047,640)**
Stock-based compensation	—	—	—	627,700	—	627,700
Issuance of common stock	50,664	5	—	215,108	—	215,113
Net loss	—	—	—	—	(6,755,356)	(6,755,356)
Foreign currency translation adjustments	—	—	(39,227)	—	—	(39,227)
Balance at March 31, 2024	8,381,825	$ 838	$ (400,123)	$ 167,391,262	$ (177,991,387)	$ (10,999,410)
Stock-based compensation	—	—	—	562,719	—	562,719
Issuance of common stock	42,583	4	—	182,974	—	182,978
Reverse stock split adjustment	121,953	12	—	(12)	—	—
Net income	—	—	—	—	12,910,656	12,910,656
Foreign currency translation adjustments	—	—	14,563	—	—	14,563
Balance at June 30, 2024	8,546,361	$ 854	$ (385,560)	$ 168,136,943	$ (165,080,731)	$ 2,671,506
Stock-based compensation	—	—	—	523,577	—	523,577
Reverse stock split adjustment	3	—	—	—	—	—
Net loss	—	—	—	—	(4,702,501)	(4,702,501)
Foreign currency translation adjustments	—	—	22,935	—	—	22,935
Balance at September 30, 2024	**8,546,364**	**$ 854**	**$ (362,625)**	**$ 168,660,520**	**$ (169,783,232)**	**$ (1,484,483)**

Nine Months Ended September 30, 2023

	Common stock		Accumulated other comprehensive	Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	loss	capital	deficit	equity (deficit)
Balance at December 31, 2022	**7,068,790**	**$ 707**	**$ (351,311)**	**$ 152,537,354**	**$ (141,074,640)**	**$ 11,112,110**
Stock-based compensation	—	—	—	624,621	—	624,621
Issuance of common stock from the exercise of warrants	112,793	11	—	1,299,364	—	1,299,375
Net loss	—	—	—	—	(8,042,501)	(8,042,501)
Foreign currency translation adjustments	—	—	(22,005)	—	—	(22,005)
Balance at March 31, 2023	7,181,583	718	(373,316)	154,461,339	(149,117,141)	4,971,600
Stock-based compensation	—	—	—	650,186	—	650,186
Issuance of common stock, net of issuance costs	37,883	4	—	452,191	—	452,195
Net loss	—	—	—	—	(8,762,232)	(8,762,232)
Foreign currency translation adjustments	—	—	(31,151)	—	—	(31,151)
Balance at June 30, 2023	7,219,466	722	(404,467)	155,563,716	(157,879,373)	(2,719,402)
Stock-based compensation	—	—	—	636,086	—	636,086
Issuance of common stock, net of issuance costs	971,563	97	—	8,108,605	—	8,108,702
Net loss	—	—	—	—	(8,299,096)	(8,299,096)
Foreign currency translation adjustments	—	—	(15,030)	—	—	(15,030)
Balance at September 30, 2023	**8,191,029**	**$ 819**	**$ (419,497)**	**$ 164,308,407**	**$ (166,178,469)**	**$ (2,288,740)**

See accompanying notes.

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

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net income (loss)	$ 1,452,799	$ (25,103,829)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	35,957	28,383
Right of use asset - operating lease	350,112	275,549
Stock-based compensation	1,713,996	1,910,893
Loss on disposal of property and equipment	600,000	—
Non-cash royalty revenue related to sale of future royalties	(63,725)	—
Non-cash interest expense on liability related to sale of future royalties	256,295	—
Changes in operating assets and liabilities:		
Other receivables	430,325	573,401
Prepaid expenses	2,923,497	86,053
Deposits	(57,063)	(1,752,975)
Other current assets	—	(831,379)
Other non-current assets	30,653	(24,764)
Operating lease liabilities	(359,171)	(294,151)
Accounts payable	(2,336,871)	2,959,446
Accrued expenses	(1,207,805)	(6,068,350)
Interest payable	385,432	—
Deferred grant funding	(3,986,794)	(2,641,232)
Deferred revenue - current	—	205,206
Net cash provided by (used in) operating activities	167,637	(30,677,749)
Cash flows from investing activities		
Purchases of property and equipment	(10,197)	(22,099)
Net cash used in investing activities	(10,197)	(22,099)
Cash flows from financing activities		
Net proceeds from issuance of common stock and common stock warrants	398,091	8,560,897
Proceeds from the exercise of common stock warrants	—	1,299,375
Repayment of liability on sale of future royalties	(1,910)	—
Issuance of note payable	561,663	601,174
Payments on note payable	(392,002)	(133,594)
Net cash provided by financing activities	565,842	10,327,852
Effect of exchange rate changes on cash and cash equivalents	(1,729)	(68,185)
Net change in cash and cash equivalents	721,553	(20,440,181)
Cash and cash equivalents, beginning of period	10,811,056	34,669,605
Cash and cash equivalents, end of period	$ 11,532,609	$ 14,229,424
Reconciliation of cash, cash equivalents and restricted cash to amounts reported in the consolidated balance sheets:		
Cash and cash equivalents	$ 11,232,609	13,894,424
Restricted cash included in other non-current assets	300,000	335,000
Total cash, cash equivalents and restricted cash	$ 11,532,609	$ 14,229,424
Supplemental disclosure of non-cash investing and financing activities:		
Operating right-of-use assets obtained in exchange for new operating lease liabilities, net	$ 358,315	$ —
Additions to property and equipment and reduction of deposits	$ 676,041	$ —

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, sexual health, pelvic pain, fertility, infectious disease and menopause, and aim to expand treatment options, enhance outcomes and improve ease of use for women.

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 portfolio includes drug and drug/device product candidates and potential product candidates in various stages of development.

The first U.S. Food and Drug Administration (FDA)-approved product to emerge from the Company's portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO. 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, which became fully effective in June 2022. Under the license agreement, Organon (and/or its affiliates, agents or sublicensees) is solely responsible for the marketing, distribution and sale of XACIATO in the United States (and outside the U.S. if approved in non-U.S. jurisdictions in the future). Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023 and, in January 2024, Organon announced that XACIATO was available nationwide.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying 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, 2023, or the 2023 10-K.

Reclassifications

Certain reclassifications have been made to the Company's prior year amounts to conform to the current year presentation.

Reverse Stock Split

The Company effected a 1-for-12 reverse split of its issued common stock on July 1, 2024. At the effective time of the reverse stock split, every 12 shares of the Company's common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split did not change the number of authorized shares or the par value per share of the Company's common stock. See Note 4, Stockholders' Equity, for additional information regarding the reverse stock split.

All common stock share and per share data presented in the accompanying condensed consolidated financial statements have been retroactively adjusted to reflect the impact of the reverse stock split for all periods presented, without giving effect to whole shares issued in lieu of fractional shares. In addition, proportionate adjustments were made in accordance with the applicable terms of outstanding stock options and warrants, the Company's stock incentive plans and an existing agreement to the (a) per share exercise prices of, and the number of shares underlying, the Company's outstanding stock options, (b) number of shares available for the grant of awards under the Company's stock incentive plans, and (c) per share exercise prices of, and the number of shares underlying, outstanding warrants to purchase shares of the Company's common stock and warrants potentially issuable by the Company in its sole discretion pursuant to an existing agreement.

Cash and Cash Equivalents

The Company considers cash and all highly liquid investments with an original maturity of three months or less to be cash and cash equivalents. The Company has an aggregate of approximately $0.3 million in restricted cash as of September 30, 2024 and December 31, 2023, related to (i) letters of credit established under real property leases for the Company's wholly-owned subsidiary, Dare MB Inc., that serve as security for potential future default of lease payments, and (ii) collateralized cash for the Company's credit cards. The restricted cash is unavailable for withdrawal or for general obligations and is included in other non-current assets on the Company's consolidated balance sheet.

Going Concern

The Company prepared its condensed 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, net losses, and negative cash flows from operations and expects significant losses from operations, net losses and negative cash flows from operations 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 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 the Company's ability to continue as a going concern.

As of September 30, 2024, the Company had an accumulated deficit of approximately $169.8 million, unrestricted cash and cash equivalents of approximately $11.2 million, deferred grant funding liabilities under the Company's grant agreements related to DARE-LARC1 and its bacteria-based live biotherapeutic product of approximately $9.8 million, and working capital of approximately $1.8 million. The Company's cash and cash equivalents at September 30, 2024 includes grant funds received under such agreements that may be applied solely toward direct costs for the development of DARE-LARC1 and its bacteria-based live biotherapeutic product, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support the entire operations of the Company. For the nine months ended September 30, 2024, the Company incurred a loss from operations of approximately $18.1 million and reported net income of approximately $1.5 million and cash flow from operations of approximately $0.2 million. The Company's net income and cash flow from operations for the nine months ended September 30, 2024 were positively impacted by the approximately $20.4 million of net proceeds the Company received from the sale in April 2024 of its rights to future royalty and milestone payments and revenue. See below and Note 8, Royalty Purchase Agreements.

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 condensed consolidated financial statements. The Company will need to raise substantial additional capital to continue to fund its operations and to successfully execute its current strategy.

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. 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 these uncertainties.

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 to the consolidated financial statements included in the 2023 10-K. Since the date on which the 2023 10-K was filed with the U.S. Securities and Exchange Commission, or the SEC, there have been no material changes to the Company's significant accounting policies except for as follows:

Sale of Future Payments

On April 29, 2024, the Company entered into and closed a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (US) LLC ("XOMA") pursuant to which the Company sold its right, title and interest in the following to XOMA (i) all future net royalty and potential net milestone payments the Company would otherwise receive from Organon based on net sales of XACIATO, (ii) a portion of future net sales of Ovaprene and a portion of a potential future milestone payment the Company may receive under its license agreement with Bayer related to Ovaprene, and (iii) a portion of future net sales of Sildenafil Cream. The Company received $22.0 million from XOMA in connection with entering into the royalty purchase agreements. Under the terms of the royalty purchase agreements, if XOMA receives total payments under the royalty purchase agreements equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the royalty purchase agreements. If the Company earns any such payments, they will be accounted for as variable consideration under ASC 606, *Revenue Recognition,* and will be recorded as income when such payments are received. See Note 8, Royalty Purchase Agreements for additional information regarding the terms of the royalty purchase agreements.

The Company evaluated the expected cash flows to XOMA from royalties and milestone payments expected to be earned on XACIATO, Ovaprene and Sildenafil Cream over the period that the Company expects it will take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements, and determined to allocate the $22.0 million it received from XOMA in connection with entering into the royalty purchase agreements, net of transaction costs of approximately $1.6 million, to the traditional royalty purchase agreement for XACIATO, and none of it to the synthetic royalty purchase agreement for Ovaprene and Sildenafil Cream. The cash flows to XOMA from royalties and milestone payments expected to be earned on Ovaprene and Sildenafil Cream are expected to be de minimis over the period that the Company expects it will take for XOMA to receive total payments of $88.0 million under the royalty purchase agreements because, unlike XACIATO, Ovaprene and Sildenafil Cream are still in development stage and not commercial assets.

The Company determined that the traditional royalty purchase agreement represents a complete sale of a nonfinancial asset (the Company's right, title and interest in and to future payments related to commercial sales of XACIATO) for which XOMA bears all benefit and for which the Company has no obligations or involvement going forward, and therefore should be accounted for within the scope of Accounting Standards Codification ("*ASC") 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets*. The $22.0 million net of transaction costs of approximately $1.6 million was recorded as other income on the Company's condensed consolidated statements of operations and comprehensive income (loss).

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 September 30, 2024 and December 31, 2023. 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 September 30, 2024 or December 31, 2023.

	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Balance at September 30, 2024				
Current assets:				
Cash equivalents [1]	$ 10,618,835	$ —	$ —	$ 10,618,835
Balance at December 31, 2023				
Current assets:				
Cash equivalents [1]	$ 9,982,079	$ —	$ —	$ 9,982,079

[1] Represents cash held in money market funds.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2024-3, Disaggregation of Income Statement Expenses. ASU 2024-3 requires new financial statement disclosures in tabular format, disaggregating information about prescribed categories underlying any relevant income statement expense captions. ASU 2024-3 is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Upon adoption, ASU 2024-03 may be applied prospectively or retrospectively. The Company is evaluating the disclosure impact of ASU 2024-03 on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. ASU 2023-09 will be effective for annual periods beginning January 1, 2025 and will be applied on a prospective basis with the option to apply the standard retrospectively. The Company is evaluating the disclosure impact of ASU 2023-09 on its consolidated financial statements.

In November 2023, the FASB, issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company is evaluating the disclosure impact of ASU 2023-07 on its consolidated financial statements.

The Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the condensed consolidated financial statements.

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 which became effective in June 2022, whereby Organon licensed 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. In July 2022, the Company received a $10.0 million non-refundable and non-creditable payment from Organon, which was recorded as license fee revenue. In July 2023, the Company received a $1.0 million payment from Organon in connection with the amendment to the license agreement the parties entered into, which was also recorded as license fee revenue. In the fourth quarter of 2023, in connection with the first commercial sale in the U.S. of XACIATO in accordance with the license agreement, as amended, the Company received the $1.8 million milestone payment from Organon.

Under the terms of the license agreement, as amended, the Company is entitled to receive tiered double-digit royalties based on net sales and up to $180.0 million in tiered commercial sales milestones and regulatory milestones. Royalty payments will be subject to customary reductions and offsets.

At the inception of the license agreement, the Company concluded that the transaction price was $10.0 million and should not include the variable consideration related to unachieved development, regulatory, commercial milestones and future sales-based royalty payments. This consideration was determined to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. As a result of the $1.0 million payment in connection with the license agreement amendment and the $1.8 million milestone payment noted above, the transaction price was $12.8 million as of September 30, 2024.

The Company will recognize any consideration related to sales-based payments, including milestones and royalties which relate predominantly to the license granted, at the later of (i) when or as 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).

Refer to Note 8, Royalty Purchase Agreements, regarding the Company's sale to XOMA of all the Company's right, title and interest in and to, from and after April 1, 2024, all net royalty and potential net milestone payments from Organon based on net sales of XACIATO.

The Company was responsible for regulatory interactions and for providing product supply on an interim basis until Organon assumed such responsibilities, which occurred in December 2023. Prior to that time, Organon purchased 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.

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, 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.

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. The Company is responsible for the pivotal trial for Ovaprene and for its development and regulatory activities and has product supply obligations. 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 $20.0 million fee. After payment of the $20.0 million fee, Bayer will be responsible for the commercialization of Ovaprene for human contraception in the U.S. Such license would be exclusive as 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 (i) 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 (ii) the termination of the agreement. As of September 30, 2024, neither of the foregoing had occurred. The $1.0 million payment is recorded as long-term deferred license revenue in the Company's consolidated balance sheets at September 30, 2024 and December 31, 2023.

If Bayer elects to make the license effective, 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 the 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.

Refer to Note 8, Royalty Purchase Agreements, regarding XOMA's rights to a portion of potential future payments from Bayer under the Company's license agreement with Bayer.

The initial term of the agreement, which is subject to automatic renewal terms, continues until the later of the expiration of any valid claim covering the manufacture, use, sale or import of Ovaprene in the U.S. or 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 $20.0 million fee if and when due.

Strategic Agreements for Pipeline Development

Douglas License Agreement / The University of Manchester Stand-by Direct License Arrangement

In August 2023, the Company entered into a license agreement with Douglas Pharmaceuticals Limited, or Douglas, under which the Company acquired the exclusive rights to develop and commercialize a lopinavir and ritonavir combination soft gel vaginal insert for the treatment of cervical intraepithelial neoplasia and other HPV-related pathologies, and an agreement with The University of Manchester, pursuant to which The University of Manchester consented to Douglas' sublicense to the Company of certain rights it previously granted to Douglas and agreed to grant the Company a direct license to such rights if its license agreement with Douglas is terminated. Under the Company's agreement with Douglas, it received an exclusive, royalty-bearing license to research, develop and commercialize the licensed intellectual property in the United States for the treatment or prevention of all indications for women in female reproductive health. As a result of this license, the Company commenced its DARE-HPV program. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the Douglas agreement, the Company agreed to make potential future payments of up to $5.25 million in the aggregate upon achievement of certain development and regulatory milestones, and of up to $64.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement. The development and regulatory milestones may be paid in shares of the Company's common stock, in the Company's sole discretion subject to specified limitations. Additionally, Douglas is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on annual net sales of products and processes covered by the licenses granted under the agreement. As of September 30, 2024, no payments had been made under the Douglas agreement.

Hennepin License Agreement

In August 2022, the Company entered into a license agreement with Hennepin Life Sciences LLC, or Hennepin, under which the Company acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of health conditions including bacterial, fungal, and viral infections. As a result of this license, the Company commenced its DARE-GML program. Under the agreement, the Company received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. The Company is entitled to sublicense the rights granted to it under the agreement.

Under the terms of the license agreement, the Company agreed to make potential future payments of up to $6.25 million in the aggregate upon achievement of certain development and regulatory milestones, and up to $45.0 million in the aggregate upon achievement of certain commercial sales milestones for each product covered by the licenses granted under the agreement, which may be paid, in the Company's sole discretion, in cash or shares of the Company's common stock. Additionally, Hennepin is eligible to receive tiered royalties in low single-digit to low double-digit percentages based on worldwide net sales of products and processes covered by the licenses granted under the agreement. As of September 30, 2024, no payments have been made under this agreement.

MBI Acquisition

In November 2019, the Company acquired Dare MB 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.

Under the terms of the merger agreement, the Company agreed to pay 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 the Company acquired in the merger; and (c) tiered royalty payments ranging from low single-digit to low double-digit percentages based on annual net sales of such products sold by the Company (but not by sublicensee) and a percentage of sublicense revenue related to such products.

In June 2021, a total of $1.25 million of the contingent consideration became payable upon the achievement of certain of the funding and product development milestone events. In accordance with the terms of the merger agreement, the Company's board of directors elected to pay a portion of these milestone payments in shares of the Company's common stock, and in September 2021, the Company issued approximately 58,334 shares of its common stock to former stockholders of MBI and paid $75,000 in cash to the stockholders' representative in satisfaction of the $1.25 million in milestone payments associated with milestones achieved in June 2021.

TriLogic and MilanaPharm License Agreement / Hammock Assignment Agreement

In December 2018, the Company entered into an Assignment Agreement with Hammock Pharmaceuticals, Inc., or the Assignment Agreement, and 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. In December 2019, the Company entered into amendments to each of the Assignment Agreement and License Amendment. In September 2021, the Company entered into a second amendment to the License Agreement. In March 2022, the Company entered into a Consent, Waiver and Stand-By License Agreement with TriLogic, MilanaPharm and Organon, which further amended the License Agreement.

Under the terms of the License Agreement, the Company paid clinical and regulatory development milestones of $300,000 in the aggregate to MilanaPharm, the final payment of which was made in 2021, and $500,000 in connection with the first commercial sale in the United States of XACIATO in the fourth quarter of 2023. Additionally, the Company may pay up to $250,000 upon the first commercial sale in the United States of successive licensed products for each vaginal or urological use. In addition, upon achievement of $50.0 million in cumulative worldwide net sales of licensed products the Company must pay MilanaPharm $1.0 million. MilanaPharm is also eligible to receive (a) 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, and (b) high single-digit to low double-digit royalties based on annual worldwide net sales of licensed products and processes.

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. Hammock is eligible to receive up to $1.1 million in the aggregate upon achievement of certain clinical and regulatory development milestones, $850,000 of which had been paid as of September 30, 2024.

Pear Tree Acquisition

In May 2018, the Company acquired Pear Tree Pharmaceuticals, Inc., or Pear Tree, to secure exclusive, sublicensable, worldwide rights under certain patents and know-how to develop and commercialize a proprietary formulation of tamoxifen for vaginal administration. This acquisition led to the Company's DARE-VVA1 program.

Under the terms of the merger agreement, the Company agreed to pay the former stockholders of Pear Tree: (a) up to $15.5 million in the aggregate upon achievement of certain clinical development and regulatory milestones by licensed products, and (b) up to $47.0 million in the aggregate upon achievement of certain commercial milestones by licensed products. Additionally, the former stockholders of Pear Tree are eligible to receive tiered royalties based on single-digit to low double-digit percentages of annual net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, and a portion of royalties the Company receives from sublicensees. Both the milestone and royalty payments may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the merger agreement. Under the merger agreement, in addition to customary royalty reductions and offsets, royalty payments and payments based on income received from sublicensees of licensed products made by the Company to Pear Tree's licensors are creditable against all royalty and sublicense revenue share payments payable to the former stockholders of Pear Tree. As of September 30, 2024, no payments have been made under this agreement.

The Company agreed to pay licensors of Pear Tree (a) up to approximately $3.2 million in the aggregate upon achievement of certain clinical development, regulatory and commercial milestones by each licensed product, and (b) semi-annual royalties based on a single-digit percentage of net sales of licensed products by the Company or its affiliates, subject to customary reductions and offsets, or a portion of any royalties the Company or its affiliates receives from sublicensees, and a low double-digit percentage of all sublicensing fees or other lump sum payments or compensation the Company receives from sublicensees, subject to customary exclusions. The milestone payments to the licensors of Pear Tree may be made, in the Company's sole discretion, in cash or in shares of its common stock in accordance with the terms of the license agreements. Portions of certain milestone payments made to Pear Tree's licensors may be creditable against royalty payments due to Pear Tree's licensors.

Catalent JNP License Agreement

In April 2018, the Company entered into an exclusive license agreement with Catalent JNP, Inc., or 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. As a result of this license agreement, the Company commenced its DARE-HRT1, DARE-FRT1 and DARE-PTB1 programs. The Company is entitled to sublicense the rights granted to it under this agreement.

Under the terms of the license agreement, the Company paid a $250,000 non-creditable upfront license fee to Catalent in connection with the execution of the agreement and will pay a $100,000 annual license maintenance fee on each anniversary of the date of the agreement. The annual maintenance fee 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. Catalent is eligible to receive up to (a) $13.5 million in the aggregate in payments based on the achievement of specified development and regulatory milestones, $1.0 million of which had been paid as of September 30, 2024; and (b) up to $30.3 million in the aggregate in payments based on the achievement of specified commercial sales milestones for each product or process covered by the licenses granted under the agreement. Additionally, Catalent is eligible to receive 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.

Adare Development and Option Agreement

In March 2018, the Company entered into an exclusive development and option agreement with Adare Pharmaceuticals USA, Inc., or Adare, for the development and potential exclusive worldwide license of injectable formulations of etonogestrel for contraceptive protection over 6-month and 12-month periods (which the Company refers to as DARE-204 and DARE-214, respectively). The agreement, as amended, provides the Company with an option to negotiate an exclusive, worldwide, royalty-bearing license, with rights to sublicense, for the programs if the Company funds the conduct of specified development work. The Company has no obligation to exercise its option.

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 treatment of female sexual arousal disorder and/or female sexual interest/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.

SST will be eligible to receive payments of up to $18.0 million in the aggregate upon achievement of certain clinical and regulatory milestones in the U.S. and worldwide, and up to $100.0 million in the aggregate upon achievement of 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. Additionally, SST is eligible to receive tiered royalties based on percentages of annual net sales of licensed products in the single-digit to mid double-digits subject to customary royalty reductions and offsets, and a percentage of sublicense revenue. As of September 30, 2024, no payments have been made under this agreement.

ADVA-Tec License Agreement

In March 2017, the Company entered into a license agreement with ADVA-Tec, Inc., or ADVA-Tec, under which the Company was granted the exclusive right to develop and commercialize Ovaprene for human contraceptive use worldwide.

Under the terms of the license agreement, the Company will pay ADVA-Tec (a) up to $14.6 million in the aggregate based on the achievement of specified development and regulatory milestones, $1.2 million of which has been paid; and (b) up to $20.0 million in the aggregate based on the achievement of certain worldwide net sales milestones.

Additionally, ADVA-Tec is eligible to receive 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, subject to customary reductions and offsets.

If the Company sublicenses its rights under the agreement, in lieu of royalty payments to ADVA-Tec, ADVA-Tec is eligible to receive a double-digit percentage of sublicense revenue received by the Company during the royalty term; provided, however, that for sublicense revenue the Company receives prior to the first commercial sale of a licensed product that represents an upfront payment or license fee due on or around the effective date of the sublicense, ADVA-Tec is eligible to receive a single-digit percentage of that sublicense revenue. As of September 30, 2024, only the $1.2 million in aggregate milestone payments noted above have been made.

4. STOCKHOLDERS' EQUITY

Reverse Stock Split

On July 1, 2024, the Company effected a 1-for-12 reverse split of its issued common stock. At the effective time of the reverse stock split, every 12 shares of the Company's common stock was automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split reduced the number of issued and outstanding shares of the Company's common stock from approximately 101.1 million to approximately 8.5 million. The reverse stock split did not change the number of authorized shares or the par value per share of the Company's common stock.

September 2023 Registered Direct Offering

In August 2023, the Company entered into a securities purchase agreement with an institutional investor and an investor affiliated with Douglas for the purchase and sale of 833,334 shares of the Company's common stock and warrants to purchase additional shares of the Company's common stock in a registered direct offering priced at-the-market under Nasdaq rules. The offering closed on September 1, 2023. Each warrant is exercisable for one share of the Company's common stock. The terms of the warrants are further described below in this Note 4. The offering price was $8.40 per share of common stock and accompanying warrant. The aggregate gross proceeds to the Company from the offering were $7.0 million, and net proceeds were approximately $7.0 million. The offering was made pursuant to the Company's registration statement on Form S-3 (File No. 333-254862), filed with the SEC on March 30, 2021, and declared effective by the SEC on April 7, 2021, and a prospectus supplement thereunder.

March 2023 ATM Sales Agreement

In March 2023, the Company entered into a sales agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, and Cantor Fitzgerald & Co., or Cantor, to sell shares of its common stock from time to time through an "at-the-market," or ATM, equity offering program under which Stifel and Cantor act 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 or such lower amount as the Company and Stifel and Cantor agree, plus certain legal expenses. In April 2024, we mutually agreed with Cantor to terminate the Sales Agreement with respect to Cantor. Through and including May 10, 2024, shares of the Company's common stock sold under the agreement were offered and sold under the Company's shelf registration statement on Form S-3 (File No. 333-254862), the base prospectus included therein, originally filed with the SEC on March 30, 2021 and declared effective by the SEC on April 7, 2021, and the prospectus supplements thereto, the most recent of which was dated March 28, 2024 relating to the offering of up to $19.0 million of shares of the Company's common stock. From and after May 11, 2024, shares of the Company's common stock sold under the agreement were and will be offered and sold under the Company's shelf registration statement on Form S-3 (File No. 333-278380), the base prospectus included therein, originally filed with the SEC on March 29, 2024 and declared effective by the SEC on May 10, 2024, the prospectus supplement thereto dated May 10, 2024 relating to the offering of up to $18.1 million of shares of the Company's common stock, and any subsequent prospectus supplement related to the offering of shares of the Company's common stock under the sales agreement. During the nine months ended September 30, 2024 and 2023, the Company sold 93,247 and 176,113 shares of common stock, respectively, under this agreement for net proceeds of approximately $0.4 million and $1.7 million, respectively.

Common Stock Warrants

December 2023 Warrants

In connection with the royalty interest financing agreement the Company entered into in December 2023, the Company issued a warrant to purchase up to an aggregate of 422,805 shares of the Company's common stock. The warrant has a term of five years from the date of issuance and an exercise price of $4.10 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise. The warrant includes certain rights in favor of the holder upon a “fundamental transaction” as described in the warrant, including the right of the holder to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrant on the date of the consummation of such fundamental transaction.

The warrant was allocated a value of $0.8 million using a Black-Scholes option pricing model based on the relative fair value method. The Black-Scholes model used the following assumptions: expected volatility: 85.91%; risk-free interest rate: 4.05%; expected dividend yield: 0%; and expected term: 5 years. The warrant was deemed to be classified as equity and recorded within additional paid in capital on the 2023 consolidated balance sheet. As of September 30, 2024, no portion of the warrant has been exercised.

September 2023 Warrants

In connection with the registered direct offering completed in September 2023, the Company issued warrants to purchase up to an aggregate of 845,225 shares of the Company's common stock. The warrants became exercisable on March 1, 2024, expire March 1, 2029 and have an exercise price of $9.11 per share, subject to customary adjustment for stock splits and similar transactions. A holder (together with its affiliates) may not exercise any portion of a warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise. The warrants include certain rights in favor of the holders upon a “fundamental transaction” as described in the warrants, including the right of the holders to receive from the Company or the successor entity an amount of cash equal to the Black-Scholes value (as described in the warrants) of the unexercised portion of the warrants on the date of the consummation of such fundamental transaction.

The warrants were allocated a value of $2.9 million using a Black-Scholes option pricing model based on the relative fair value method as they were issued with common stock. The Black-Scholes model used the following assumptions: expected volatility: 87.77%; risk-free interest rate: 4.29%; expected dividend yield: 0%; and expected term: 5.5 years. The warrants were deemed to be classified as equity and recorded within additional paid in capital on the 2023 consolidated balance sheet. As of September 30, 2024, none of the warrants have been exercised.

February 2018 Warrants

In connection with an underwritten public offering in February 2018, the Company issued to the investors in that offering, warrants exercisable through February 2023 with an initial exercise price of $36.00 per share. 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 warrants included a price-based anti-dilution provision, which resulted in automatic reductions to the exercise price of the warrants in April 2019 and July 2020 to $11.76 per share and $11.52 per share, respectively. In January 2023, February 2018 warrants to purchase 112,793 shares of common stock were exercised for gross proceeds of approximately $1.3 million and the remaining unexercised February 2018 warrants expired on February 15, 2023.

Summary of Warrant Activity

A summary of warrant activity during the nine months ended September 30, 2024 is presented below:

	Common Stock			
	Number of Shares Underlying Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value
Outstanding December 31, 2023,	1,268,572	$ 7.49	5.17	$ —
Granted	—	—		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding and exercisable September 30, 2024,	1,268,572	$ 7.49	4.42	$ —

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. In June 2024, the Company's board of directors suspended the ESPP. There was no stock-based compensation related to the ESPP for the nine months ended September 30, 2024 or September 30, 2023.

Amended and Restated 2014 Stock Incentive Plan

The Amended and Restated 2014 Stock Incentive Plan, or the Amended 2014 Plan, provided for the grant of stock-based awards to employees, directors, consultants and advisors. As a result of the approval of the 2022 Plan (as defined below) by the Company's stockholders on June 23, 2022, no further awards have been or will be granted under the Amended 2014 Plan since June 23, 2022. Outstanding awards previously granted under the Amended 2014 Plan continue to remain outstanding in accordance with their terms.

2022 Stock Incentive Plan

In April 2022, the Company's board of directors approved the Daré Bioscience, Inc. 2022 Stock Incentive Plan, or the 2022 Plan, which was subsequently approved by the Company's stockholders on June 23, 2022, and became effective as of that date. The 2022 Plan provides for the grant of stock-based incentive awards to employees, directors, consultants, and advisors.

The number of shares of common stock authorized for issuance under the 2022 Plan is (a) 843,108; plus (b) up to 512,056 shares subject to awards granted under the Amended 2014 Plan or the 2007 Stock Incentive Plan that expire, terminate or are otherwise forfeited on or after June 23, 2022.

Summary of Stock Option Activity

The table below summarizes stock option activity under the Company's stock incentive plans and related information for the nine months ended September 30, 2024. The exercise price of all options granted during the nine months ended September 30, 2024 was equal to the market value of the Company's common stock on the date of grant. As of September 30, 2024, unamortized stock-based compensation expense of approximately $2.8 million will be amortized over a weighted average period of 1.15 years. The number of shares of common stock available for future awards granted under the 2022 Plan as of September 30, 2024 was 445,661.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value*
Outstanding at December 31, 2023	788,569	$ 17.50	7.51	$ —
Granted	224,530	5.48		—
Exercised	—	—		—
Cancelled/forfeited	(56,537)	11.81		—
Expired	(53,138)	19.97		—
Outstanding at September 30, 2024	903,424	$ 14.73	7.36	—
Exercisable at September 30, 2024	558,443	$ 17.20	6.53	—

**The aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the stock options at* September 30, 2024 *for those stock options for which the quoted market price was in excess of the exercise price.*

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2024 was $4.16.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 200,231	$ 207,081	$ 623,752	$ 617,580
General and administrative	323,346	429,006	1,090,244	1,293,313
Total	$ 523,577	$ 636,087	$ 1,713,996	$ 1,910,893

6. LEASED PROPERTIES

Clean Room Space

On July 24, 2024, the Company entered into a scope of work (the "SOW") with an unrelated third party for a controlled clean room space in Burlington, Massachusetts. The SOW will become effective upon the execution of an associated License and Services Agreement, which will govern the SOW. The term of the SOW is 22 months and is expected to commence on March 1, 2025. Upon execution of the SOW, the Company made a payment of approximately $459,000. Fixed payments will be due at the beginning of each calendar quarter and variable amounts related to support services will be due monthly based on services provided during the preceding month. The Company's total obligation in respect of the fixed payments due under the SOW is approximately $3.5 million. The SOW may be renewed each year and if renewed, the fixed payment amount may increase yearly by up to 5%.

General Office Space

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 through August 31, 2024. On March 8, 2024, the Company entered into another amendment to extend the term of the lease for three years such that the term now expires on October 31, 2027, and resulted in additional operating lease liabilities and ROU assets of approximately $0.4 million in March 2024.

MBI leased general office space in Lexington, Massachusetts. The lease for that space commenced on July 1, 2013. In February 2022, the Company entered into an amendment to extend the term of the lease for three years to December 31, 2025, subject to the landlord's right to terminate the lease on December 31, 2023, which right was exercised by the landlord in September 2022. MBI entered into a new lease for general office space and laboratory space in June 2023 that commenced on November 1, 2023 for three years, expiring on December 31, 2026, and resulted in an increase in operating lease liabilities and ROU assets of approximately $1.3 million in November 2023.

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 consisting of the current prime rate plus 200 basis points for operating leases. The depreciable lives of operating leases and leasehold improvements are limited by the expected lease term.

At September 30, 2024, the Company reported operating lease ROU assets of approximately $1.3 million in operating lease ROU assets in the condensed consolidated balance sheets.

Total operating lease costs were approximately $194,000 and $585,000 for the three and nine months ended September 30, 2024, respectively, and $125,000 and $409,000 for the three and nine months ended and September 30, 2023, 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 $160,000 and $479,000 for the three and nine months ended September 30, 2024, and $105,516 and $314,774 for the three and nine ended September 30, 2023, respectively, and these amounts are included in operating activities in the condensed consolidated statements of cash flows. At September 30, 2024, operating leases had a weighted average remaining lease term of 2.67 years and a weighted average interest rate of 10.50%.

As of September 30, 2024, future minimum lease payments under the Company's operating leases are as follows:

Remainder of 2024	$ 137,000
2025	660,000
2026	680,000
2027	130,000
Total future minimum lease payments	1,607,000
Less: accreted interest	203,000
Total operating lease liabilities	$ 1,404,000

7. ROYALTY INTEREST FINANCING

On December 21, 2023, the Company entered into a royalty interest financing agreement, or the Royalty Interest Agreement, with United in Endeavour, LLC, or UiE, under which UiE acquired a portion of the Company's royalty interest in XACIATO. The Company received $5.0 million from UiE when the parties entered into the Royalty Interest Agreement (the "Initial Investment"), and between January 1, 2024 and December 31, 2026, the Company may, in its sole discretion but subject to XOMA's prior written consent (see Note 8, Royalty Purchase Agreements), elect to receive three additional payments (each a "Supplemental Investment") from UiE of up to an aggregate of $7.0 million, for a total of up to $12.0 million.

Under the Royalty Interest Agreement, the Company agreed to make the following payments to UiE, until such time when UiE has received aggregate payments equaling a 12% internal rate of return (the “IRR”) on the Initial Investment and each Supplemental Investment, if any (the "Hard Cap"): (i) from December 21, 2023 through December 31, 2025, 50% of the amount of royalty payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the royalty payments generated and received by the Company on net sales of XACIATO by Organon have been deducted (the “Net Royalty Payments”), (ii) from January 1, 2026 through December 31, 2029, 75% of the Net Royalty Payments, and (iii) from December 21, 2023 through December 31, 2029, 10% of the amount of milestone payments remaining after all amounts that are due and payable and actually paid by the Company to any licensor or sublicensee on the milestone payments generated and received by the Company on net sales of XACIATO by Organon have been deducted. After December 31, 2029, the Company will be required to make certain additional payments to UiE to the extent UiE has not received payments equaling the Hard Cap by December 31, 2029, December 31, 2033, and December 31, 2034, respectively. In addition, if UiE has not received payments equaling the Hard Cap by December 31, 2035 and the Company has other sources of assets or income besides XACIATO sufficient to complete such payments, the Company has agreed to pay UiE quarterly payments evenly divided over a two-year term, such that UiE will have obtained the IRR, taking into account all other payments received by UiE from the Company under the Royalty Interest Agreement. UiE’s right to receive payments will terminate when UiE has received payments in an amount equal to the Hard Cap.

The Company evaluated the terms of the Royalty Interest Agreement and concluded that the features of the Royalty Interest Agreement were similar to those of a debt instrument. As a result, the Company applied the debt recognition guidance under ASC 470, Debt, and recorded the Initial Investment as a liability related to the sale of future royalties (“Royalty Obligation”) on the Company's 2023 consolidated balance sheet, which will be amortized under the effective interest method over the estimated term of the Royalty Interest Agreement. If the Company elects to receive additional Supplemental Investments, such additional Supplemental Investments will also be recorded as a liability related to the sale of future royalties when they are received and amortized under the interest method over the estimated remaining term of the Royalty Interest Agreement. In addition, in accordance with ASC 470, Debt, the Company will account for any royalties received in the future as non-cash royalty revenue in the consolidated statements of operations as a reduction to the debt balance.

As royalties and milestone payments are received by or on behalf of the Company from Organon and the Company subsequently pays or causes to be paid the amounts due to UiE in respect thereof in accordance with the Royalty Interest Agreement, the Royalty Obligation will be effectively repaid during the term of the Royalty Interest Agreement. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future payments to UiE during the term of the Royalty Interest Agreement.

At execution of the Royalty Interest Agreement, the Company's estimate of this total interest expense resulted in an effective annual interest rate of approximately 22.48%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated amounts due and payable to UiE and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect XACIATO's commercial success, and therefore the amount and timing of the Company's payments to UiE, and correspondingly, the amount of interest expense recorded by the Company, most of which are not within the Company's control. Such factors include, but are not limited to, the capabilities of Organon and its commitment of sufficient resources to market, distribute and sell the product; timely and adequate commercial supply of the finished product and its components; perceived superiority of its cure rates compared to other available treatments; patient satisfaction and willingness to use it again and refer it to others; price pressure given the high level of generic treatments and changes in health care laws and regulations; adequate coverage, pricing and reimbursement from third-party payors; and approval of new entrants, including alternative, non-antibiotic treatment options. These factors could result in increases or decreases to both royalty revenues and interest expense.

Warrants

In connection with entering into the Royalty Interest Agreement, the Company issued to UiE a warrant (the "Initial Royalty Warrant") to purchase up to 422,804 shares of the Company's common stock. In addition, for every $1,000,000 of Supplemental Investment, the Company will issue a warrant to purchase 84,561 shares of common stock, for an aggregate of warrants to purchase up to 591,927 shares of common stock (collectively the "Additional Royalty Warrants," and together with the Initial Royalty Warrant, the "Royalty Interest Agreement Warrants").

The Royalty Interest Agreement Warrants are exercisable, in full or in part, at any time on or prior to the fifth anniversary of their issuance date at an exercise price of $4.10 per share, subject to customary anti-dilution adjustments. The Royalty Interest Agreement Warrants may be exercised for cash, or if at the time of exercise there is no effective registration statement registering for resale the shares underlying the Royalty Interest Agreement Warrants, then in lieu of paying the exercise price in cash, the holders may elect to exercise on a cashless basis.

The Royalty Interest Agreement Warrants were deemed to be equity classified warrants and recorded under additional paid in capital. The fair value of the Initial Royalty Warrant was determined to be $0.8 million (Note 4) and was recorded as a debt discount against the Initial Investment.

The following table shows the activity of the Royalty Obligation since the transaction inception through the period indicated:

	September 30, 2024
Upfront payment from the sale of future royalties	$ 5,000,000
Debt issuance cost	(276,101)
Relative fair value of Initial Royalty Warrant	(834,512)
Royalty payments	(65,633)
Non-cash interest expense and interest payable associated with the sale of future royalties	666,015
Liability related to the sale of future royalties	$ 4,489,769

8. ROYALTY PURCHASE AGREEMENTS

On April 29, 2024, the Company entered into a traditional royalty purchase agreement (the "XACIATO RPA"), and a synthetic royalty purchase agreement, (the "Synthetic RPA and together with the XACIATO RPA, the "Royalty Purchase Agreements") with XOMA pursuant to which XOMA paid $22.0 million to the Company. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million, XOMA will pay $11.0 million to the Company for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to the Company, the "Contingent Purchase Price Payments").

Under the Royalty Purchase Agreements, the Company sold, assigned, transferred and conveyed its right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments the Company would otherwise have the right to receive from and after April 1, 2024 under the Company's exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of the Company under its exclusive license agreement with third-party licensors TriLogic and MilanaPharm, and (ii) all payments due and payable and actually paid by or on behalf of the Company under the Royalty Interest Agreement between the Company and UiE (such net amount, the “Purchased Receivables”);

(b) 25% of the potential future $20.0 million payment that the Company would otherwise have the right to receive under the Company's license agreement with Bayer, if Bayer, in its sole discretion, elects to make the license granted thereunder effective following completion of the pivotal clinical trial of Ovaprene; and

(c) a synthetic royalty of 4.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of the Company's investigational product Ovaprene, and 2.0% of the Company's, its affiliates’ and its sublicensees’ future net sales of the Company's investigational product Sildenafil Cream, 3.6%; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent Purchase Price Payments made to the Company, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (such amounts described in the foregoing clauses (b) and (c), collectively, the “Revenue Participation Right”).

Pursuant to the XACIATO RPA, XOMA, at its sole cost and discretion, may repay in full and retire all of the Company's payment obligations to UiE under the Royalty Interest Agreement. If XOMA does so, no further amounts in respect of the Royalty Interest Agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the XACIATO RPA. As of April 29, 2024, the Company cannot elect to receive any additional funding from UiE under the Royalty Interest Agreement without XOMA’s prior written consent. In connection with the synthetic royalty purchase agreement, the Company granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream (Note 7).

The $22.0 million the Company received from XOMA, less transaction costs of approximately $1.6 million, was allocated to the XACIATO RPA and recorded as other income on the Company's consolidated statements of operations in the second quarter of 2024. See Note 2, Basis of Presentation and Summary of Significant Accounting Policies, for additional information.

9. COMMITMENTS AND CONTINGENCIES

Insurance Financing

In each of July 2024 and 2023, the Company obtained financing for certain director and officer and other insurance premiums. The total premiums, taxes and fees financed each year was approximately $0.6 million with an annual interest rate of approximately 8.0%. In consideration of the premium payment by the lender to the insurance companies or the agent or broker, the Company unconditionally promised to pay the lender the amount financed plus interest and other charges permitted under the agreements and the Company assigned to the lender a first priority lien on and a security interest in the financed insurance policies. With respect to the financing obtained in July 2024, the Company will make monthly installment payments through April 20, 2025. With respect to the financing obtained in July 2023, the Company made monthly installment payments through April 20, 2024. The financed amount is recognized as an insurance financing cost included in other current assets and accrued expenses in the Company's consolidated balance sheets. As of September 30, 2024, the Company's remaining obligation for the financing obtained in July 2024 was approximately $0.4 million. As of December 31, 2023, the Company's remaining obligation for the financing obtained in July 2023 was approximately $0.3 million. The Company had no remaining obligations for the financing obtained in July 2023 as of September 30, 2024.

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's 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 is responsible for the other costs related to the conduct of the Ovaprene Phase 3. The Company made aggregate payments of $5.5 million to NICHD, $0.5 million of which was paid in July 2024 and $5.0 million of which was paid in prior years. The Company had no remaining obligation under the CRADA at September 30, 2024.

10. 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 several of its product candidates. 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.

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 of approximately $300,000 was to be used for what is referred to as the "Phase I" segment of the project outlined in the Company's grant application. The Phase I segment ended in July 2023. The Company received aggregate reimbursements under the award of approximately $216,000 during the grant period which ended in July 2023. No further funds are available under this award for the Phase I segment.

In December 2023, the Company received a notice of award of approximately $2.0 million for the "Phase II" segment of the project. The Company recorded credits to research and development expense for costs related to the NICHD award of approximately $274,000 and $549,000 during the three and nine months ended September 30, 2024, respectively. At September 30, 2024, the Company recorded a receivable of approximately $92,000 for expenses incurred through such date that it believes are eligible for reimbursement under the grant. No receivable was recorded at December 31, 2023 as no expenses eligible for reimbursement were incurred through such date.

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 was to be used to explore device insertion and removal in nonclinical studies.

The Company recorded credits to research and development expense of approximately $32,000 for costs related to the NICHD award during the three and nine months ended September 30, 2023. The Company received aggregate reimbursements under the NICHD award of approximately $278,000 during the grant period, which ended in June 2023. No further funds are available under this award.

DARE-204 and DARE-214

In May 2022, the Company received a notice of award of a grant from NICHD of approximately $249,000 to support end-user research to better understand women's preferences for a long-acting injectable contraceptive method. The findings from the research will inform the Company's target product profile and guide its development priorities for DARE-204 and DARE-214.

The Company recorded credits to research and development expense of approximately $32,000 and $113,000 for costs related to the NICHD award during the three and nine months ended September 30, 2023, respectively. The Company received aggregate reimbursements under the NICHD award of approximately $249,000 during the grant period, which ended in September 2023. No further funds are available under this award.

DARE-PTB2

In July 2023, the Company received a notice of award of a grant from NICHD of approximately $385,000 to support preclinical development of a potential new therapeutic for the prevention of idiopathic preterm birth. The grant funds will support activities related to the conduct and completion of proof-of-concept target validation studies in collaboration with the University of South Florida, which are to occur over a 12-month period.

The Company recorded credits to research and development expense of approximately $17,000 and $285,000 for costs related to the NICHD award for the three and nine months ended September 30, 2024, respectively. The Company received aggregate reimbursements under the NICHD award of approximately $385,000 during the grant period, which ended in July 2024. No further funds are available under this award.

Other Non-Dilutive Grant Funding

As described below, the Company has received funding under grant agreements it entered into with the Bill & Melinda Gates Foundation, or the Foundation, in June 2021, November 2022, and January 2024. The Company is required to apply the funds it receives under the agreements solely toward direct costs for the applicable funded projects, other than approximately 5%-15% of such funds, which it may apply toward general overhead and administrative expenses that support the entire operations of the Company. The Company receives funding in advance and tracks and reports eligible expenses incurred to the Foundation. Funds received that have not been spent are recorded as cash and cash equivalents and as a deferred grant funding liability in the Company’s consolidated balance sheets. The deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. The grant agreements include the Foundation's standard discretionary termination provisions. Any grant funds that have not been used or committed to the funded project must be returned promptly to the Foundation upon expiration or termination of the agreement.

2021 DARE-LARC1 Grant Agreement

In June 2021, the Company entered into an agreement with the Foundation under which the Company was awarded up to $49.0 million to support the development of DARE-LARC1. The agreement, as amended, supports technology development and preclinical activities over the period of June 30, 2021 to November 1, 2026, to advance DARE-LARC1 in nonclinical proof of principle studies and other investigational new drug, or IND, enabling work to allow for the submission of an IND application with the FDA, approval of which will be required to commence testing in humans.

As of September 30, 2024, the Company has received a cumulative total of approximately $29.3 million in non-dilutive funding under the agreement, including $4.5 million during 2023 and $1.0 million during the three months ended June 30, 2024. Additional payments are contingent upon the DARE-LARC1 program's achievement of specified development and reporting milestones. The Company recorded credits to research and development expense of approximately $0.8 million and $4.8 million for costs related to this award for the three and nine months ended September 30, 2024, respectively, and $2.5 million and $7.0 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, the Company recorded approximately $9.7 million and $13.5 million, respectively, of deferred grant funding liability related to this award in the Company's condensed consolidated balance sheets.

2022 DARE-LBT Grant Agreement

In November 2022, the Company entered into an agreement with the Foundation under which the Company was awarded $585,000 to support the development of DARE-LBT over the period of November 11, 2022 to February 29, 2024.

The Company received the full amount of the award in November 2022. The Company recorded credits to research and development expense of approximately $0 and $0.2 million for costs related to this award for the three and nine months ended September 30, 2024, respectively, and approximately $80,000 and $109,000 for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, the Company recorded approximately $5,000 and $246,000 respectively, of deferred grant funding liability related to this award in the Company's condensed consolidated balance sheets.

2024 Biotherapeutic Product Grant Agreement

In January 2024, the Company entered into an agreement with the Foundation under which the Company was awarded $750,000 to fund activities related to bacteria-based live biotherapeutic product development. The Company received the full amount of the award in January 2024.

The Company recorded credits to research and development expense of approximately $0.3 million and $0.7 million for costs related to this award for the three and nine months ended September 30, 2024, respectively. As of September 30, 2024, the Company has recorded approximately $30,000 of deferred grant funding liability in the Company's condensed consolidated balance sheets.

11. NET INCOME (LOSS) PER SHARE

The Company computes basic net income (loss) per share, or EPS, using the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted EPS is based upon the weighted average number of common shares and potentially dilutive securities (common share equivalents) outstanding during the period. Dilutive securities include the dilutive effect of in-the-money options and warrants, which is calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option or warrant, the amount of compensation cost, if any, for future service that the Company has not yet recognized, and the amount of estimated tax benefits that would be recorded in paid-in capital, if any, when the option or warrant is exercised are assumed to be used to repurchase shares in the current period. Dilutive securities are excluded from the diluted EPS calculation if their effect is anti-dilutive.

The following potentially dilutive outstanding securities were excluded from diluted EPS for the period indicated because of their anti-dilutive effect:

Potentially dilutive securities	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options	903,424	788,657	903,424	788,657
Warrants	1,268,572	833,875	1,241,818	833,875
Total	2,171,996	1,622,532	2,145,242	1,622,532

12. SUBSEQUENT EVENTS

2024 Contraceptive Product Candidate Grant Agreement

On November 11, 2024, the Company entered into a grant agreement with the Foundation under which the Company was awarded a new grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country settings who need or would prefer to use such a product to avoid an unplanned pregnancy. An initial payment of approximately $5.4 million is due to the Company in 2024. Additional payments are contingent upon the Company's achievement of specified development and reporting milestones during the term of the grant agreement, which extends through October 2026. The Company will track and report eligible expenses incurred to the Foundation.

ARPA-H Non-Dilutive Grant Award

On October 23, 2024, the Company entered into a subaward agreement with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell (the "CMF") under which the Company is entitled to receive funding of up to $10.0 million in milestone-based payments subject to the Company's achievement over an approximately 24-month period of specified research activities and objectives relating to the advancement of the Company's DARE-HPV development program, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women. The subaward agreement was the result of the Company's selection by the Advanced Research Projects Agency for Health (“ARPA-H”), an agency within the U.S. Department of Health and Human Services, as an awardee of ARPA-H's Sprint for Women’s Health, which was announced by First Lady Jill Biden in February 2024 as the first major deliverable of the White House Initiative on Women’s Health Research. The CMF is a consortium management firm that received funding from ARPA-H for the subaward agreement.

Equity Line

On October 21, 2024, the Company entered into a purchase agreement and 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 has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of the Company’s common stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company’s sole discretion, over the 24-month period commencing on the date that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the purchase agreement is declared effective by the SEC and a final prospectus in connection therewith is filed and the other conditions in the Purchase Agreement are satisfied. In connection with entering into the purchase agreement, the Company issued 137,614 shares of its common stock to Lincoln Park in consideration for its commitment to purchase shares thereunder.

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, 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2023, or our 2023 10-K, filed with the Securities and Exchange Commission, or SEC, on March 30, 2023. 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 2023 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, sexual health, pelvic pain, fertility, infectious disease and menopause. 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.

The first FDA-approved product to emerge from our portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, or XACIATO (pronounced zah-she-AH-toe). We achieved FDA approval of XACIATO three years after acquiring rights to the program. XACIATO was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize XACIATO. In accordance with the license agreement, as amended, we are no longer working on the development, manufacture or commercialization of XACIATO. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023 and, in January 2024, Organon announced that XACIATO was available nationwide.

Our product pipeline includes diverse programs that target unmet needs in women's health in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease and menopause, 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 portfolio of product candidates. However, we also explore 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 five product candidates in advanced clinical development (Phase 2-ready to Phase 3):

- **Ovaprene®**, a hormone-free, monthly intravaginal contraceptive;
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the female genitalia on demand for the treatment of female sexual arousal disorder (FSAD);
- **DARE-HRT1**, an intravaginal ring designed to deliver both bio-identical estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe vasomotor symptoms, as part of menopausal hormone therapy;
- **DARE-VVA1**, a proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of vulvar and vaginal atrophy associated with menopause; and
- **DARE-HPV**, a proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of human papillomavirus (HPV)-related cervical diseases.

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

- **DARE-PDM1,** a proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea;
- **DARE-204** and **DARE-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively;
- **DARE-FRT1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for luteal phase support as part of an in vitro fertilization treatment plan; and
- **DARE-PTB1**, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth.

In addition, our portfolio includes five preclinical stage programs:

- **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;
- **DARE-LBT**, a novel hydrogel formulation for vaginal delivery of live biotherapeutics to support vaginal health;
- **DARE-GML**, an intravaginally-delivered potential multi-target antimicrobial agent formulated with glycerol monolaurate (GML), which has shown broad antimicrobial activity, killing bacteria and viruses;
- **DARE-RH1**, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and
- **DARE-PTB2**, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein.

The product candidates and potential product candidates in our portfolio will require review and approval from the FDA, or a comparable foreign regulatory authority, prior to being marketed or sold. See below and ITEM 1. "BUSINESS," in Part I of our 2023 10-K for additional information regarding our product candidates.

Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or 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. Until we secure additional capital to fund our operating needs, we will focus our resources primarily on advancement of Ovaprene and Sildenafil Cream. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 and DARE-HPV programs, but we also expect such expenses will be supported, with respect to DARE-LARC1, through at least 2026 by non-dilutive funding provided under a grant agreement we entered into in June 2021, and with respect to DARE-HPV, through October 2026 by non-dilutive funding provided under a subaward agreement we entered into in October 2024.

As discussed below, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. We are also subject to a number of other risks common to biopharmaceutical companies, including, but not limited to, dependence on key employees, reliance on third-party collaborators, service providers and suppliers, being able to develop commercially viable products in a timely and cost-effective manner, dependence on intellectual property we own or in-license and the need to protect that intellectual property and maintain those license agreements, uncertainty of market acceptance of products, uncertainty of third-party payor coverage, pricing and reimbursement for products, rapid technology change, intense competition, compliance with government regulations, product liability claims, and exposure to cybersecurity threats and incidents.

The process of developing and obtaining regulatory approvals for prescription drug and drug/device products in the United States and in foreign jurisdictions is inherently uncertain and requires the expenditure of substantial financial resources without any guarantee of success. To the extent we receive regulatory approvals to market and sell our product candidates, the commercialization of any product and compliance with subsequently applicable laws and regulations requires the expenditure of further substantial financial resources without any guarantee of commercial success. The amount of post-approval financial resources required for commercialization and the potential revenue we may receive from sales of any product will vary significantly depending on many factors, including whether, and the extent to which, we establish our own sales and marketing capabilities and/or enter into and maintain commercial collaborations with third parties with established commercialization infrastructure.

Ovaprene® Program Update

In December 2023, we announced commencement of the multi-center, single arm, non-comparative, pivotal Phase 3 clinical study of Ovaprene to evaluate its effectiveness as a contraceptive along with its safety and acceptability (ClinicalTrials.gov ID: NCT06127199). The study aims to enroll sufficient participants across approximately 20 study sites in the U.S. to have approximately 250 participants complete approximately 12 months (13 menstrual cycles) of use. Based on typical dropout rates for contraceptive efficacy studies, we will seek to enroll more than double the number of subjects we target to complete 13 menstrual cycles of use. Enrollment is currently proceeding at 10 study sites. Based on the current average enrollment rate, we anticipate that approximately 125 women, which is half of our target number of participants to complete the study, will complete approximately 6 months of Ovaprene use by the end of the second quarter of 2025. With the grant funds we expect to receive this year under the grant agreement we entered into in November 2024, we plan to add additional study sites, which we expect to accelerate the overall study timeline.

The primary objective of the study is to assess the typical use pregnancy rate over 13 menstrual cycles, or the estimated Pearl Index for Ovaprene. Secondary objectives are to assess Ovaprene's 13-cycle use cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and assessments of vaginal health. If successful, we expect the study to support the submission of a premarket approval application for Ovaprene to the FDA, as well as regulatory filings in Europe and other countries worldwide, to allow for marketing approvals of Ovaprene.

The Phase 3 study is being 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 NICHD, part of the NIH, 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 to NICHD to be applied toward the costs of conducting the Phase 3 study, all of which had been paid as of September 30, 2024. NICHD is responsible for the other costs related to the conduct of the Phase 3 study and for managing the payment of expenses to the contract research organization for the study, the clinical sites, and other parties involved with the study. Depending on the duration of the enrollment period and number of subjects enrolled in the Phase 3 study, there may be future costs associated with the study that are not reflected in the current budget under the CRADA. We and NICHD are in discussions regarding the CRADA, which may include discussing a mechanism to potentially provide for additional future payments by us in support of the Phase 3 study.

Sildenafil Cream, 3.6% Program Update

In 2023, we completed our exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6%, or Sildenafil Cream, in premenopausal women with FSAD and, in January 2024, we announced the successful completion of an end-of-Phase 2 meeting with the FDA. We and the FDA aligned on key elements of the Phase 3 program to support a new drug application, or NDA, filing, including confirming that FSAD is acceptable as an indication, the clinical trials can be conducted in a premenopausal-only FSAD population, and 12-weeks of blinded treatment to assess efficacy may be acceptable, provided that the trials are adequately powered for efficacy assessment. This is a shorter period of blinded treatment than the 24 weeks recommended in the FDA's 2016 draft guidance for industry on developing drugs for the treatment of low sexual interest, desire and/or arousal in women. Ongoing discussions with the FDA are focused on aligning on primary and secondary patient reported outcome endpoints for the Phase 3 pivotal trials of Sildenafil Cream, as well as additional information on data that may be needed in an NDA submission to appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration. We have also requested clarification on the safety database (size and duration exposure) that the FDA will require for an NDA submission. Initiating a Phase 3 study is contingent on aligning with the FDA regarding the foregoing. Based on FDA feedback we have received, two successful Phase 3 clinical studies of Sildenafil Cream will be required to support an NDA for Sildenafil Cream for the treatment of FSAD, and we anticipate that each Phase 3 study will be approximately $15.0 million in direct costs. We will take into account our capital resources before initiating a Phase 3 study.

Other Development Program Updates

We continue to work on the development of our other clinical and preclinical-stage programs, including:

- *DARE-HRT1*, conducting activities necessary to enable submission of an investigational new drug, or IND, application to the FDA for a pivotal Phase 3 clinical study of DARE-HRT1 for moderate-to-severe vasomotor symptoms;

- *DARE-VVA1*, conducting activities in preparation for a Phase 2 clinical study of DARE-VVA1 for moderate-to-severe dyspareunia based on our FDA-cleared IND;

- *DARE-HPV*, conducting activities necessary to enable submission of an IND application to the FDA for a Phase 2, randomized, placebo-controlled, double-blind clinical study of DARE-HPV for clearance of high-risk HPV infection in women, which will be supported with funding we receive as an ARPA-H Sprint for Women’s Health awardee (see “Recent Events” below); and

- *DARE-PTB1*, conducting activities necessary to enable submission of an IND application to the FDA for a Phase 1 clinical study.

We do not plan to commence the Phase 3 study of DARE-HRT1 until after we secure additional capital. See ITEM 1. "BUSINESS," in Part I of our 2023 10-K for additional information regarding our clinical and preclinical-stage programs.

Royalty Monetization Transactions

Traditional and Synthetic Royalty Purchase Agreements with XOMA

On April 29, 2024, we entered into a traditional royalty purchase agreement and a synthetic royalty purchase agreement with XOMA (US) LLC, or XOMA (which, together, we refer to as the Royalty Purchase Agreements), and XOMA paid $22.0 million to us. In addition, if XOMA receives total payments under the Royalty Purchase Agreements (as described below) equal to an amount that exceeds $88.0 million (which we refer to as the Revenue Sharing Threshold), XOMA will pay $11.0 million to us for each successive $22.0 million XOMA receives under the Royalty Purchase Agreements (such $11.0 million payments to us we refer to as the Contingent Purchase Price Payments).

Under the Royalty Purchase Agreements, we sold, assigned, transferred and conveyed our right, title and interest in and to the following to XOMA:

(a) 100% of the royalties and potential milestone payments we would otherwise have the right to receive from and after April 1, 2024 under our exclusive license agreement with Organon, based on net sales of XACIATO, net of (i) all royalty and milestone payments due and payable and actually paid by or on behalf of us under our exclusive license agreement with third-party licensors TriLogic Pharma, LLC and MilanaPharm LLC, and (ii) all payments due and payable and actually paid by or on behalf of us under our royalty interest financing agreement with United in Endeavour, LLC, or UiE, (such net amount we refer to as the Purchased Receivables);

(b) 25% of the potential future $20.0 million payment that we would otherwise have the right to receive under our license agreement with Bayer HealthCare LLC, or Bayer, relating to Ovaprene, if Bayer, in its sole discretion, elects to make the license granted thereunder effective following completion of the pivotal clinical trial of Ovaprene; and

(c) a synthetic royalty of 4.0% of our, our affiliates' and our sublicensees' future net sales of Ovaprene, and 2.0% of our, our affiliates' and our sublicensees' future net sales of Sildenafil Cream; *provided, however*, that, if XOMA receives total payments under the Royalty Purchase Agreements, net of any Contingent Purchase Price Payments made to us, equal to an amount that exceeds $110.0 million, the foregoing percentages will be reduced to 2.5% and 1.25%, respectively (such amounts described in the foregoing clauses (b) and (c) we collectively refer to as the Revenue Participation Right).

Pursuant to the traditional royalty purchase agreement, XOMA, at its sole cost and discretion, may repay in full and retire all of our payment obligations to UiE under our royalty interest financing agreement with UiE. If XOMA does so, no further amounts in respect of that agreement will be deducted from the net royalties and net milestone payments that XOMA is entitled to receive under the traditional royalty purchase agreement. As of April 29, 2024, we cannot elect to receive any additional funding from UiE under our royalty interest financing agreement with UiE without XOMA's prior written consent.

In connection with the synthetic royalty purchase agreement, we granted to XOMA a security interest in certain product assets related to Ovaprene and Sildenafil Cream.

The Royalty Purchase Agreements contain certain representations and warranties regarding our rights and obligations with respect to our license agreement with Organon, our license agreement with Bayer and our in-license agreements relating to XACIATO, Ovaprene and Sildenafil Cream, as well as customary representations and warranties for a transaction of this nature. The Royalty Purchase Agreements also contain customary covenants for a transaction of this nature, including covenants that limit or restrict our ability to incur indebtedness or liens related to the Purchased Receivables, the Revenue Participation Right, and certain product assets related to Ovaprene and Sildenafil Cream (except pursuant to a suitable intercreditor agreement). The Royalty Purchase Agreements do not restrict our ability to out-license any of our products or product candidates.

Royalty Interest Financing Agreement with UiE

In December 2023, we entered into a royalty interest financing agreement with UiE pursuant to which we sold an interest in the royalty and milestone payments we receive from Organon in respect of net sales of XACIATO. On the effective date of the agreement, we received a payment of $5.0 million from UiE. Until December 31, 2026, in accordance with the terms of the royalty interest financing agreement, we are entitled to elect to receive three additional payments from UiE of up to an aggregate of $7.0 million. See ITEM 1. "BUSINESS- Royalty Interest Financing Agreement," in Part I of our 2023 10-K and Note 7, Royalty Interest Financing, to our condensed consolidated financial statements contained in this report for additional information. As discussed above, as of April 29, 2024, under the terms of our traditional royalty purchase agreement with XOMA, we cannot elect to receive any additional funding from UiE under the royalty interest financing agreement without XOMA's prior written consent.

Recent Events

2024 Contraceptive Product Candidate Grant Agreement

In November 2024, we entered into a grant agreement with the Bill & Melinda Gates Foundation, or the Foundation, under which we were awarded a new grant of up to approximately $10.7 million to support (i) expansion of the number of study sites in the ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in low- and middle-income country (LMIC) settings who need or would prefer to use such a product to avoid an unplanned pregnancy. We will receive an initial payment under the grant agreement of approximately $5.4 million in 2024. Additional payments are contingent upon our achievement of specified development and reporting milestones during the term of the grant agreement, which extends through October 2026. For a description of material terms and conditions of the grant agreement, see Part II, Item 5 of this report.

ARPA-H Non-Dilutive Grant Award

In October 2024, we entered into a subaward agreement with National Collegiate Inventors and Innovators Alliance, Inc. d/b/a VentureWell under which we are entitled to receive up to $10.0 million in milestone-based payments subject to our achievement of specified research activities and objectives relating to advancement of our DARE-HPV program, including commencement of a Phase 2 clinical study to evaluate the safety and preliminary efficacy of DARE-HPV for the clearance of high-risk HPV infection in women, over an approximately 24-month period ending in October 2026. We anticipate that more than half of the award amount will become payable to us during the first 12 months of the performance period under the subaward agreement. The subaward agreement was the result of our selection by the Advanced Research Projects Agency for Health (ARPA-H), an agency within the U.S. Department of Health and Human Services, as an awardee of ARPA-H's Sprint for Women's Health, which was announced by First Lady Jill Biden in February 2024 as the first major deliverable of the White House Initiative on Women's Health Research.

Equity Line

In October 2024, we entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Under the terms and subject to the conditions of the purchase agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $15.0 million in shares of our common stock. Such sales of our common stock to Lincoln Park, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 24-month period commencing on the date that a registration statement covering the resale by Lincoln Park of shares that have been and may be issued under the purchase agreement is declared effective by the SEC and a final prospectus in connection therewith is filed and the other conditions in the purchase agreement are satisfied. We refer to the date on which all such conditions are satisfied, as the Commencement Date. We agreed to file such a registration statement with the SEC on or before December 5, 2024.

From time to time after the Commencement Date, at our sole discretion, on any business day selected by us on which the closing sale price of our common stock is not below $0.50 per share, we may direct Lincoln Park to purchase up to 30,000 shares of our common stock (or up to 35,000 and 40,000 shares if the closing sale price of our common stock on the day on which we initiate a purchase is not below $5.00 or $7.50, respectively, subject to customary adjustments for stock splits and similar transactions) at a purchase price equal to the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10-business day period immediately preceding the business day on which we initiate the purchase. However, Lincoln Park's maximum commitment in any single purchase may not exceed $500,000. In addition, we may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the purchase agreement, at a purchase price per share calculated as specified in the purchase agreement, but in no case lower than the minimum price per share we stipulate in our notice to Lincoln Park initiating these purchases.

In addition, under applicable Nasdaq rules, we may not issue or sell to Lincoln Park under the purchase agreement more than 1,711,172 shares of our common stock, which we refer to as the Exchange Cap, unless (i) we obtain stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the equity line agreement equals or exceeds $3.59 per share (which represents the lower of (A) the official closing price per share of our common stock on Nasdaq immediately preceding the signing of the purchase agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the purchase agreement). We may also not sell shares to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 4.99% of our then outstanding shares of common stock, which limitation we refer to as the beneficial ownership cap. Lincoln Park, upon written notice to us, may increase the beneficial ownership cap to up to 9.99%. Any increase in the beneficial ownership cap will not be effective until the 61st day after such written notice is delivered to us.

In connection with entering into the purchase agreement, we issued 137,614 shares of our common stock to Lincoln Park in consideration for its commitment to purchase shares thereunder.

Non-Compliance with Nasdaq Minimum Market Value of Listed Securities Requirement

On August 12, 2024, we received written notice from Nasdaq notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) to maintain a minimum Market Value of Listed Securities, or MVLS, of $35.0 million that is required for continued listing on The Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 days, or until February 10, 2025, to regain compliance with the minimum MVLS rule. We will regain compliance if at any time during the 180 day period, our MVLS closes at $35.0 million or more for a minimum of 10 consecutive business days. If we do not regain compliance prior to February 10, 2025, Nasdaq will notify us that our securities are subject to delisting, at which time we may appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we were to appeal the delisting determination, such an appeal would be successful. We intend to actively monitor our MVLS and may, if appropriate, consider implementing available options to regain compliance with the minimum MVLS rule. There can be no assurance that we will be able to regain compliance with such rule or maintain compliance with any other listing requirements. See the risk factor titled, “If we fail to regain and maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock,” in Item 1A below.

Regained Compliance with Nasdaq Minimum Bid Price Requirement

On July 18, 2024, we were notified by letter from the Nasdaq Office of General Counsel that we had regained compliance with the bid price requirement in Nasdaq Listing Rule 5550(a)(2) by maintaining a closing bid price of our common stock of $1.00 or greater for ten consecutive trading days as of July 15, 2024 and that the matter is now closed.

Reverse Stock Split

On July 1, 2024, we effected a 1-for-12 reverse split of our issued common stock. At the effective time of the reverse stock split, every 12 shares of our common stock was automatically reclassified and combined into one share of our common stock. No fractional shares were issued as a result of the reverse stock split. Stockholders who would have otherwise been entitled to receive a fractional share instead automatically had their fractional interests rounded up to the next whole share. The reverse stock split reduced the number of issued and outstanding shares of our common stock from approximately 101.1 million to approximately 8.5 million. The reverse stock split did not change the number of authorized shares or the par value per share of our common stock.

All common stock share and per share data presented in this report for prior periods have been retroactively adjusted to reflect the impact of the reverse stock split, without giving effect to whole shares issued in lieu of fractional shares. See Notes 2 and 4 to our condensed consolidated financial statements contained in this report for additional information.

Financial Overview

Revenue

Our revenue reflects payments earned under our license agreement with Organon to commercialize XACIATO. Pursuant to our traditional royalty purchase agreement with XOMA, from and after April 1, 2024, all of the royalties and potential milestone payments we would otherwise have the right to receive under our license agreement with Organon based on net sales of XACIATO will be paid to XOMA, net of payments made under our exclusive license agreement with third-party licensors TriLogic Pharma, LLC and MilanaPharm LLC and under our royalty interest financing agreement with UiE. Accordingly, from and after April 1, 2024, any revenue we recognize under our license agreement with Organon based on net sales of XACIATO will be payable to UiE as non-cash royalty revenue.

In the future, we may generate revenue from license fees, milestone payments, and research and development payments in connection with strategic collaborations, as well as product sales of future products, if any. Our ability to generate such revenue will depend on the extent to which clinical development of our product candidates is successful and we or a strategic collaborator receive regulatory approvals to market such product candidates, as well as the eventual commercial success of the approved products. If we fail to complete the development of our 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

The majority of our operating expenses during a fiscal year are research and development, or R&D, expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. R&D expenses consist primarily of:

- direct program costs, including:
  - expenses incurred under agreements with clinical research organizations (CROs), investigative sites and other third parties that assist in the conduct of our clinical trials and nonclinical studies and conduct other R&D and regulatory affairs activities on our behalf,
  - contract manufacturing expenses, primarily for the production of materials for use in our clinical trials and nonclinical studies,
  - transaction costs related to acquisitions of companies, technologies and related intellectual property, and other assets, and
  - milestone payments due to third parties under acquisition and in-licensing arrangements based on our product candidates' achievement of R&D and regulatory milestones specified therein, and
- indirect costs, including:
  - personnel-related costs, including salaries, bonuses, benefits, payroll taxes, and stock-based compensation expenses for employees engaged in R&D functions,
  - the costs of services performed by third parties, including consulting services,
  - facilities-related costs, including rent and maintenance costs, and insurance, depreciation, supplies, and miscellaneous expenses, and
  - costs related to travel, conference participation, service contracts, information technology, dues and subscriptions.

We recognize R&D expenses as they are incurred. External expenses are recognized based on our evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the amount of services that has been performed at each reporting date. Nonrefundable payments we make prior to the receipt of goods or services to be used in R&D are recognized as an expense as the related goods are delivered or services are performed. Milestone payments to third parties under acquisition, license, and option agreements are recognized as they are incurred or when we deem their incurrence to be probable.

At any one time, we are working on multiple programs at various stages of development. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each development program on an ongoing basis in response to the results of ongoing and future clinical trials and preclinical studies, regulatory developments, and our ongoing assessments as to the commercial potential of each product candidate. We generally track direct R&D costs on a specific basis and will present direct costs for our key development programs on a program-by-program basis. We plan to present direct costs for all other programs on a consolidated basis generally by stage of development. Specifically, we will present consolidated direct costs for (a) such programs that are in (i) advanced clinical development (Phase 2-ready to Phase 3), (ii) Phase 1 clinical development or that we believe are Phase 1-ready, and (iii) preclinical stage, and (b) other development programs. We do not track indirect costs on a program-by-program basis because those costs generally are deployed across multiple development programs.

Investment in the development of and seeking regulatory approval for our clinical-stage and Phase 1-ready product candidates and the development of any other potential product candidates we may advance into and through clinical trials in the pursuit of regulatory approvals, will increase our R&D expenses. Activities associated with the foregoing 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 R&D expenses due to, among other factors, milestone payments.

Until the first commercial sale of XACIATO, we recognized contract manufacturing expenses associated with producing commercial supplies of XACIATO and costs of regulatory affairs activities related to XACIATO as R&D expenses. Following the first commercial sale of XACIATO, and during the interim period when we were the NDA holder of XACIATO and provided commercial supplies of XACIATO to Organon, those expenses were recognized as general and administrative expenses.

We recognize the Australian Research and Development Tax Incentive Program, or the Tax Incentive, as a reduction of R&D expenses. The amounts are determined based on our eligible R&D expenditures and are non-refundable, provided that in order to qualify for the Tax Incentive the filing entity must have revenue of less than AUD $20.0 million during the tax year for which a reimbursement claim is made and cannot be controlled by an income tax exempt entity. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured or reliably estimated.

We have received, and may in the future receive, funding through grants and other financial awards from governmental entities, private foundations and other organizations that support activities related to the development of certain of our product candidates. As we incur eligible expenses under those grants or awards, we recognize grant funding in our statements of operations as a reduction to R&D expenses (contra-R&D expense). For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies – Grant Funding, to our consolidated financial statements contained in our 2023 10-K and Note 10, Grant Awards, to our condensed consolidated financial statements contained in this report. For the three and nine months ended September 30, 2024 and 2023, we recognized contra-R&D expense of approximately $1.5 million and $6.6 million, respectively, and $2.6 million and $7.3 million, respectively.

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. Our future R&D expenses and the probability of success of our product candidates may be affected by numerous factors, including the number, scope, rate of progress, expense, and results of our clinical trials and nonclinical R&D activities, the countries in which our clinical trials are conducted, the phase of clinical development of our product candidates, the cost and timing of manufacturing our product candidates, our ability to scale up manufacturing as needed to support later-stage clinical trials and, if approved, commercialization of our product candidates, the extent of changes in government regulation and regulatory guidance relating to development and approval of our product candidates, the timing, receipt, and terms of any clearances to conduct clinical trials and any marketing approvals from applicable regulatory authorities, competition and commercial viability of our product candidates, the extent to which we establish and maintain intellectual property rights, the extent to which we establish and maintain license, collaboration, or other arrangements. As a result, we cannot accurately determine the duration and completion costs of development projects or if, when and to what extent we will generate revenue from the commercialization of any of our product candidates.

License Fee Expenses

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

Royalty Expenses

Royalty expenses consist of product sales-based payments we owe to upstream licensors.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, facility expenses, expenses for outside professional services, including legal, audit and accounting services, commercial-readiness expenses, and milestone expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Facility expenses consist of rent and other related costs. Commercial-readiness expenses consist of consultant and advisor costs. Milestone expenses consist of amounts that become due to third parties under our in-license or other agreements under which we acquired rights to technology or other intellectual property we use in a product based on the product's achievement of commercial milestones specified therein.

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, that we 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 accompanying condensed consolidated financial statements, refer to Item 7 in Management’s Discussion and Analysis of Financial Condition and Results of Operations in our 2023 10-K. There have been no significant changes in the critical accounting policies and estimates as previously described in our 2023 10-K, except as described in Note 2 to our condensed consolidated financial statements contained in this report with respect to the Royalty Purchase Agreements.

Results of Operations

We recorded a net loss of approximately $4.7 million and net income of approximately $1.5 million for the three and nine months ended September 30, 2024, respectively, as compared to a net loss of approximately $8.3 million and approximately $25.1 million for the three and nine months ended September 30, 2023, respectively. Our net income (loss) for the three and nine months ended September 30, 2024 was positively impacted by the approximately $20.4 million of net proceeds we received from the sale in April 2024 of our rights to future royalty and milestone payments and revenue to XOMA. See "—Royalty Monetization Transactions—Traditional and Synthetic Royalty Purchase Agreements with XOMA," above.

Comparison of Three Months Ended September 30, 2024 and 2023 (Unaudited)

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

	Three Months Ended September 30,		Change	
	2024	2023	$	%
Revenue				
License fee revenue	$ —	$ 1,000,000	$ (1,000,000)	(100)%
Royalty revenue	41,691	—	41,691	100 %
Total revenue	41,691	1,000,000	(958,309)	(96)%
Operating expenses				
General and administrative expenses	2,041,268	2,696,779	(655,511)	(24)%
Research and development expenses	2,656,772	6,674,636	(4,017,864)	(60)%
License fee expenses	25,000	25,000	—	— %
Total operating expenses	4,723,040	9,396,415	(4,673,375)	(50)%
Loss from operations	(4,681,349)	(8,396,415)	3,715,066	(44)%
Other income (expense)	(21,152)	97,319	(118,471)	(122)%
Net loss	(4,702,501)	(8,299,096)	3,596,595	(43)%
Other comprehensive income (loss)				
Foreign currency translation adjustments	22,935	(15,030)	37,965	(253)%
Comprehensive loss	$ (4,679,566)	$ (8,314,126)	$ 3,634,560	(44)%

Revenues

Revenues for the three months ended September 30, 2024 and 2023 related to our license agreement with Organon to commercialize XACIATO.

General and administrative expenses

The decrease of approximately $0.7 million in general and administrative expenses for the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily attributable to decreases in (i) professional services expense of approximately $0.3 million, (ii) commercial readiness expenses of approximately $0.2 million, (iii) stock-based compensation expense of approximately $0.1 million, and (iv) general corporate overhead expense which includes rent and facilities costs and insurance expense of approximately $26,000.

Research and development expenses

The following table summarizes our R&D expenses for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Three Months Ended September 30,		Change	
	2024	2023	$	%
Direct program costs:				
Ovaprene	$ 1,940,536	$ 1,420,103	$ 520,433	37 %
Sildenafil Cream, 3.6%	(60,905)	2,825,128	(2,886,033)	(102)%
Other advanced clinical stage programs	139,352	805,108	(665,756)	(83)%
Phase 1 and Phase 1-ready clinical stage programs *	(222,293)	377,258	(599,551)	(159)%
Preclinical stage programs *	(651,118)	(216,193)	(434,925)	201 %
Other development programs	1,206	33,392	(32,186)	(96)%
Total direct program costs	1,146,778	5,244,796	(4,098,018)	(78)%
Indirect costs:				
Personnel-related (including stock compensation)	1,453,823	1,235,978	217,845	18 %
Outside services (including consulting)	(4,022)	5,559	(9,581)	(172)%
Facilities-related (including depreciation)	16,711	23,054	(6,343)	(28)%
Other indirect R&D costs	43,482	165,249	(121,767)	(74)%
Total indirect R&D costs	1,509,994	1,429,840	80,154	6 %
Total R&D expenses	$ 2,656,772	$ 6,674,636	$ (4,017,864)	(60)%

** Includes contra R&D expenses related to grant funding and/or the Australian Research and Development Tax Incentive Program.*

The decrease in R&D expenses for the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily attributable to a decrease in costs related to development activities for Sildenafil Cream as a result of the completion of the Phase 2b RESPOND clinical study completed in June 2023, partially offset by increases in costs related to our ongoing pivotal Phase 3 clinical trial of Ovaprene and manufacturing and regulatory affairs activities for Ovaprene.

License fee expenses

For each of the three months ended September 30, 2024 and September 30, 2023, 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 condensed consolidated financial statements contained in this report.

Other income (expense)

The decrease of approximately $0.1 million in other income for the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily due to a decrease in interest earned on cash balances in the current period.

Comparison of Nine Months Ended September 30, 2024 and 2023 (Unaudited)

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

	Nine Months Ended September 30,		Change	
	2024	2023	$	%
Revenue				
License fee revenue	$ —	$ 1,000,000	$ (1,000,000)	(100)%
Royalty revenue	73,431	—	73,431	100 %
Total revenue	73,431	1,000,000	(926,569)	(93)%
Operating expenses				
General and administrative expenses	7,159,979	8,954,877	(1,794,898)	(20)%
Research and development expenses	10,894,066	17,738,543	(6,844,477)	(39)%
Royalty expenses	7,674	—	7,674	100 %
License fee expenses	75,000	75,000	—	— %
Total operating expenses	18,136,719	26,768,420	(8,631,701)	(32)%
Loss from operations	(18,063,288)	(25,768,420)	7,705,132	(30)%
Other income (expense)				
Sale of royalty and milestone rights, net	20,379,376	—	20,379,376	100 %
Other income (expense), net	(863,289)	664,591	(1,527,880)	(230)%
Net income (loss)	$ 1,452,799	$ (25,103,829)	$ 26,556,628	(106)%
Other comprehensive loss				
Foreign currency translation adjustments	(1,729)	(68,186)	66,457	(97)%
Comprehensive income (loss)	$ 1,451,070	$ (25,172,015)	$ 26,623,085	(106)%

Revenues

Revenues for the nine months ended September 30, 2024 and 2023 related to our license agreement with Organon to commercialize XACIATO.

General and administrative expenses

The decrease of approximately $1.8 million in general and administrative expenses for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily attributable to decreases in (i) commercial-readiness expenses of approximately $0.5 million, (ii) personnel costs of approximately $0.4 million due to reduced headcount, (iii) a one-time fraud loss in the first quarter of 2023 of approximately $0.2 million, net of proceeds we received under an insurance policy, related to criminal fraud commonly referred to as "business email compromise fraud" to which we were subject, (iv) professional services expense of approximately $0.2 million, (v) stock-based compensation expense of approximately $0.2 million, and (vi) general corporate overhead expense, which includes rent and facilities costs and insurance expense, of approximately $0.2 million.

Research and development expenses

The following table summarizes our R&D expenses for the periods indicated, together with the changes in those items in terms of dollars and percentage:

	Nine Months Ended September 30,		Change	
	2024	2023	$	%
Direct program costs:				
Ovaprene	$ 7,103,894	$ 2,221,831	$ 4,882,063	220 %
Sildenafil Cream, 3.6%	1,105,605	7,417,777	(6,312,172)	(85)%
Other advanced clinical stage programs	934,656	2,509,921	(1,575,265)	(63)%
Phase 1 and Phase 1-ready clinical stage programs *	(228,952)	1,947,029	(2,175,981)	(112)%
Preclinical stage programs *	(2,809,707)	(1,188,548)	(1,621,159)	136 %
Other development programs	24,132	139,039	(114,907)	(83)%
Total direct program costs	6,129,628	13,047,049	(6,917,421)	(53)%
Indirect costs:				
Personnel-related (including stock compensation)	4,555,077	4,335,854	219,223	5 %
Outside services (including consulting)	543	28,557	(28,014)	(98)%
Facilities-related (including depreciation)	60,344	64,439	(4,095)	(6)%
Other indirect R&D costs	148,474	262,644	(114,170)	(43)%
Total indirect R&D costs	4,764,438	4,691,494	72,944	2 %
Total R&D expenses	$ 10,894,066	$ 17,738,543	$ (6,844,477)	(39)%

* Includes contra R&D expenses related to grant funding and/or the Australian Research and Development Tax Incentive Program.

The decrease in R&D expenses for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily attributable to a decrease in costs related to development activities for Sildenafil Cream as a result of the completion of the Phase 2b RESPOND clinical study completed in June 2023, partially offset by increases in costs related to our ongoing pivotal Phase 3 clinical trial of Ovaprene and manufacturing and regulatory affairs activities for Ovaprene.

Royalty expenses

Royalty expenses for the nine months ended September 30, 2024 related to our license agreement with MilanaPharm and our royalty interest financing agreement with UiE. There were no royalty expenses for the nine months ended September 30, 2023 because we did not recognize any royalty revenue during that period.

License fee expenses

For each of the nine months ended September 30, 2024 and September 30, 2023, we accrued $75,000 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 condensed consolidated financial statements contained in this report.

Other income (expense)

Sale of royalty and milestone rights, net

The increase of $20.4 million in other income for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was due to the proceeds received in April 2024 under the Royalty Purchase Agreements we entered into with XOMA, $22.0 million of which was recorded as income, net of approximately $1.6 million in transaction costs.

Other income (expense), net

The decrease of $1.5 million in other income (expense) for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily due to a loss on the disposal of a fixed asset of $0.6 million, interest expense related to the Royalty Interest Agreement in the current period of approximately $0.6 million, and decreased interest earned on cash balances in the current period.

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 and, although we reported net income and positive cash flow from operations for the nine months ended September 30, 2024 as a result of approximately $20.4 million of net proceeds we received from the sale in April 2024 of our rights to future royalty and milestone payments and revenue, we expect significant losses from operations, net losses and negative cash flows from operations for at least the next several years as we continue to develop and seek to bring to market our product candidates. At September 30, 2024, our accumulated deficit was approximately $169.8 million, our cash and cash equivalents were approximately $11.2 million, and our working capital was approximately $1.8 million. 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, even after taking into account the non-dilutive funding we expect to receive under our October 2024 grant agreement with the Foundation and as an October 2024 awardee of ARPA-H's Sprint for Women's Health and the additional capital we may raise under the equity line arrangement we established in October 2024. 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.

Our cash and cash equivalents at September 30, 2024 includes funds received under our grant agreements related to DARE-LARC1 and bacteria-based live biotherapeutic product development, and such funds may be applied solely toward direct costs of such matters, other than approximately 10% of such funds, which may be applied toward general overhead and administration expenses that support our entire operations. For additional information about these grant agreements, see "—Deferred Grant Funding" and "—Grant Agreements," below.

The majority of our operating expenses during a fiscal year are R&D expenses, a significant portion of which, excluding those funded by non-dilutive grants, are associated with the clinical development for our product candidates that have reached the human clinical study development phase. In large part, we can control the pace of advancement of our development programs and therefore, we can control the timing of when we incur most of our R&D expenses. 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 R&D services, payments to third-party licensors upon the occurrence of 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, and in particular, if we determine to engage in commercialization activities directly as opposed to through a third-party collaborator. We anticipate our general and administrative expenses for 2024 will be less than our general and administrative expenses for 2023.

We closely monitor our cash resources and we implemented cost-savings measures in 2024, primarily by controlling our spend on R&D activities related to clinical-stage programs other than Ovaprene and Sildenafil Cream. Our R&D expenses for the remainder of 2024 and into 2025, until we secure additional capital to fund our operating needs, will continue to be primarily associated with our ongoing pivotal Phase 3 clinical study of Ovaprene and with advancing Sildenafil Cream toward a Phase 3 clinical study. However, we plan to continue to advance preclinical development of DARE-LARC1, the costs of which are being supported by grant funding, and, with the support of ARPA-H's Sprint for Women's Health funding, to advance development of DARE-HPV toward a Phase 2 clinical study. Based on anticipated costs for two Phase 3 studies of Sildenafil Cream, we will need to raise significant additional capital to advance Sildenafil Cream through Phase 3 development. We currently anticipate our R&D expenses for 2024 will be less than our R&D expenses for 2023.

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. We have also received a significant amount of cash through non-dilutive grants, strategic collaborations and royalty monetization transactions. We will continue to evaluate and may pursue a variety of capital raising options on an on-going basis, including sales of equity (including sales of our common stock under our equity line arrangement and in ATM offerings), debt financings, government or other grant funding, collaborations, structured financings, and strategic alliances or other similar types of arrangements. Many aspects of our ability to obtain additional capital are not entirely within our control and 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. Our ability to raise capital through sales of our common stock will depend on a variety of factors including, among others, market conditions, the trading price and volume of our common stock, our clinical and commercial developments, and investor sentiment. In addition, macroeconomic factors and volatility in the financial market, which may be exacerbated in the short term by concerns over inflation, interest rates, economic recession, adverse developments affecting financial institutions or the financial services industry, impacts of the wars in Ukraine and the Middle East, strained relations between the U.S. and several other countries, and social and political discord and unrest in the U.S., among other things, may make equity or debt financings more difficult, more costly or more dilutive to our stockholders, and may increase competition for, or limit the availability of, funding from other potential third-party sources of capital, such as strategic collaborators and sources of grant funding. 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 raise capital through collaborations, structured financings, strategic alliances or other similar types of arrangements, we may be required to relinquish some or all of our rights to potential revenue or to intellectual property rights for our product candidates on terms that are not favorable to us.

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 2023 10-K titled, *We will need to raise substantial additional capital to continue our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.*

Deferred Grant Funding

We have received substantial funding under grant agreements with the Foundation, and we generally receive funds under those agreements before we incur the eligible expenses. Funds received that have not been spent are recorded both as cash and cash equivalents and as a deferred grant funding liability in our consolidated balance sheets. Our deferred grant funding liability also includes grant funds spent but not yet expensed in accordance with GAAP. As of September 30, 2024, our deferred grant funding liability was approximately $9.8 million, which primarily consisted of unspent funds for the DARE-LARC1 program. For more information about our grant agreements, see "—Grant Agreements" below, Note 2, Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding to our consolidated financial statements in our 2023 10-K, and Note 10, Grant Awards-Other Non-Dilutive Grant Funding and Note 12, Subsequent Events to our condensed consolidated financial statements contained in this report.

Cash Flows

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

	Nine months ended September 30,	
	2024	2023
Net cash provided by (used in) operating activities	$ 167,637	$ (30,677,749)
Net cash used in investing activities	(10,197)	(22,099)
Net cash provided by financing activities	565,842	10,327,852
Effect of exchange rate changes on cash and cash equivalents	(1,729)	(68,185)
Net increase (decrease) in cash and cash equivalents	$ 721,553	$ (20,440,181)

Net cash provided by (used in) operating activities

Cash provided by operating activities for the nine months ended September 30, 2024 included net income of $1.5 million, increased by non-cash stock-based compensation expense of approximately $1.7 million. Components providing operating cash were a decrease in prepaid expenses of approximately $2.9 million, a decrease in other receivables of approximately $0.4 million, and an increase in interest payable of approximately $0.4 million. Components reducing operating cash were a decrease in deferred grant funding of approximately $4.0 million, a decrease in accounts payable of approximately $2.3 million, a decrease in accrued expenses of approximately $1.2 million, and a decrease in deposits of approximately $57,000.

Cash used in operating activities for the nine months ended September 30, 2023 included the net loss of $25.1 million, decreased by non-cash stock-based compensation expense of approximately $1.9 million. Components providing operating cash were an increase in accounts payable of approximately $3.0 million, a decrease in other receivables of approximately $0.6 million, an increase in deferred revenue of approximately $0.2 million related to XACIATO commercial product supply, and a decrease in prepaid expenses of approximately $0.1 million. Components reducing operating cash were a decrease in accrued expenses of approximately $6.1 million, a decrease in deferred grant funding of approximately $2.6 million, an increase in deposits of approximately $1.8 million primarily related to deposits paid for the construction of capital equipment, an increase in other current assets of approximately $0.8 million primarily related to the financing of certain director and officer and other liability insurance premiums recorded as insurance financing payable, deferred financing costs related to our ATM sales agreement, and inventory of XACIATO commercial supply, and a one-time fraud loss of $0.2 million related to a "business email compromise fraud" to which we were subject, net of insurance reimbursement, which was recognized in general and administrative expenses.

Net cash used in investing activities

Net cash used in investing activities in each of the nine months ended September 30, 2024 and September 30, 2023 was de minimis. Our investing activities consisted primarily of purchases of property and equipment.

Net cash provided by financing activities

Cash provided by financing activities for the nine months ended September 30, 2024 was approximately $0.6 million and primarily consisted of proceeds from (i) the financing of certain director and officer and other liability insurance premiums, and (ii) the sale of our common stock under our ATM sales agreement, partially offset by payments on the insurance financing payable.

Cash provided by financing activities for the nine months ended September 30, 2023 was approximately $10.3 million and primarily consisted of proceeds from (i) the sale of our common stock and warrants in the registered direct offering completed in September 2023, (ii) sales of our common stock under our ATM sales agreement, (iii) the exercise of warrants, and (iv) the financing of certain director and officer and other liability insurance premiums.

License and Royalty Agreements

We agreed to make royalty and milestone payments, and in some cases annual license fee payments, under the license and development agreements related to XACIATO, Ovaprene, and Sildenafil Cream and under other agreements related to our other clinical and preclinical candidates. During the fourth quarter of 2024, based on our current expectations regarding the development of our product candidates, we expect approximately $1.0 million of such payments to upstream licensors to become payable. With respect to our license agreement relating to XACIATO, royalties payable by us to upstream licensors will be funded by royalty payments made by our licensee, Organon. For further discussion of these potential payments, see Note 3 to our condensed consolidated financial statements contained in this report.

Grant Agreements

We have received substantial funding under grant agreements with the Foundation, and we generally receive funds under those agreements before we incur the eligible expenses. Unspent grant funds are recorded as deferred grant funding liability in our consolidated balance sheets and our deferred grant funding liability as of September 30, 2024 primarily consisted of unspent grant funds for the DARE-LARC1 program. For more information, see Note 2, Basis of Presentation and Summary of Significant Accounting Policies—Grant Funding to our consolidated financial statements in our 2023 10-K, and Note 10, Grant Awards-Other Non-Dilutive Grant Funding and Note 12, Subsequent Events to our condensed consolidated financial statements contained in this report.

Other Contractual Obligations

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 principal executive and 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 principal executive and financial officer, of the effectiveness of our disclosure controls and procedures, our principal executive and financial officer concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) were effective as of September 30, 2024 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 2023 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. Except as discussed below, there have been no material changes from the risk factors disclosed in Part I, Item 1A. Risk Factors in our 2023 10-K.

The Revenue Sharing Threshold may never be achieved and, as a result, we may not realize any future income based on sales of XACIATO.

We have sold our right, title and interest in 100% of the royalties and potential milestone payments we would otherwise have the right to receive under our license agreement with Organon based on net sales of XACIATO, net of payments to upstream third-party licensors and UiE. Whether we receive any future income based on net sales of XACIATO will depend on whether the Revenue Sharing Threshold is reached, which may not occur. Whether the Revenue Sharing Threshold is reached will depend, in part, on Organon's future commercial success with XACIATO, which is outside of our control, and the successful development and commercialization of Ovaprene and/or Sildenafil Cream, which are subject to significant risks and uncertainties, some of which are outside of our control, as discussed in Part I, Item 1A. Risk Factors of our 2023 10-K.

The grants and other non-dilutive funding awards supporting several of our development programs do not guarantee that the pre-clinical or clinical development work being funded will be successful or that we will be able or will choose to fund the additional development work that will be required in the future to advance the product candidates toward regulatory approval.

The grants supporting pre-clinical development of DARE-LARC1, DARE-LBT, and activities to aid in the identification and development a novel non-hormonal intravaginal contraceptive candidate, and the ARPA-H funding we expect to receive in support of DARE-HPV's development do not guarantee that pre-clinical or, as applicable, clinical development will be successful, or, even if we are successful with all specified development activities, that we will be able or will choose to fund the additional clinical and nonclinical development work that will be required in the future to advance the product candidates toward regulatory approval. Further, the grant agreements or other non-dilutive funding award agreements supporting these development programs generally feature milestone-based payments and there is no assurance that we will be able to achieve or otherwise demonstrate satisfaction of the specified development and reporting milestones required to receive future payments under the agreements. Additionally, the counterparties to these agreements may modify, suspend, discontinue payment of funds or terminate the agreements in certain circumstances largely in their discretion. Accordingly, we may never receive future payments under these agreements or realize the full potential amount of the grant or other funding award.

If we fail to regain and maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

Our common stock is listed on The Nasdaq Capital Market. On August 12, 2024, we received written notice from Nasdaq notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) to maintain a minimum Market Value of Listed Securities, or MVLS, of $35.0 million that is required for continued listing on The Nasdaq Capital Market. The notice has no effect at this time on the listing of our common stock on The Nasdaq Capital Market.

We have a period of 180 days, or until February 10, 2025, to regain compliance with the minimum MVLS rule. We will regain compliance if at any time during the 180 day period, our MVLS closes at $35.0 million or more for a minimum of 10 consecutive business days. If we do not regain compliance prior to February 10, 2025, Nasdaq will notify us that our securities are subject to delisting, at which time we may appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we were to appeal the delisting determination, such an appeal would be successful.

There are many factors that affect the trading price of our common stock, and many of those factors are outside of our control. We intend to actively monitor our MVLS and may, if appropriate, consider implementing available options to regain compliance with the minimum MVLS rule. There can be no assurance that we will be able to regain compliance with such rule or that we will be able to satisfy all other continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock on The Nasdaq Capital Market even if we regain compliance with the minimum MVLS rule. For example, until we regained compliance on July 18, 2024, we were not in compliance with the continued listing standard commonly referred to as the minimum bid price rule since July 19, 2023.

The suspension or delisting of our common stock, for whatever reason, could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, for whatever reason, may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

The sale of our common stock in ATM offerings or under our equity line arrangement may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.

We have used at-the-market, or ATM, offerings to fund a significant portion of our operations in prior years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2021, we sold an aggregate of approximately 3.0 million shares of our common stock in ATM offerings. We sold substantially fewer shares in ATM offerings in 2022 and 2023 and to-date in 2024, however, we may sell significant amounts of shares in ATM offerings again in the future. In addition, we may sell up to $15.0 million in shares of our common stock under our equity line arrangement. The purchase price for the shares we may sell under our equity line arrangement will vary based the market price of our common stock at the time we initiate a sale. While sales of shares of our common stock in ATM offerings and under our equity line arrangement may enable us to raise capital at a lower cost compared with other types of equity financing transactions; such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

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) On November 11, 2024, we entered into a grant agreement with the Foundation under which we were awarded a new grant of up to approximately $10.7 million (the "Grant") to support (i) expansion of the number of study sites in our ongoing Phase 3 clinical trial of Ovaprene, and (ii) activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive candidate, suitable for and acceptable to women in LMIC settings who need or would prefer to use such a product to avoid an unplanned pregnancy. The term of the grant agreement is November 11, 2024 to October 31, 2026 (the "Grant Period"). An initial payment of approximately $5.4 million is due to us in 2024. Additional payments are contingent upon our achievement of specified development and reporting milestones during the Grant Period.

Under the grant agreement, we agreed to make the Funded Developments available and accessible at an affordable price to people most in need within developing countries, or in support of the U.S. educational system and public libraries, as applicable, and to promptly and broadly disseminate the knowledge and information gained from the project funded by the Grant (the "Global Access Commitment"). Under the grant agreement, "Funded Developments" means the products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from the project funded by the Grant. In connection with the Global Access Commitment, we also granted the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform, and display Funded Developments and essential background technology (the "Humanitarian License"). We are required to ensure that the Humanitarian License survives the assignment or transfer of Funded Developments and essential background technology. If we demonstrate to the satisfaction of the Foundation that the global access contemplated by the Global Access Commitment can best be achieved without the Humanitarian License, the Foundation and Daré will make good faith efforts to modify or terminate the Humanitarian License, as appropriate.

The Foundation may modify, suspend, or discontinue any payment of grant funds or terminate the grant agreement if (a) the Foundation is not reasonably satisfied with our progress on the project funded by the Grant, (b) there are significant changes to our leadership or other factors that the Foundation reasonably believes may threaten the project's success, (c) there is a change in control of Daré, (d) there is a change in our tax status, or (e) we fail to comply with the grant agreement. Any funds we receive under the grant agreement, and any interest or other income generated thereby, that are not used or committed for use in accordance with the grant agreement must be returned promptly to the Foundation upon the expiration or termination of the grant agreement.

The foregoing description of the grant agreement does not purport to be complete and is qualified in its entirety by reference to the grant agreement, a copy of which we intend to file as an exhibit to our annual report on Form 10-K for the fiscal year ending December 31, 2024, with certain private or confidential provisions or terms omitted.

(b) None.

(c) During the period from July 1, 2024 to September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exhibit No.	
31.1	Certification of Principal Executive Officer and 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 and 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
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					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 would likely cause competitive harm to the Company if publicly disclosed.
*	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: November 14, 2024

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

Date: November 14, 2024

By: /s/ MarDee Haring-Layton
MarDee Haring-Layton
Chief Accounting Officer
(Principal Accounting Officer)

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. I am 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2024

/s/ Sabrina Martucci Johnson

Sabrina Martucci Johnson

President and Chief Executive Officer

(Principal executive officer and 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 June 30, 2024, 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: August 12, 2024

/s/ Sabrina Martucci Johnson

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