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

FORM 10-Q

☒ **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 000-31615

DURECT CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**94-3297098**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10240 Bubb Road
Cupertino, California 95014
(Address of principal executive offices, including zip code)

(408) 777-1417
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock $0.0001 par value per share	**DRRX**	**The NASDAQ Stock Market LLC (The 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 11, 2024, there were 31,041,981 shares of the registrant's common stock outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this Quarterly Report on Form 10-Q or elsewhere by management from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "could," "potentially," "possibility," and similar expressions are forward-looking statements. Such forward-looking statements contained herein are based on current expectations and beliefs. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. Forward-looking statements made in this report include, but are not limited to, statements about:

- potential uses and benefits of larsucosterol to treat alcohol-associated hepatitis ("AH"), metabolic dysfunction-associated steatohepatitis ("MASH"), or other conditions;
- the potential benefits of Breakthrough Therapy Designation;
- the results and timing of clinical trials, including clinical trial plans and timelines for larsucosterol;
- the likelihood of future clinical trial results of larsucosterol being positive with statistical significance and/or similar to results from previous trials, the possible commencement of future clinical trials;
- our communication with the U.S. Food and Drug Administration ("FDA") regarding the trial design for a Phase 3 clinical trial for larsucosterol in AH and our ability to confirm the efficacy and safety of larsucosterol in AH patients to support a New Drug Application filing with the FDA;
- our plans and ability to obtain sufficient capital resources to initiate a Phase 3 clinical trial of larsucosterol in AH and present topline results within two years of initiation;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our products and product candidates, including larsucosterol and POSIMIR;
- the potential milestone, sub-license fees and royalty payments we may receive from Orient Pharma Co., Ltd.;
- market opportunities for product candidates in our product development pipeline;
- potential regulatory filings for or approval of larsucosterol;
- the progress and results of our research and development programs and our evaluation of additional development programs;
- requirements for us to purchase pre-clinical, clinical trial and commercial supplies of product candidates and/or products, as well as raw materials or active pharmaceutical ingredients from third parties, and the ability of third parties to provide us with our requirements for such supplies and raw materials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval and timing of responses to our regulatory submissions;
- the impact of FDA, European Medicines Agency and other government regulation on our business;
- our ability to obtain, assert and protect patents and other intellectual property rights, including intellectual property licensed to our collaborators, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with our products and the product candidates we develop and/or license to third-party collaborators;
- our employees, including the number of employees and the continued services of key management, technical and scientific personnel;

•our future performance, including our anticipation that we will not derive meaningful revenues from our products and product candidates in development for at least the next twelve months, potential for future inventory write-offs and our expectations regarding our ability to achieve profitability;

•sufficiency of our cash resources, anticipated capital requirements and capital expenditures, our ability to comply with covenants of our term loan, our need or desire for additional financing, including potential sales under our shelf registration statement and our ability to continue to operate as a going concern;

•our expectations regarding research and development expenses, and selling, general and administrative expenses;

•the composition of future revenues; and

•accounting policies and estimates.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q. Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the "Overview" section of the Management's Discussion and Analysis of Financial Condition and Results of Operations herein and Part I, Item 1A., "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the Securities and Exchange Commission (the "SEC") on March 28, 2024 and any additional risk factors that may be described herein or in our subsequent filings with the SEC "Risk Factors" section. These forward-looking statements reflect our view only as of the date of this report. We undertake no obligations to update any forward-looking statements. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the SEC.

PART I. FINANCIAL INFORMATION

tem 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,086	$ 28,400
Short-term investments	1,290	1,280
Accounts receivable, net	1,016	1,261
Inventories, net	2,376	2,219
Prepaid expenses and other current assets	657	1,511
Total current assets	14,425	34,671
Property and equipment, net	52	91
Operating lease right-of-use assets	3,142	3,980
Goodwill	6,169	6,169
Long-term restricted investments	150	150
Other long-term assets	128	128
Total assets	$ 24,066	$ 45,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 498	$ 1,777
Accrued liabilities	4,798	5,966
Term loan, current portion, net	10,466	16,663
Operating lease liabilities, current portion	1,308	1,381
Warrant liabilities	3,137	1,224
Total current liabilities	20,207	27,011
Operating lease liabilities, non-current portion	1,966	2,702
Other long-term liabilities	676	693
Commitments and contingencies		
Stockholders' equity:		
Common stock	23	23
Additional paid-in capital	605,828	603,780
Accumulated other comprehensive loss	—	(14)
Accumulated deficit	(604,634)	(589,006)
Stockholders' equity	1,217	14,783
Total liabilities and stockholders' equity	$ 24,066	$ 45,189

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

DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Collaborative research and development and other revenue	$ 369	$ 506	$ 1,471	$ 1,657
Product revenue, net	1,558	1,238	4,454	4,222
Total revenues	1,927	1,744	5,925	5,879
Operating expenses:				
Cost of product revenues	513	312	1,158	1,059
Research and development	2,164	7,199	8,530	23,738
Selling, general and administrative	3,217	3,790	9,325	11,712
Total operating expenses	5,894	11,301	19,013	36,509
Loss from operations	(3,967)	(9,557)	(13,088)	(30,630)
Other income (expense):				
Interest and other income	163	653	711	1,681
Interest and other expenses	(364)	(700)	(1,338)	(2,175)
Change in fair value of warrant liabilities	(117)	7,016	(1,913)	8,601
Issuance cost for warrants	—	(427)	—	(1,627)
Loss on issuance of warrants	—	—	—	(2,033)
Other income (expense), net	(318)	6,542	(2,540)	4,447
Net loss	(4,285)	(3,015)	(15,628)	(26,183)
Net change in unrealized gain (loss) on available-for-sale securities, net of reclassification adjustments and taxes	7	(6)	14	1
Total comprehensive loss	$ (4,278)	$ (3,021)	$ (15,614)	$ (26,182)
Net loss per share				
Basic	$ (0.14)	$ (0.11)	$ (0.51)	$ (1.04)
Diluted	$ (0.14)	$ (0.14)	$ (0.51)	$ (1.07)
Weighted-average shares used in computing net loss per share				
Basic	31,039	27,211	30,906	25,175
Diluted	31,039	27,511	30,906	25,433

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

DURECT CORPORATION

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except per share amounts)
(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at December 31, 2023	30,334	$ 23	$ 603,780	$ (14)	$ (589,006)	$ 14,783
Issuance of common stock pursuant to the 2021 Sales Agreement, net of issuance costs of $13	702	—	648	—	—	648
Stock-based compensation expense from stock options and ESPP shares	—	—	508	—	—	508
Net loss	—	—	—	—	(7,643)	(7,643)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	4	—	4
Balance at March 31, 2024	31,036	$ 23	$ 604,936	$ (10)	$ (596,649)	$ 8,300
Issuance of common stock upon exercise of stock options and from the ESPP	3	—	3	—	—	3
Stock-based compensation expense from stock options and ESPP shares	—	—	431	—	—	431
Net loss	—	—	—	—	(3,700)	(3,700)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	3	—	3
Balance at June 30, 2024	31,039	$ 23	$ 605,370	$ (7)	$ (600,349)	$ 5,037
Stock-based compensation expense from stock options and ESPP shares	—	—	458			458
Net loss	—	—			(4,285)	(4,285)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—		7		7
Balance at September 30, 2024	31,039	$ 23	$ 605,828	$ —	$ (604,634)	$ 1,217
Balance at December 31, 2022	22,785	$ 23	$ 586,357	$ (13)	$ (561,382)	$ 24,985
Issuance of common stock in the February 2023 registered direct offering	1,700	—	—	—	—	—
Stock-based compensation expense from stock options and ESPP shares	—	—	2,338	—	—	2,338
Net loss	—	—	—	—	(11,987)	(11,987)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	6	—	6
Balance at March 31, 2023	24,485	$ 23	$ 588,695	$ (7)	$ (573,369)	$ 15,342
Issuance of common stock pursuant to the 2021 Sales Agreement, net of issuance costs of $13	118	—	658	—	—	658
Issuance of common stock upon exercise of stock options and from the ESPP	6	—	23	—	—	23
Stock-based compensation expense from stock options and ESPP shares	—	—	657	—	—	657
Net loss	—	—	—	—	(11,181)	(11,181)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes				1	—	1
Balance at June 30, 2023	24,609	$ 23	$ 590,033	$ (6)	$ (584,550)	$ 5,500
Issuance of common stock in the July 2023 registered direct offering, net of issuance costs of $673	2,991	—	8,540	—	—	8,540
Issuance of common stock upon warrant exercises	924	—	2,726			2,726
Stock-based compensation expense from stock options and ESPP shares	—	—	661	—	—	661
Net loss	—	—	—	—	(3,015)	(3,015)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	(6)	—	(6)
Balance at September 30, 2023	28,524	$ 23	$ 601,960	$ (12)	$ (587,565)	$ 14,406

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

DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (15,628)	$ (26,183)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and accretion	72	154
Stock-based compensation	1,401	1,923
Change in fair value of warrant liabilities	1,913	(8,601)
Loss on issuance of warrants	—	2,033
Issuance cost for warrants	—	427
Other	205	469
Changes in assets and liabilities:		
Accounts receivable	245	2,540
Inventories	(160)	(409)
Prepaid expenses and other assets	854	1,000
Accounts payable	(1,279)	(1,792)
Accrued liabilities	(1,193)	2,172
Deferred revenue	—	178
Total adjustments	2,058	94
Net cash used in operating activities	(13,570)	(26,089)
Cash flows from investing activities		
Purchases of property and equipment	—	(52)
Purchases of available-for-sale securities	(2,166)	(80)
Proceeds from maturities of short-term investments	2,200	—
Net cash provided by (used in) investing activities	34	(132)
Cash flows from financing activities		
Payments on equipment financing obligations	—	(1)
Payments on term loan principal	(6,429)	(2,857)
Net proceeds from issuances of common stock pursuant to the 2021 Sales Agreement	648	658
Net proceeds from issuance of common stock upon exercise of stock options and from the ESPP	3	23
Proceeds from issuances of warrants and common stock	—	10,000
Net proceeds from issuances of warrants and common stock in the July 2023 registered direct offering	—	13,900
Net cash (used in) provided by financing activities	(5,778)	21,723
Net decrease in cash, cash equivalents, and restricted cash	(19,314)	(4,498)
Cash, cash equivalents, and restricted cash, beginning of the period (1)	28,550	43,633
Cash, cash equivalents, and restricted cash, end of the period (1)	$ 9,236	$ 39,135

(1) Includes restricted cash of $150,000 included in long-term restricted investments on the condensed balance sheets at September 30, 2024, December 31, 2023 and September 30, 2023, respectively.

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

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Nature of Operations

DURECT Corporation (the “Company”) was incorporated in the state of Delaware on February 6, 1998. The Company is a biopharmaceutical company advancing novel and potentially lifesaving investigational therapies derived from its endogenous epigenetic regulator program. Larsucosterol, the Company's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases ("DNMTs"), epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-associated hepatitis ("AH") patients. Larsucosterol is in clinical development for the potential treatment of AH, for which the U.S. Food and Drug Administration (“FDA”) has granted Fast Track Designation and Breakthrough Therapy Designation; metabolic dysfunction-associated steatohepatitis (“MASH”), previously known as non-alcoholic steatohepatitis or NASH has also been explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved and has been exclusively licensed to Innocoll Pharmaceuticals for commercialization in the United States. The Company also manufactures and sells osmotic pumps used in laboratory research, and manufactures certain excipients for certain clients for use as raw materials in their products.

Basis of Presentation

These condensed financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the “SEC”), and therefore do not include all the information and footnotes necessary for a complete presentation of the Company’s results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). The unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at September 30, 2024, the operating results and comprehensive loss, and stockholders’ equity for the three and nine months ended September 30, 2024 and 2023, and cash flows for the nine months ended September 30, 2024 and 2023. The balance sheet as of December 31, 2023 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company's audited financial statements and notes thereto, included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC.

The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

Liquidity and Need to Raise Additional Capital

As of September 30, 2024, the Company had an accumulated deficit of $604.6 million as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans for the next twelve months following the issuance of these financial statements. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidates. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year from the issuance of these financial statements. Management’s plans in order to meet its operating cash flow requirements include seeking additional collaborative agreements for certain of its programs as well as financing activities such as public offerings and private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments.

There are no assurances that such additional funding will be obtained and that the Company will succeed in its future operations. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations. As further described in Note 6, the Company classified the remaining balance of its term loan as a current liability on the Company’s balance sheets as of September 30, 2024 and December 31, 2023. These financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event the Company can no longer continue as a going concern.

Inventories, net

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company capitalizes inventories produced in preparation for product launches after receiving regulatory approval on a product. The Company may be required to expense previously capitalized inventory costs upon a change in management’s judgment due to new information that suggests that the inventory will not be saleable.

The Company's inventories consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	$ 137	$ 165
Work in process	1,236	1,164
Finished goods	1,003	890
Total inventories	$ 2,376	$ 2,219

Leases

ASC 842 requires the Company to recognize an operating lease right-of-use asset and corresponding operating lease liability for the Company's leased properties. The Company's operating lease right-of-use assets and liabilities are recognized under ASC 842 based on the present value of lease payments over the remaining lease term at the lease commencement date. In determining the net present value of lease payments, we estimate the incremental borrowing rate based on the information available, including remaining lease term. As of September 30, 2024, the weighted-average remaining lease term was 2.86 years for the Company's leased properties.

Revenue Recognition

Product Revenue, Net

The Company manufactures and sells ALZET osmotic pumps used in laboratory research, and manufactures and sells certain excipients used by pharmaceutical companies as raw materials in certain of their products, including POSIMIR, a marketed animal health product and Methydur.

Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon shipment to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less.

Trade Discounts and Allowances: The Company provides certain customers with discounts that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns: The Company generally offers customers a limited right of return for products that have been purchased. The Company estimates the amount of its product sales that are probable of being returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities primarily using its historical sales information. The Company expects product returns to be minimal.

Collaborative Research and Development and Other Revenue

The Company enters into license agreements, under which it licenses certain rights to its product candidates or products to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; reimbursement of development costs incurred by the Company under approved work plans; development, regulatory, intellectual property and commercial milestone payments; payments for manufacturing supply services the Company provides itself or through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in collaborative research and development revenues, except for revenues from royalties on net sales of licensed products and earn-out revenues, which are classified as other revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. For arrangements that are determined to include multiple performance obligations, the Company must develop assumptions that require judgment to determine the estimated stand-alone selling price for each performance obligation identified. These assumptions may include: forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company expects to recognize revenue for the variable consideration currently being constrained when it is probable that a significant revenue reversal will not occur.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For performance obligations comprised of licenses that are bundled with other promises, the Company utilizes its judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the Company applies an appropriate method of measuring progress for purposes of recognizing related revenues from the allocated transaction price. For performance obligations recognized over time, the Company evaluates the measure of progress each reporting period and recognizes revenues on a cumulative catch-up basis as collaborative research and development revenues.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

Manufacturing Supply Services: Arrangements that include a promise for future supply of raw materials or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide a material right to the customer and if so, they are accounted for as separate performance obligations and allocated a portion of the transaction price based on the estimated standalone selling price of the material right. If the Company is entitled to additional payments when the customer exercises these options, the deferred transaction price and any additional payments are recorded in collaborative research and development revenue when the customer obtains control of the goods.

Royalties and Earn-outs: For arrangements that include sales-based royalties or earn-outs, including milestone payments based on first commercial sale or the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty or earn-out has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized material royalty revenue resulting from the Company's collaborative arrangements or material earn-out revenues from any of the Company's agreements.

Research and development services: Revenue from research and development services that are determined to represent a distinct performance obligation related to services performed under the collaborative arrangements with the Company's third-party collaborators is recognized over time as the related research and development services are performed using an appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and recognizes revenue on a cumulative catch-up basis, as collaborative research and development revenue. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when the Company does not expend the required level of effort during a specific period in comparison to funds received under the respective agreement.

The Company receives payments from its customers based on development cost schedules established in each contract. Up-front payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Total revenue by geographic region based on customers' locations for the three and nine months ended September 30, 2024 and 2023 are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
United States	$ 1,209	$ 883	$ 3,364	$ 3,304
Europe	428	525	1,615	1,569
Japan	155	124	442	406
Other	135	212	504	600
Total	$ 1,927	$ 1,744	$ 5,925	$ 5,879

Prepaid and Accrued Clinical Costs

The Company incurs significant costs associated with third party consultants and organizations for pre-clinical studies, clinical trials, contract research, regulatory advice and other research and development-related services. The Company is required to estimate periodically the cost of services rendered but unbilled based on management's estimates. Estimates are determined each reporting period by reviewing the terms and conditions of the underlying contracts, reviewing open purchase orders and by having detailed discussions with internal clinical personnel and third-party service providers as to the nature and status of the services performed in relation to amounts billed. The costs for unbilled services are estimated by applying the rates and fees applicable in the underlying contracts. If these good faith estimates are inaccurate, actual expenses incurred could materially differ from these estimates.

Prepaid and Accrued Manufacturing Costs

The Company incurs significant costs associated with third party consultants and organizations for manufacturing, validation, testing and other research and development-related services. The Company is required to estimate periodically the cost of services rendered but unbilled based on management's estimates. Estimates are determined each reporting period by reviewing the terms and conditions of the underlying contracts, reviewing open purchase orders and by having detailed discussions with internal personnel and third-party service providers as to the nature and status of the services performed in relation to amounts billed. The costs for unbilled services are estimated by applying the rates and fees applicable in the underlying contracts. If these good faith estimates are inaccurate, actual expenses incurred could materially differ from these estimates.

Research and Development Expenses

Research and development expenses are primarily comprised of salaries and benefits associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development costs are expensed as incurred. Research and development costs paid to third parties under sponsored research agreements are recognized as the related services are performed. In addition, research and development expenses incurred that are reimbursed by the Company's partners are recorded as collaborative research and development revenue.

Selling, general and administrative Expenses

Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other costs associated with finance, accounting, legal, business development, sales and marketing and other administrative personnel, overhead and facility costs, and other general and administrative costs.

Comprehensive Loss

Components of other comprehensive loss are comprised entirely of unrealized gains and losses on the Company's available-for-sale securities for all periods presented. Total comprehensive loss has been disclosed in the Company's Condensed Unaudited Statements of Operations and Comprehensive Loss.

Common Stock Warrants

The Company accounts for its common stock warrants in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). Based upon the provisions of ASC 480 and ASC 815, the Company accounts for common stock warrants and pre-funded warrants as current liabilities if the warrant fails the equity classification criteria. Common stock warrants and pre-funded warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liabilities within the statements of operations.

The Company values its pre-funded warrants and common stock warrants classified as liabilities using the Black-Scholes option pricing model or other acceptable valuation models, including the Monte-Carlo simulation model.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding and common stock equivalents (i.e., options to purchase common stock) outstanding during the period, if dilutive, using the treasury stock method for options.

The numerators and denominators in the calculation of basic and diluted net loss per share were as follows (in thousands except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Basic loss per share computation:				
Net loss	$ (4,285)	$ (3,015)	$ (15,628)	$ (26,183)
Weighted average number of shares outstanding - basic	31,039	27,211	30,906	25,175
Net loss per share - basic	$ (0.14)	$ (0.11)	$ (0.51)	$ (1.04)
Diluted loss per share computation:				
Net loss	$ (4,285)	$ (3,015)	$ (15,628)	$ (26,183)
Change in fair value of pre-funded warrant liabilities	—	738	—	996
Net loss adjusted for change in fair value of warrant liabilities	$ (4,285)	$ (3,753)	$ (15,628)	$ (27,179)
Weighted average shares used to compute basic net loss per share	31,039	27,211	30,906	25,175
Dilutive effect of pre-funded warrants	—	300	—	258
Weighted average shares used to compute diluted net loss per share	31,039	27,511	30,906	25,433
Net loss per share - diluted	$ (0.14)	$ (0.14)	$ (0.51)	$ (1.07)

Options to purchase approximately 3.7 million and 3.8 million shares of common stock were excluded from the denominator in the calculation of diluted net loss share for the three and nine months ended September 30, 2024, respectively, as the effect would be anti-dilutive. Options to purchase approximately 3.5 million and 3.4 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and nine months ended September 30, 2023, respectively, as the effect would be anti-dilutive.

Both the pre-funded warrants and the common warrants to purchase shares of common stock entitle the holders thereof to participate in dividends and other distributions of assets by the Company to its holders of common shares, but are not required to absorb losses incurred. As a result, all warrants were excluded from basic net loss per share calculations during the three and nine months ended September 30, 2024 and 2023, respectively. For diluted net loss per share purposes, warrants are included in the number of shares outstanding if the effect is dilutive. The dilutive effect of pre-funded warrants was 300,000 shares and 258,242 shares for the three and nine months ended September 30, 2023, respectively. Additional common warrants to purchase 3.6 million shares were excluded from the denominator in the calculation of diluted net loss share for the three and nine months ended September 30, 2024, as the effect would be anti-dilutive. Additional common warrants to purchase 4.0 million and 2.4 million shares were excluded from the denominator in the calculation of diluted net loss per share for the three and nine months ended September 30, 2023, respectively, as the effect would be anti-dilutive.

Recent Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update (“ASU”) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07). The amendments in ASU 2023-07 are intended to improve reportable segment disclosure, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related disclosures.

Note 2. Strategic Agreements

The collaborative research and development and other revenues associated with the Company’s collaborators or counterparties were $369,000 and $1.5 million for the three and nine months ended September 30, 2024, respectively, compared with $506,000 and $1.7 million for the corresponding periods in 2023. The collaborative research and development and other revenue included (a)

amounts related to earn-out revenue from Indivior UK Limited ("Indivior") with respect to PERSERIS net sales; (b) feasibility programs and research and development activities funded by our collaborators and (c) royalty revenue from Orient Pharma Co., Ltd. ("Orient Pharma") with respect to Methydur net sales.

Agreement with Innocoll

On December 21, 2021, the Company entered into a license agreement (as amended, the "Innocoll Agreement") with Innocoll Pharmaceuticals Limited ("Innocoll"). Pursuant to the Innocoll Agreement, the Company has granted Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize in the United States, POSIMIR®, the Company's FDA-approved post-surgical pain product, with respect to all uses and applications in humans. The Innocoll Agreement provides for the assignment of the Company's supply agreement with its contract manufacturing organization to Innocoll and also provides Innocoll with the right, within the United States, to expand the approved indications of POSIMIR. The Company retains, outside the United States, all of the global rights to POSIMIR.

The Company is entitled to receive tiered, low double-digit to mid-teen royalties on net product sales of POSIMIR in the United States. The Company may earn additional milestone payments of up to $122.0 million in the aggregate, depending on the achievement of certain regulatory, commercial, and intellectual property milestones with respect to POSIMIR.

There were no revenues recognized related to the Innocoll Agreement for the three and nine months periods ended September 30, 2024 and 2023, and none of the agreement milestones have been met. On November 8, 2024, the Company received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to the Company, and the Company is evaluating next steps with respect to the commercialization of POSIMIR.

Patent Purchase Agreement with Indivior

In September 2017, we entered into an agreement with Indivior (the "Indivior Agreement"), under which we assigned to Indivior certain patents that may provide further intellectual property protection for PERSERIS, Indivior's extended-release injectable suspension for the treatment of schizophrenia in adults. In consideration for such assignment, Indivior made non-refundable upfront and milestone payments to DURECT totaling $17.5 million. Additionally, under the terms of the agreement with Indivior, the Company is entitled to receive quarterly earn-out payments into 2026 based on a single digit percentage of U.S. net sales of PERSERIS. Indivior commercially launched PERSERIS in the U.S. in February 2019. The Indivior Agreement contains customary representations, warranties and indemnities of the parties. Amounts recognized during the three and nine months ended September 30, 2024 and 2023 related to earn-out revenues from PERSERIS have been immaterial and are included in collaborative research and development and other revenue. In July 2024, Indivior announced discontinuation of sales and marketing for PERSERIS due to the highly competitive market and impending changes that are expected to intensify payor management in the treatment category in which PERSERIS participates.

Note 3. Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company follows a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. These levels of inputs are the following:

- Level 1—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 for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the 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 Company's financial instruments are valued using quoted prices in active markets or based upon other observable inputs. Money market funds are classified as Level 1 financial assets. Certificates of deposit, commercial paper, municipal bonds, corporate debt securities, and U.S. Government agency securities are classified as Level 2 financial assets. The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities. The Company's Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The fair value of commercial paper is based upon the time to maturity and discounted using the three-month treasury bill rate. The average remaining maturity of the Company's Level 2 investments as of September 30, 2024 is less than twelve months and these investments are rated by S&P and Moody's at AAA or AA- for securities and A1, A2, P1 or P2 for commercial paper.

The following is a summary of available-for-sale securities as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 865	$ —	$ —	$ 865
Certificates of deposit	150	—	—	150
Commercial paper	7,673	1	(1)	7,673
	$ 8,688	$ 1	$ (1)	$ 8,688
Reported as:				
Cash and cash equivalents	$ 7,249	$ —	$ (1)	$ 7,248
Short-term investments	1,289	1	—	1,290
Long-term restricted investments	150	—	—	150
	$ 8,688	$ 1	$ (1)	$ 8,688

	December 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 951	$ —	$ —	$ 951
Certificates of deposit	150	—	—	150
Commercial paper	24,896	—	(14)	24,882
	$ 25,997	$ —	$ (14)	$ 25,983
Reported as:				
Cash and cash equivalents	$ 24,566	$ —	$ (13)	$ 24,553
Short-term investments	1,281	—	(1)	1,280
Long-term restricted investments	150	—	—	150
	$ 25,997	$ —	$ (14)	$ 25,983

The following is a summary of the cost and estimated fair value of available-for-sale securities at September 30, 2024, by contractual maturity (in thousands):

	September 30, 2024	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 7,673	$ 7,673
Mature after one year through five years	150	150
	$ 7,823	$ 7,823

There were no securities that have had an unrealized loss for more than 12 months as of September 30, 2024.

As of September 30, 2024, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Warrant Liabilities

The following table summarizes the activity of the Company's Level 3 warrant liabilities during the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Fair value at beginning of period - February 2023 issuance (Pre-funded warrants)	$ —	$ 1,485	$ —	$ —
Initial fair value at the original issuance date	—	—	—	1,743
Change in fair value during the period	—	(738)	—	(996)
Fair value at end of period - February 2023 issuance (Pre-funded warrants)	$ —	$ 747	$ —	$ 747
Fair value at beginning of period - February 2023 issuance (Common warrants)	$ 714	$ 8,963	$ 312	$ —
Initial fair value at the original issuance date	—	—	—	10,290
Change in fair value during the period	12	(4,780)	414	(6,107)
Fair value of liability classified warrants exercised	—	(2,827)	—	(2,827)
Fair value at end of period - February 2023 issuance (Common warrants)	$ 726	$ 1,356	$ 726	$ 1,356
Fair value at beginning of period - July 2023 issuance (Common warrants)	$ 2,306	$ —	$ 912	$ —
Initial fair value at the original issuance date	—	5,788	—	5,788
Change in fair value during the period	105	(1,397)	1,499	(1,397)
Fair value at end of period - July 2023 issuance	$ 2,411	$ 4,391	$ 2,411	$ 4,391
Total fair value at end of period	$ 3,137	$ 6,494	$ 3,137	$ 6,494

February 2023 Warrants

In February 2023, the Company issued pre-funded warrants to purchase an aggregate of 300,000 shares of common stock and common warrants to purchase an aggregate of 2,000,000 shares of common stock in a registered direct offering.

Pre-Funded Warrants

The pre-funded warrants were accounted for as current liabilities on the balance sheets and were adjusted to estimated fair value at period end through "other income (expense)" on the statements of operations. The estimated fair value of the outstanding pre-funded warrants was $1.7 million, zero and zero as of February 8, 2023 (i.e., the issuance date), December 31, 2023 and September 30, 2024, respectively. In November 2023, all 300,000 shares of the pre-funded warrants were exercised in accordance with the financing agreement, resulting in an issuance of 300,000 shares of common stock to the holder. The Company calculated the estimated fair value of the pre-funded warrants using a Black-Scholes option pricing model with the following key assumptions:

	February 8, 2023 (issuance)
Common stock price	$ 5.81
Exercise price per share	$ 0.00001
Expected volatility	86.60%
Risk-free interest rate	3.82%
Contractual term (in years)	5.00
Expected dividend yield	—%

Common Warrants

The common warrants are accounted for as current liabilities on the balance sheets and are adjusted to estimated fair value at period end through "other income (expense)" on the statements of operations. The estimated fair value of the outstanding common warrants was $10.3 million, $312,000 and $726,000 as of February 8, 2023 (i.e., the issuance date), December 31, 2023 and September 30, 2024, respectively. In September 2023, 1,400,000 shares of the common warrants were exercised through the alternative cashless exercise provision in accordance with the financing agreement, resulting in a net issuance of 924,000 shares to the holder. The aggregate number of shares of our common stock issuable in such alternative cashless exercise equals the product of (x)

the aggregate number of shares of our common stock that would be issuable upon exercise of the common warrant in accordance with the terms of such common warrant if such exercise were by means of a cash exercise rather than a cashless exercise and (y) 0.66. The Company calculated the estimated fair value of the common warrants using a Monte Carlo simulation model with the following key assumptions. The Company took the likelihood of achieving certain clinical events and related impact on the Company's common stock price into account, as appropriate.

The exercise price for the outstanding common warrants (i.e., 600,000 shares) was adjusted down from $5.00 per share to $0.51 per share as of December 31, 2023 as a result of an anti-dilution provision in the common warrants issued in the February 2023 financing that was triggered by the sale of our common stock in the open market in November 2023. There were 600,000 shares of outstanding common warrants as of September 30, 2024.

	February 8, 2023 (issuance)	December 31, 2023	September 30, 2024
Common stock price	$ 5.81	$ 0.59	$ 1.34
Exercise price per share	$ 5.00	$ 0.51	$ 0.51
Expected volatility	86.60%	118.00%	122.00%
Risk-free interest rate	3.82%	3.93%	3.58%
Contractual term (in years)	5.00	4.10	3.50
Expected dividend yield	—%	—%	—%

July 2023 warrants

In July 2023, the Company issued common warrants to purchase an aggregate of 2,991,027 shares of common stock in a registered direct offering.

The common warrants are accounted for as current liabilities on the balance sheets and are adjusted to estimated fair value at period end through “other income (expense)” on the statements of operations. The estimated fair value of the outstanding common warrants was $5.8 million, $912,000 and $2.4 million as of July 21, 2023 (i.e., the issuance date), December 31, 2023 and September 30, 2024, respectively. The Company calculated the estimated fair value of the common warrants using a Black-Scholes option pricing model with the following key assumptions:

	July 21, 2023 (issuance)	December 31, 2023	September 30, 2024
Common stock price	$ 3.05	$ 0.59	$ 1.34
Exercise price per share	$ 4.89	$ 4.89	$ 4.89
Expected volatility	88.60%	115.60%	117.51%
Risk-free interest rate	4.18%	3.88%	3.58%
Contractual term (in years)	5.00	4.60	3.81
Expected dividend yield	—%	—%	—%

There have been no exercises of the common warrants issued in the July 2023 registered direct offering.

Note 4. Accrued Liabilities

Accrued liabilities as of September 30, 2024 and December 31, 2023 were comprised as follows (in thousands):

	September 30, 2024	December 31, 2023
Accrued contract research and manufacturing costs	$ 2,780	$ 2,340
Accrued compensation and benefits	980	1,320
Accrued clinical costs	50	1,578
Others	988	728
Total	$ 4,798	$ 5,966

Note 5. Stock-Based Compensation

As of September 30, 2024, the Company has two stock-based compensation plans. The stock-based compensation cost that has been included in the statements of operations and comprehensive loss is shown as below (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Cost of product revenues	$ 3	$ 4	$ 11	$ 13
Research and development	176	306	552	899
Selling, general and administrative	279	351	838	1,011
Total stock-based compensation	$ 458	$ 661	$ 1,401	$ 1,923

As of September 30, 2024 and December 31, 2023, $11,000 and $14,000 of stock-based compensation cost was capitalized in inventory on the Company's balance sheets for each period, respectively.

The Company uses the Black-Scholes option pricing model to value its stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. The Company considered its historical volatility in developing its estimate of expected volatility.

The Company used the following assumptions to estimate the fair value of stock options granted and shares purchased under its employee stock purchase plan for the three and nine months ended September 30, 2024 and 2023. There were no stock options granted to employees for the three and nine months ended September 30, 2024.

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Stock Options				
Risk-free rate	3.68%	4.17%	3.68%	3.96-4.17%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	7.25	7.5	7.25	7.0-7.5
Volatility	110%	88%	110%	87-88%

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Employee Stock Purchase Plan				
Risk-free rate	5.43%	5.14%	5.43-5.50%	4.58-5.14%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	0.5	0.5	0.5	0.5
Volatility	246%	88%	246%	88-104%

In July 2024, the Company issued a restricted stock unit ("RSU") grant of 275,000 shares of common stock to Timothy M. Papp, Chief Financial Officer of the Company pursuant to the terms of the Company's 2000 Stock Plan. The estimated fair value of RSUs is based on the closing price of the Company's common stock on the grant date, which was $1.67 per share.

Note 6. Term Loan

In July 2016, the Company entered into a $20.0 million secured single-draw term loan (as amended, the “Loan Agreement”) with Oxford Finance LLC (“Oxford Finance”). The Company and Oxford Finance entered into five subsequent amendments to the Loan Agreement in February 2018, November 2018, December 2019, March 2021 and May 2021. For amendments 1-3 and 5, the Company paid Oxford Finance loan modification fees of $100,000, $900,000, $825,000 and $712,500, respectively. As amended, the Loan Agreement provides for interest only payments through June 1, 2023, followed by consecutive monthly payments of principal and interest in arrears starting on June 1, 2023 and continuing through the maturity date of the term loan of September 1, 2025. The Loan Agreement provides for a floating interest rate (7.95% initially and 12.61% as of September 30, 2024) based on an index rate plus a spread. In addition, a payment equal to 10% of the principal amount of the term loan is due when the term loan becomes due or upon the prepayment of the facility. If the Company elects to prepay the loan, there is also a prepayment fee of between 0.75% and 2.5% of the principal amount of the term loan depending on the timing of prepayment. The $150,000 facility fee that was paid at the original closing, the loan modification fees and other debt offering/issuance costs have been recorded as debt discount on the Company’s balance sheets and together with the final $2.0 million payment are being amortized to interest expense using the effective interest method over the revised term of the loan. The Company made principal payments of $2.1 million and $6.4 million for the three and nine months ended September 30, 2024, compared with $2.1 million and $2.9 million for the corresponding periods in 2023, respectively.

The term loan is secured by substantially all of the assets of the Company, except that the collateral does not include any intellectual property (including licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by the Company, which covenants limit the Company’s ability to convey, sell, lease, transfer, assign or otherwise dispose of certain assets of the Company; engage in any business other than the businesses currently engaged in by the Company or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; and make payments on any subordinated debt.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, the Company’s failure to fulfill certain obligations of the Company under the Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in the Company’s business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender’s lien in the collateral or in the value of such collateral. In the event of default by the Company under the Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan Agreement, which could harm the Company’s financial condition. The conditionally exercisable call option related to the event of default is considered to be an embedded derivative which is required to be bifurcated and accounted for as a separate financial instrument. In the periods presented, the value of the embedded derivative is not material, but could become material in future periods if an event of default became more probable than is currently estimated.

As of September 30, 2024, the Company was in compliance with all material covenants under the Loan Agreement and there had been no material adverse change. In accordance with ASC 470-10-45-2, the term loan was classified as a current liability on the Company’s balance sheets as of September 30, 2024 and December 31, 2023 due to the timing of repayment obligations and due to recurring losses, liquidity concerns and a subjective acceleration clause in the Company’s Loan Agreement.

The fair value of the term loan approximates the carrying value. Future maturities due under the term loan as of September 30, 2024, are as follows (in thousands):

Three months ending December 31, 2024	$	2,143
2025		8,429
Total minimum payments		10,572
Less unamortized debt discount and accrued final payment		(106)
Carrying value of term loan, net	$	10,466

Note 7. Commitments

Operating Leases

The Company has lease arrangements for its facilities as follows.

Location	Approximate Square Feet	Operation	Expiration
Cupertino, CA	30,149 sq. ft.	Office, Laboratory and Manufacturing	Lease expires 2027 (with an option to renew for an additional five years)
Vacaville, CA	24,634 sq. ft.	Manufacturing	Lease expires 2028 (with an option to renew for an additional five years)

Under these leases, the Company is required to pay certain maintenance expenses in addition to monthly rent. Rent expense is recognized on a straight-line basis over the lease term for leases that have scheduled rental payment increases. The lease expense includes the amortization of the right-of-use assets with the associated interest component estimated by applying the effective interest method. Rent expenses under all operating leases were $345,000 and $1.2 million for the three and nine months ended September 30, 2024, compared with $492,000 and $1.4 million for the corresponding periods in 2023, respectively.

Future minimum payments under these noncancelable leases are as follows (in thousands):

	Operating Leases
Three months ending December 31, 2024	$ 565
2025	1,401
2026	1,443
2027	432
2028	227
	$ 4,068

Note 8. Stockholders' Equity

In July 2021, the Company filed a shelf registration statement on Form S-3 with the SEC (the "2021 Registration Statement") (File No. 333-258333), which upon being declared effective in August 2021, allowed the Company to offer up to $250.0 million of securities from time to time in one or more public offerings, inclusive of up to $75.0 million of shares of the Company's common stock which the Company could sell, subject to certain limitations, pursuant to a sales agreement dated July 30, 2021 with Cantor Fitzgerald & Co. (the "2021 Sales Agreement"). The 2021 Registration Statement expired on August 16, 2024.

On August 14, 2024, the Company filed a shelf registration statement on Form S-3 with the SEC (the "2024 Registration Statement") (File No. 333-281550), which upon being declared effective on August 23, 2024, allowed us to offer up to $250.0 million of securities from time to time in one or more public offerings. In addition, due to the SEC's "baby shelf" rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a 12-month period, we are currently only able to issue a limited number of shares under our 2024 Registration Statement, which aggregate to no more than one-third of our public float.

Registered Direct Offerings

February 2023 Financing

On February 3, 2023, the Company entered into a securities purchase agreement with two institutional investors relating to the purchase and sale of an aggregate of (i) 1,700,000 shares of its common stock, par value $0.0001 per share, (ii) pre-funded warrants to purchase 300,000 shares of common stock, and (iii) accompanying common warrants, to purchase an aggregate of 2,000,000 shares of common stock, in a registered direct offering (the "February Offering"). The issuance date of the common stock, the pre-funded warrants and the accompanying common warrants was February 8, 2023. The aggregate net proceeds to the Company from the February Offering were approximately $8.8 million after deducting $1.2 million in placement agent fees and other offering expenses, which were allocated to warrant liabilities and included in loss on issuance of warrants on the statement of operations for the year ended December 31, 2023.

The pre-funded warrants were exercisable immediately following the closing date of the February Offering and have an unlimited term and an initial exercise price of $0.00001 per share. The common warrants were immediately exercisable and have a five-year term and an initial exercise price of $5.00 per share, which was lowered to $4.89 per share as a result of an anti-dilution provision in the common warrants issued in the February Offering that was triggered by the July Offering (as defined below) and then

lowered to $0.51 that was triggered by the sale of our common stock in the open market in November 2023. The combined offering price was $5.00 per share and accompanying common warrant, or in the case of pre-funded warrants, $4.99999 per pre-funded warrant and accompanying common warrant. A holder (together with its affiliates) may not exercise any portion of a pre-funded warrant or common 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 Company accounts for the pre-funded warrants and the common warrants as current liabilities based upon the guidance of ASC 480 and ASC 815. The Company evaluated the common and pre-funded warrants under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity ("ASC 815-40") and concluded that they do not meet the criteria to be classified in stockholders' equity. Specifically, the exercise of the pre-funded warrants could be settled in cash upon the occurrence of a tender offer or exchange that involves 50% or more of the Company's common stock. Because a change of 50% or more of the Company's common stock may not result in a change in control of the Company, the Company believes that the scope exception related to the occurrence of a fundamental transaction in ASC 815-40 is not met. The common warrants have the same characteristics as the pre-funded warrants related to the occurrence of a fundamental transaction, therefore the common warrants are also precluded from equity classification. In addition, the holder of the common warrants is permitted to receive the highest volume weighted average price ("VWAP") from the date of announcement of the fundamental transaction through the date the holder provides notice of repurchase, as a way to protect the holder against reductions in the stock price in a fundamental transaction, while allowing the holder to keep the benefits of an upside, which precludes the common warrants from being considered indexed to the Company's stock. Since the common and pre-funded warrants meet the definition of derivatives under ASC 815, the Company recorded these warrants as current liabilities on the balance sheets at the estimated fair value, with subsequent changes in their respective estimated fair values recognized in the statements of operations and comprehensive loss at each reporting date.

Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company's common stock. Because liability-classified financial instruments are initially and subsequently carried at fair value, the Company's financial results will reflect the volatility in these estimate and assumption changes. Changes in estimated fair value are recognized as a component of other income (expense) in the statements of operations.

At the date of issuance, the Company valued the common warrants using a Monte-Carlo valuation model due to the presence of an alternative cashless settlement feature in the financing agreement that provides the warrant holders with an alternative settlement feature to receive a fixed percentage of the shares underlying the warrants for no consideration. Because this feature allows for the warrant holders to use an alternative mechanism to exercise their warrants in a manner that would yield different values, a Monte-Carlo valuation model was determined to be appropriate. The Monte-Carlo valuation resulted in an estimated fair value of the common warrants at issuance of $10.3 million. The pre-funded warrants were valued using the Black-Scholes option valuation model which is a common valuation method that is generally used for valuing warrants that are for the exercise of a fixed number of shares at a fixed exercise price per share. The Black-Scholes method was determined to be appropriate for the pre-funded warrants given the lack of alternative mechanisms to settle the warrants in a manner that would yield different values, such as an alternative cashless settlement feature. The Black-Scholes valuation resulted in an estimated fair value of the pre-funded warrants at issuance of $1.7 million.

Since the estimated fair value of the warrants at issuance was greater than the gross proceeds of $10.0 million received, the Company recorded approximately $2.0 million (i.e., the difference of the estimated fair values of the warrants and the gross proceeds received) as a loss on issuance of warrants on the statements of operations at issuance.

In September 2023, 1,400,000 shares of the common warrants were exercised in connection with the alternative cashless exercise of the warrants and the Company issued 924,000 shares to the holder. The Company recorded a gain of $3.4 million resulting from the exercise of the warrants in the accompanying statements of operations for the year ended December 31, 2023 and recorded $2.8 million in additional-paid-in capital upon the issuance of the shares on the balance sheets as of December 31, 2023.

In November 2023, 300,000 shares of the pre-funded warrants were exercised in connection with the cashless exercise of the warrants and the Company issued 300,000 shares to the holder. The Company recorded a gain of $561,000 resulting from the exercise of the pre-funded warrants in the accompanying statements of operations for the year ended December 31, 2023 and recorded $186,000 in additional-paid-in capital upon the issuance of the shares on the balance sheets as of December 31, 2023.

As of September 30, 2024 and December 31, 2023, common warrants to purchase 600,000 shares of the Company's common stock were outstanding with an exercise price of $0.51 per share. At September 30, 2024, the Company updated the estimated fair value of the outstanding common warrants using a Monte-Carlo valuation model resulting in an estimated fair value of $726,000, an increase of $414,000 for these common warrants compared to the estimated fair value at December 31, 2023.

As of September 30, 2024 and December 31, 2023, there were no pre-funded warrants outstanding.

The loss of $12,000 in common warrants and the gain of $5.5 million in common warrants and pre-funded warrants resulting from the change in the estimated fair value of the liabilities for such warrants were recorded as a change in the estimated fair value of warrant liabilities in the accompanying statements of operations and comprehensive loss for the three months ended September 30, 2024 and 2023, respectively.

The loss of $414,000 in common warrants and the gain of $7.1 million in common warrants and pre-funded warrants resulting from the change in the estimated fair value of the liabilities for such warrants was recorded as a change in the estimated fair value of warrant liabilities in the accompanying statements of operations and comprehensive loss for the nine months ended September 30, 2024 and 2023, respectively.

The common warrant liability will be adjusted to estimated fair value at each balance sheet date until the warrants are settled. Changes in the estimated fair value of the warrant liabilities are recognized as a component of other income (expense), net in the statements of operations and comprehensive loss.

July 2023 Financing

On July 19, 2023, the Company entered into a securities purchase agreement with several institutional investors relating to the purchase and sale of an aggregate of (i) 2,991,027 shares of its common stock, par value $0.0001 per share, and (ii) accompanying common warrants to purchase an aggregate of 2,991,027 shares of common stock, in a registered direct offering (the “July Offering”). The issuance date of the common stock and the accompanying common warrants was July 21, 2023. The aggregate net proceeds to the Company from the July Offering were approximately $13.9 million after deducting $1.1 million in placement agent fees and other offering expenses.

The common warrants were immediately exercisable and have a five-year term and an initial exercise price of $4.89 per share. The combined offering price was $5.015 per share and accompanying common warrant. A holder (together with its affiliates) may not exercise any portion of the common warrants 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 common stock and common warrants are separate freestanding instruments. The estimated fair value of the common stock issued in the July Offering as of the date of issuance (i.e., July 21, 2023) was $9.1 million, which was the number of shares of 2,991,027 multiplied by the price per share as of the date of issuance of $3.05 per share. The common stock issued in the July Offering was classified as equity on the Company’s balance sheets. The Company allocated the offering expenses related to the July 2023 offering of $1.1 million based on the relative fair values of common stock and common warrants issued. The Company recognized an expense for the amount allocated to the common warrants of $427,000 (included within other expense, net) upon the closing of the July Offering in the year ended December 31, 2023. The Company recorded the amount allocated to the common stock of $673,000 as a reduction in additional paid-in capital on its balance sheets as of December 31, 2023.

The Company accounted for the common warrants issued in the July Offering as current liabilities based upon the guidance of ASC 815. The Company evaluated the common warrants under ASC 815-40, Derivatives and Hedging—Contracts in Entity’s Own Equity (“ASC 815-40”) and concluded that they do not meet the criteria to be classified in stockholders’ equity. Upon a fundamental transaction, holders of the common warrants are permitted to settle warrants for a value determined using the Black Scholes formula that incorporates a leveraged common stock price. Specifically, for purposes of the calculation, the stock price is determined as the higher of the VWAP measured over the period from the date of announcement of the fundamental transaction through the date the holder provides notice of repurchase, and the value received by common stockholders in such fundamental transaction. This in effect protects the holder against reductions in the stock price that may result from a fundamental transaction, while allowing the holder to keep the benefits of an upside. This feature precludes the common warrants from being considered indexed to the Company’s stock.

Since the common warrants meet the definition of derivatives under ASC 815, the Company recorded these warrants as current liabilities on the balance sheets at the estimated fair value, with subsequent changes in their respective estimated fair values recognized in the statements of operations and comprehensive loss at each reporting date.

Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company’s common stock. Because liability-classified financial instruments are initially and subsequently carried at fair value, the Company’s financial results will reflect the volatility in these estimate and assumption changes. Changes in estimated fair value are recognized as a component of other income (expense) in the statements of operations.

The Company valued the common warrants issued in the July Offering using the Black-Scholes option valuation model. The Black-Scholes method was determined to be appropriate given the lack of alternative mechanisms to settle the warrants in a manner that would yield different values, such as an alternative cashless settlement feature. The estimated fair value of these warrants as of the issuance date and as of December 31, 2023 was $5.8 million and $912,000, respectively.

As of September 30, 2024 and December 31, 2023, none of the warrants issued in the July Offering have been exercised. Common warrants to purchase 2,991,027 shares of the Company's common stock were outstanding with an exercise price of $4.89 per share. At September 30, 2024, the Company updated the estimated fair value of the outstanding common warrants using the Black-Scholes option valuation model resulting in an estimated fair value of $2.4 million, an increase of $1.5 million for these common warrants compared to the estimated fair value at December 31, 2023. The loss of $105,000 and $1.5 million resulting from the change in the estimated fair value of the liabilities for the warrants was recorded as a change in the estimated fair value of warrant liabilities in the accompanying statements of operations and comprehensive loss for the three and nine months ended September 30, 2024, respectively.

The common warrant liability will be adjusted to estimated fair value at each balance sheet date until the warrants are settled. Changes in the estimated fair value of the warrant liabilities are recognized as a component of other income (expense), net in the statements of operations and comprehensive loss.

The pre-funded warrants and the common warrants issued in the February Offering and the July Offering in 2023 are participating securities which, by definition, entitle the holders thereof to participate in dividends and other distributions of assets by the Company to its holders of common shares as though the holder then held common shares.

ATM Financings

During the three months ended September 30, 2024, there were no sales of the Company's common stock in the open market. During the nine months ended September 30, 2024, the Company raised net proceeds (net of commissions) of approximately $648,000 from the sale of 702,090 shares of the Company's common stock in the open market at a weighted average price of $0.94 per share pursuant to the 2021 Registration Statement and the 2021 Sales Agreement.

During the three and nine months ended September 30, 2023, there were no sales of the Company's common stock in the open market.

As of November 11, 2024, the Company had up to $250.0 million of the Company's securities available for sale under the 2024 Registration Statement. However, due to the SEC's "baby shelf" rules discussed above, only up to approximately $15.8 million of our securities are available for sale under the 2024 Registration Statement.

Note 9. Subsequent Events

On November 8, 2024, the Company received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to the Company, and the Company is evaluating next steps with respect to the commercialization of POSIMIR. The Company does not expect that this termination will have a material impact on its financial statements.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations for the three and nine months ended September 30, 2024 should be read in conjunction with (i) our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 28, 2024 as well as Part I, Item 1A., "Risk Factors" section included therein and any additional risk factors that may be described herein or in our subsequent filings with the SEC. References to the "Company," "DURECT," "we," "us" and "our" refer to DURECT Corporation.

Overview

We are a biopharmaceutical company advancing novel and potentially lifesaving investigational therapies derived from our Epigenetic Regulator Program. Larsucosterol, a new chemical entity in clinical development, is the lead candidate in our Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, larsucosterol has been shown in both *in vitro* and *in vivo* studies to play an important regulatory role in lipid metabolism, stress and inflammatory responses, and cell death and survival. We are developing larsucosterol for alcohol-associated hepatitis ("AH"), a life-threatening acute liver condition with no approved therapeutics and 28-Day and 90-Day historical mortality rates of 20%-26% and 29%-31%, respectively. After completing a Phase 2a trial in which 100% of AH patients treated with larsucosterol survived the 28-Day study period, we conducted a double-blind, placebo-controlled Phase 2b clinical trial called AHFIRM (trial in AH to evaluate saFety and effIcacy of laRsucosterol treatMent). Through our AHFIRM trial, we evaluated larsucosterol's potential to reduce mortality or liver transplantation compared to a placebo with or without steroids at the investigators' discretion. In total, we enrolled 307 patients at leading hospitals in the U.S., Australia, E.U. and U.K. In November 2023, we announced topline data from the AHFIRM trial that showed a compelling efficacy signal in favor of larsucosterol in the key secondary endpoint of mortality at 90 days. Both the 30 mg and 90 mg larsucosterol doses demonstrated clinically meaningful trends in reduction of mortality at 90 days with mortality reductions of 41% (p=0.068) in the 30 mg arm and 35% (p=0.124) in the 90 mg arm compared with placebo. The numerical improvement in the primary endpoint of mortality or liver transplant at 90 days did not achieve statistical significance for either dose of larsucosterol. Both doses of larsucosterol in AHFIRM showed a more pronounced reduction in mortality in patients enrolled in the U.S., representing 76% of patients enrolled in the trial. The reductions in mortality at 90 days were 57% (p=0.014) in the 30 mg arm and 58% (p=0.008) in the 90 mg arm compared with placebo in the U.S. Larsucosterol was safe and well tolerated. There were fewer treatment-emergent adverse events ("TEAEs") in the larsucosterol arms compared with placebo. In May 2024, we announced that the FDA granted Breakthrough Therapy Designation ("BTD") to larsucosterol for the treatment of AH. In July 2024, we held a Type B meeting with the FDA to discuss the design of our planned Phase 3 clinical trial of larsucosterol in AH that, if successful, could support a potential New Drug Application filing. In September 2024, we provided details on the design of our upcoming registrational Phase 3 trial which will evaluate larsucosterol for the treatment of patients with severe AH. The proposed Phase 3 trial design incorporates feedback from the Type B meeting held with the FDA under the BTD. It is designed as a randomized, double-blind, placebo-controlled, multi-center study conducted in the U.S., which will evaluate the safety and efficacy of larsucosterol for the treatment of patients with severe AH. The primary outcome measure will be a 90-day survival endpoint. The Phase 3 trial is planned to enroll approximately 200 patients randomized in a 1:1 ratio across two arms: (1) larsucosterol (30 mg) or (2) placebo, which will be added to the current standard of care, with or without methylprednisolone capsules in the placebo patients at the investigators' discretion. Patients enrolled in the trial will be followed for an additional 90 days to collect additional safety and outcomes data. Our plan is to initiate a Phase 3 clinical trial of larsucosterol in AH, subject to obtaining sufficient funding, and present topline results within two years of initiation. We have also investigated larsucosterol in patients with metabolic dysfunction-associated steatohepatitis ("MASH"), previously known as non-alcoholic steatohepatitis or NASH with encouraging results in a Phase 1b clinical trial and may consider further development of larsucosterol for this and other indications.

In addition to our Epigenetic Regulator Program, we developed a novel and proprietary post-surgical pain product called POSIMIR® that utilizes our innovative SABER® platform technology to enable continuous sustained delivery of bupivacaine, a non-opioid local analgesic, over three days in adults. In February 2021, POSIMIR received FDA approval for post-surgical pain reduction for up to 72 hours following arthroscopic subacromial decompression. In December 2021, we entered into a license agreement (as amended, the "Innocoll Agreement") with Innocoll Pharmaceuticals Limited ("Innocoll"), pursuant to which we granted to Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize POSIMIR in the United States. In September 2022, Innocoll launched POSIMIR in the U.S. On November 8, 2024, we received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to us, and we are evaluating next steps with respect to the commercialization of POSIMIR. We do not expect that this termination will have a material impact on our financial statements.

As a result of the assignment of certain patent rights, we have in the past received single digit sales-based earn-out payments from U.S. net sales of Indivior UK Limited ("Indivior")'s PERSERIS® (risperidone) drug for schizophrenia and single-digit royalties from net sales of Orient Pharma Co., Ltd. ("Orient Pharma")'s Methydur Sustained Release Capsules ("Methydur") for the treatment of attention deficit hyperactivity disorder ("ADHD") in Taiwan. In July 2024, Indivior announced discontinuation of sales and marketing for PERSERIS due to the highly competitive market and impending changes that are expected to intensify payor management in the treatment category in which PERSERIS participates. We do not expect that this discontinuation will have a material impact on our financial statements. We also manufacture and sell ALZET® osmotic pumps used in laboratory research.

NOTE: POSIMIR is a trademark or registered trademark of Innocoll Pharmaceuticals, Ltd. in the U.S. and a trademark or registered trademark of DURECT Corporation in countries other than the U.S. SABER, ALZET, DURECT, and the DURECT logo are trademarks or registered trademarks of DURECT Corporation in the U.S. and other countries. Other trademarks referred to belong to their respective owners. Full prescribing information for POSIMIR, including BOXED WARNING and Medication Guide can be found at www.posimir.com. Full prescribing information for PERSERIS, including BOXED WARNING and Medication Guide can be found at www.perseris.com.

Collaborative Research and Development and Other Revenue

Collaborative research and development and other revenue consists of three broad categories: (a) the recognition of upfront license payments over the period of our continuing involvement with the third party, (b) the reimbursement of qualified research expenses by third parties, (c) milestone payments in connection with our collaborative agreements and (d) royalties and earn-out payments from our agreements with third parties.

Product Revenues

We also currently generate product revenue from the sale of two product lines:

- ALZET® osmotic pumps which are used for animal research; and
- certain key excipients that are included in Methydur and one excipient that is included in POSIMIR and in a marketed animal health product.

Because we consider our core business to be developing and commercializing pharmaceuticals, we do not intend to significantly increase our investments in or efforts to sell or market any of our existing product lines. However, we expect that we will continue to make efforts to increase our revenues related to collaborative research and development by entering into new collaborations.

Operating Results

Since our inception in 1998, we have generally had a history of operating losses. As of September 30, 2024, we had an accumulated deficit of $604.6 million as well as negative cash flows from operating activities. Our net losses were $4.3 million and $15.6 million for the three and nine months ended September 30, 2024, respectively, compared with $3.0 million and $26.2 million for the corresponding periods in 2023. These losses have resulted primarily from costs incurred to research and develop our product candidates and, to a lesser extent, from selling, general and administrative costs associated with our operations and product sales. We expect our research and development expenses and our selling, general and administrative expenses in the near future to be comparable to the third quarter of 2024. We also expect to incur continuing losses and negative cash flows from operations for the foreseeable future. As disclosed in the "Liquidity and Capital Resources" section, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The most significant accounting estimates and assumptions relate to revenue recognition, prepaid and accrued clinical costs, prepaid and accrued manufacturing costs and valuation of warrant liabilities. Actual amounts could differ significantly from these estimates. There have been no material changes to our other critical accounting estimates as compared to the disclosures in our Annual Report on Form 10-K for the year ended December 31, 2023.

Results of Operations

Three and nine months ended September 30, 2024 and 2023

Collaborative research and development and other revenue

We recognize revenue from collaborative research and development activities and service contracts. We expect our collaborative research and development and other revenue to decrease in the near term due to Indivior's discontinuation of sales and marketing of PERSERIS.

The collaborative research and development and other revenue associated with our collaborators or counterparties were $369,000 and $1.5 million for the three and nine months ended September 30, 2024, respectively, compared with $506,000 and $1.7 million for the corresponding periods in 2023. The collaborative research and development and other revenue included (a) amounts related to earn-out revenue from Indivior with respect to PERSERIS net sales; (b) feasibility programs and research and development activities funded by our collaborators and (c) royalty revenue from Orient Pharma with respect to Methydur net sales.

The decrease in collaborative research and development and other revenue in the three months ended September 30, 2024 compared with the corresponding period in 2023 was primarily due to lower earn-out revenue recognized from Indivior, partially offset by higher royalty revenue recognized from Orient Pharma. The decrease in collaborative research and development and other revenue in the nine months ended September 30, 2024 compared with the corresponding period in 2023 was primarily due to lower revenue recognized from the feasibility agreements with other companies, partially offset by higher earn-out revenue recognized from Indivior and royalty revenue recognized from Orient Pharma.

Product revenue, net

A portion of our revenues is derived from product sales, which include our ALZET osmotic pump product line and certain excipients that are included in POSIMIR, Methydur and in a marketed animal health product. Net product revenues were $1.6 million and $4.5 million for the three and nine months ended September 30, 2024, respectively, compared with $1.2 million and $4.2 million for the corresponding periods in 2023. The increases in the three and nine months ended September 30, 2024 were primarily attributable to higher revenue from our ALZET osmotic pump product line as a result of higher unit sales prices and higher revenue from certain excipients that are included in Methydur and in a marketed animal health product compared to the corresponding periods in 2023.

Cost of product revenues

Cost of product revenues was $513,000 and $1.2 million for the three and nine months ended September 30, 2024, respectively, compared with $312,000 and $1.1 million for the corresponding periods in 2023. The increases in the three and nine months ended September 30, 2024 were primarily due to higher units sold as well as higher inventory reserve recorded for our ALZET product line and higher units sold of certain excipients that are included in Methydur and in a marketed animal health product compared to the corresponding periods in 2023. Stock-based compensation expense recognized related to cost of product revenues was $3,000 and $11,000 for the three and nine months ended September 30, 2024, respectively, compared to $4,000 and $13,000 for the corresponding periods in 2023.

As of September 30, 2024, we had eight manufacturing employees compared with nine as of September 30, 2023. We expect the number of employees involved in manufacturing will remain consistent in the near future.

Research and development

Research and development expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation costs associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs.

Research and development expenses were $2.2 million and $8.5 million for the three and nine months ended September 30, 2024, respectively, compared to $7.2 million and $23.7 million for the corresponding periods in 2023. We incurred lower research and development costs associated with larsucosterol, the depot injectable programs as well as other research programs in the three and nine months ended September 30, 2024 compared to the corresponding periods in 2023, as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $176,000 and $552,000 for the three and nine months ended September 30, 2024, respectively, compared to $306,000 and $899,000 for the corresponding periods in 2023. As of September 30, 2024, we had 17 research and development employees compared with 38 as of September 30, 2023. We expect the number of employees involved in research and development will remain consistent in the near future and that research and development expenses in the near future will be comparable with the third quarter of 2024.

Research and development expenses associated with our major development programs were as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Larsucosterol	$ 2,149	$ 6,391	$ 8,415	$ 21,081
Depot injectable programs	—	—	2	319
Others	15	808	113	2,338
Total research and development expenses	$ 2,164	$ 7,199	$ 8,530	$ 23,738

Larsucosterol

Our research and development expenses for larsucosterol were $2.1 million and $8.4 million in the three and nine months ended September 30, 2024, respectively, compared to $6.4 million and $21.1 million for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower clinical trial related expenses as we completed the AHFIRM trial and lower employee-related costs for this drug candidate compared with the corresponding periods in 2023.

Depot injectable programs

Our research and development expenses for depot injectable programs were zero and $2,000 in the three and nine months ended September 30, 2024, respectively, compared to zero and $319,000 for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower employee-related costs and lower outside expenses for these programs compared with the corresponding periods in 2023.

Other DURECT research programs

Our research and development expenses for all other programs were $15,000 and $113,000 in the three and nine months ended September 30, 2024, respectively, compared to $808,000 and $2.3 million for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower employee-related costs and lower outside expenses associated with these programs compared with the corresponding periods in 2023.

Our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete are highly speculative and subjective due to numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation, uncertainties of future preclinical and clinical study results, uncertainties with our collaborators' commitment to and progress in the programs and uncertainties associated with process development and manufacturing as well as sales and marketing. In addition, with respect to our development programs subject to third-party collaborations, the timing and expenditures to complete the programs are subject to the control of our collaborators. Therefore, we cannot reasonably estimate the timing and costs of the efforts necessary to complete the research and development programs. For additional information regarding these risks and uncertainties, see Part I, Item 1A., "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024, and any additional risk factors that may be described herein or in our subsequent filings filed with the SEC.

Selling, general and administrative. Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other costs associated with finance, accounting, legal, business development, sales and marketing and other administrative personnel, overhead and facility costs, and other general and administrative costs.

Selling, general and administrative expenses were $3.2 million and $9.3 million in the three and nine months ended September 30, 2024, respectively, compared to $3.8 million and $11.7 million for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower employee expenses, lower audit related expenses and lower patent expenses compared to the corresponding periods in 2023. Stock-based compensation expense recognized related to selling, general and administrative personnel was $279,000 and $838,000 for the three and nine months ended September 30, 2024, respectively, compared to $351,000 and $1.0 million for the corresponding periods in 2023.

We had 21 selling, general and administrative employees as of September 30, 2024 compared with 25 as of September 30, 2023. We expect selling, general and administrative expenses in the near future to be comparable to the third quarter of 2024.

Other income (expense). Other expense was $318,000 and $2.5 million in the three and nine months ended September 30, 2024, respectively, compared to other income of $6.5 million and $4.4 million for the corresponding periods in 2023.

Interest and other income

Interest and other income was $163,000 and $711,000 in the three and nine months ended September 30, 2024, respectively, compared to $653,000 and $1.7 million for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower balances in our cash, cash equivalents and investments compared with the corresponding periods in 2023.

Interest and other expenses

Interest and other expenses were $364,000 and $1.3 million in the three and nine months ended September 30, 2024, respectively, compared to $700,000 and $2.2 million for the corresponding periods in 2023. The decreases in the three and nine months ended September 30, 2024 were primarily due to lower principal balances on our term loan compared with the corresponding periods in 2023.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities during the three months ended September 30, 2024 was comprised of a non-cash loss of $117,000 for the common warrants issued in February 2023 and July 2023. The change in fair value of warrant liabilities during the nine months ended September 30, 2024 was comprised of a non-cash loss of $1.9 million for the common warrants issued in February 2023 and July 2023.

The change in fair value of warrant liabilities during the three months ended September 30, 2023 was comprised of a non-cash gain of $7.0 million for the liability-classified warrants issued in February 2023 and July 2023 as well as the alternative cashless exercise of common warrants issued in February 2023. The change in fair value of warrant liabilities during the nine months ended September 30, 2023 comprised of a non-cash gain of $8.6 million for the liability-classified warrants issued in February 2023 and July 2023 as well as the alternative cashless exercise of common warrants issued in February 2023.

Issuance cost for warrants

The issuance cost for warrants was zero in both the three and nine months ended September 30, 2024. The issuance cost for warrants was $427,000 and $1.6 million in the three and nine months ended September 30 2023, respectively.

Loss on issuance of warrants

Loss on issuance of warrants was zero in both the three and nine months ended September 30, 2024. Loss on issuance of warrants was zero and $2.0 million in the three and nine months ended September 30, 2023, respectively.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $10.5 million at September 30, 2024 compared to cash, cash equivalents, and investments of $29.8 million at December 31, 2023. These balances include $150,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of September 30, 2024 and December 31, 2023. The decrease in cash, cash equivalents and investments was primarily due to cash used in ongoing operating activities and principal and interest payments on the term loan, partially offset by net proceeds of $648,000 from the sale of our common stock in the open market pursuant to the 2021 Sales Agreement (as described below) and payments received from collaboration partners and customers. For more information on our registered direct offerings that took place in February and July 2023, see Note 8 “Stockholders’ Equity—Registered Direct Offerings” to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q.

Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers.

As discussed below, we do not have sufficient cash resources to fund our planned operations, existing debt and contractual commitments and planned capital expenditures. Our auditors have issued a going concern opinion as of, and for the year ended, December 31, 2023. Unless we secure funding from collaborations, additional equity or debt financing, of which there can be no assurance, we may not be able to continue operations.

Cash Flows

We used $13.6 million of cash in operating activities for the nine months ended September 30, 2024 compared to $26.1 million for the corresponding period in 2023. The decrease in cash used in operating activities was primarily due to lower costs incurred to research and develop our product candidates and, to a lesser extent, from selling, general and administrative costs associated with our operations and product sales, partially offset by lower payments from our collaborators. The cash used in operations was primarily to

fund operations as well as our working capital requirements. We anticipate that cash used in operating activities in the near future will be comparable to the third quarter of 2024.

We received $34,000 of cash from investing activities for the nine months ended September 30, 2024 compared to using $132,000 of cash in investing activities for the corresponding period in 2023. The increase in cash provided by investing activities was primarily due to an increase in net proceeds from maturities of available-for-sale securities and a decrease in purchases of available of available-for-sale securities for the nine months ended September 30, 2024 compared with the corresponding period in 2023.

We used $5.8 million of cash in financing activities for the nine months ended September 30, 2024 compared to receiving $21.7 million of cash from financing activities for the nine months ended September 30, 2023. The decrease in cash received from financing activities was primarily due to no cash proceeds received from registered direct financings and higher principal payments on the term loan with Oxford Finance LLC ("Oxford Finance") during the nine months ended September 30, 2024 compared with the corresponding period in 2023.

Shelf Registration Statement

In July 2021, we filed a shelf registration statement on Form S-3 with the SEC (the “2021 Registration Statement”) (File No. 333-258333), which upon being declared effective in August 2021, allowed us to offer up to $250.0 million of securities from time to time in one or more public offerings, inclusive of up to $75.0 million of shares of our common stock which we could sell, subject to certain limitations, pursuant to the 2021 Sales Agreement. The 2021 Registration Statement expired on August 16, 2024.

On August 14, 2024, we filed a shelf registration statement on Form S-3 with the SEC (the “2024 Registration Statement”) (File No. 333-281550), which upon being declared effective on August 23, 2024, allowed us to offer up to $250.0 million of securities from time to time in one or more public offerings. In addition, due to the SEC’s “baby shelf” rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company’s public float in a 12-month period, we are currently only able to issue a limited number of shares under our 2024 Registration Statement, which aggregate to no more than one-third of our public float.

During the nine months ended September 30, 2024, we raised net proceeds (net of commissions) of approximately $648,000 from the sale of our common stock in the open market under the 2021 Sales Agreement.

As of November 11, 2024, we had up to $250.0 million of our securities available for sale under the 2024 Registration Statement. However, due to the SEC’s “baby shelf” rules discussed above, only up to approximately $15.8 million of our securities are available for sale under the 2024 Registration Statement.

Any material sales in the public market of our common stock, under the 2024 Registration Statement, could adversely affect prevailing market prices for our common stock.

Term Loan

In July 2016, we entered into a Loan and Security Agreement (as amended, the "Loan Agreement") with Oxford Finance, pursuant to which Oxford Finance provided a $20.0 million secured single-draw term loan to us with an initial maturity date of August 1, 2020. The term loan was fully drawn at close and the proceeds were used for working capital and general business requirements. Following five amendments, we made interest only payments under the amended Loan Agreement until June 1, 2023, and are making consecutive monthly payments of principal and interest in arrears to be paid through September 1, 2025, the final maturity date of the term loan. The Loan Agreement provides for a floating interest rate (7.95% initially and 12.61% as of September 30, 2024) based on an index rate plus a spread and an additional payment equal to 10% of the principal amount of the term loan, which is due when the term loan becomes due or upon the prepayment of the facility. If we elect to prepay the term loan, there is also a prepayment fee between 0.75% and 2.5% of the principal amount of the term loan depending on the timing of prepayment. Our debt repayment obligations under the Loan Agreement may prove a burden to the Company as they become due, particularly following the expiration of the interest-only period.

The term loan is secured by substantially all of our assets, except that the collateral does not include any intellectual property (including licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; and make payments on any subordinated debt.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the 2016 Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the term loan, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. In the event of default by us under the 2016 Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement. As a result, the term loan was reclassified to current liabilities from non-current liabilities on our balance sheet as of September 30, 2024 and December 31, 2023 due to recurring losses, liquidity concerns and a subjective acceleration clause in the Loan Agreement.

Going Concern

As of September 30, 2024, we had cash, cash equivalents and investments totaling $10.5 million compared to cash, cash equivalents, and investments of $29.8 million at December 31, 2023. In the nine months ended September 30, 2024, we raised net proceeds (net of commissions) of approximately $648,000 from the sale of our common stock in the open market under the 2021 Sales Agreement.

In accordance with ASU No. 2014-15 Presentation of Financial Statements – Going Concern (subtopic 205-40), our management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. Based on our evaluation, substantial doubt exists regarding our ability to continue as a going concern for a period of one year from the issuance of our financial statements.

Presently, we do not have sufficient cash resources to fund our planned operations, existing debt and contractual commitments and planned capital expenditures through at least the next 12 months from issuance of these financial statements. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We expect to incur continuing losses and negative cash flows from operations for the foreseeable future.

We may decide to raise additional capital through a variety of sources in the short-term and in the long-term, including but not limited to:

•the public equity markets;

•private equity financings;

•collaborative arrangements;

•asset sales; and/or

•public or private debt.

There can be no assurance that we will enter into additional collaborative agreements or maintain existing collaborative agreements, will earn collaborative revenues or that additional capital will be available on favorable terms to the Company, if at all. If adequate funds are not available, we may be required to significantly reduce or re-focus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders (assuming convertible debt securities were converted into shares). These factors raise substantial doubt regarding our ability to continue as a going concern. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2023.

During the nine months ended September 30, 2024, there were no significant changes in our commercial commitments and contractual obligations as compared with the information presented in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 28, 2024.

Human Capital

As of November 11, 2024, we had 45 employees, including 17 in research and development, 8 in manufacturing and 20 in selling, general and administrative.

tem 3. Quantitative and Qualitative Disclosures about Market Risk

As of September 30, 2024, our exposure to market risk has not changed materially since December 31, 2023. For more information on financial market risks related to changes in interest rates, reference is made to Part II, Item 7A., “Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024.

tem 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures: The Company’s principal executive and principal financial officers reviewed and evaluated the Company’s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, the Company’s principal executive and principal financial officers concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q the Company’s disclosure controls and procedures are effective at ensuring that information required to be disclosed by the Company in reports that the Company files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including the Company’s principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting: There were no significant changes in the Company’s internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) during the Company’s most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the factors discussed in Part I, Item 1A., "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024, which could materially affect our business, financial position, or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial position, or future results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC. The risk factor set forth below supplements and updates the risk factors previously disclosed and should be read together with the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and with any risk factors we may include in subsequent filings with the SEC.

We will require and may have difficulty or be unsuccessful in raising needed capital in the future to continue to operate as a going concern

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to conduct the research, development, manufacturing and clinical testing of larsucosterol.

Presently, we do not have sufficient cash resources to meet our plans for the next twelve months from the issuance of the financial statements included herein. Our recurring losses from operations, negative cash flows and need for additional capital raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2023. We will require additional financing to fund our operations or we will have to significantly curtail or discontinue our operations to conserve our capital resources. Additional funds may not be available on acceptable terms, if at all, and such availability will depend on a number of factors, some of which are outside of our control, including general capital markets conditions and investors' view of our prospects and valuation. In addition, our ability to raise capital in the public capital markets may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Quarterly Report on Form 10-Q, we are only permitted to utilize the shelf registration statement subject to Instruction I.B.6. to Form S-3, which is referred to as the "baby shelf" rule. For so long as our public float is less than $75 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms. Further, investors' perception of our ability to continue as a going concern may make it more difficult for us to obtain financing, or necessitate that we obtain financing on terms that are more favorable to investors, and could result in the loss of confidence by investors, suppliers and employees. Our continued operations are contingent on our ability to raise additional capital or license or otherwise monetize our assets. If we do not acquire sufficient additional funding or alternative sources of capital to meet our working capital needs, we will have to substantially curtail or discontinue our operations, resulting in delays in the development of larsucosterol and in generating revenue.

Our actual capital requirements will depend on many factors, including:

•continued progress and cost of our research and development programs;

•progress with clinical trials, including a Phase 3 clinical trial for larsucosterol in alcohol-associated hepatitis (AH);

•the time and costs involved in obtaining regulatory approvals, if any;

•costs involved in establishing manufacturing capabilities for pre-clinical, non-clinical, clinical and commercial quantities of our product candidates;

•success in entering into collaboration agreements and achieving milestones under such agreements;

•regulatory actions with respect to our products and product candidates;

•costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property rights;

•costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our products, products we have a financial interest in and, eventually, product candidates;

•competing technological and market developments;

•market acceptance of our products, products we have a financial interest in and, eventually, product candidates;

•any failure to comply with the covenants in our debt instruments that results in acceleration of repayment obligations;

•costs for recruiting and retaining employees and consultants; and

•unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. For example, we do not currently have sufficient capital resources to conduct a Phase 3 trial of larsucosterol. We may seek to raise additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which, in each case, may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies, products or product candidates that we would otherwise seek to develop or commercialize ourselves.

We do not control the commercialization of PERSERIS or Methydur

We have relied on Indivior for the commercialization of PERSERIS. In July 2024, Indivior announced that they were discontinuing sales and marketing activities related to PERSERIS. Accordingly, we expect payments based on sales of PERSERIS to decline in the future. Further, we rely on Orient Pharma for the commercialization of Methydur. If Orient Pharma does not successfully grow Methydur sales, the royalty payments we receive under our agreement with them will be limited. The sales of each of these products may be negatively impacted by challenging macroeconomic conditions.

Our ability to obtain revenues from the commercialization of POSIMIR is uncertain.

We have relied on Innocoll to commercialize POSIMIR in the United States pursuant to the Innocoll Agreement, which entitled us to tiered, low double-digit to mid-teen royalties on net product sales of POSIMIR in the United States, and milestone payments of up to $122.0 million in the aggregate, depending on the achievement of certain regulatory, commercial, and intellectual property milestones with respect to POSIMIR. The current approved labeling for POSIMIR is limited, and Innocoll has been responsible for completing post-marketing non-clinical studies and any additional studies required by the FDA, as well as for manufacturing POSIMIR. On November 8, 2024, we received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to us, and we are evaluating next steps with respect to the commercialization of POSIMIR. There can be no assurance that we will be able to generate revenues from the commercialization of POSIMIR.

For certain of our product candidates, we depend to a large extent on third-party collaborators, and we have limited or no control over their development, sales, distribution and disclosure for those product candidates

Our performance for certain of our product candidates depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain regulatory approvals. We have entered into agreements with Indivior and Orient Pharma under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute certain products or product candidates, subject to payments to us in the form of product royalties, earn-out and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these product candidates, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Enforcing any of these agreements in the event of a breach by the other party could require the expenditure of significant resources and consume a significant amount of management time and attention. Our collaborators may also conduct their activities in a manner that is different from the manner we would recommend or would have chosen had we been developing such product candidates ourselves. Further, our collaborators may elect not to develop or commercialize product candidates arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these product candidates. If any of these events occur, we may not recognize revenue from the commercialization of our product candidates based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our products or product candidates. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Cancellation of third-party collaborations may adversely affect potential economic benefits

Third-party collaboration agreements typically allow the third party to terminate the agreement (or a specific program within an agreement) at will by providing notice. Termination can result from failure of the collaboration to achieve anticipated milestones, from changes in strategy of the other party or for other reasons. In these cases, the product rights typically revert to us or certain rights of the partner to use our proprietary technology are terminated. If there have been payments under such agreements that are being recognized over time, termination of such agreements (or programs) can lead to a near-term increase in our reported revenues resulting from the immediate recognition of the balance of such payments. Termination deprives us of potential future economic benefits under such agreements, and may make it more difficult, unattractive or impossible to enter into agreements with other third parties for use of the assets and/or technologies that were subject to the terminated agreement. For example, on November 8, 2024, Innocoll notified us of their termination of the Innocoll Agreement, effective as of May 6, 2025, pursuant to which we could have received royalties and milestone payments beyond May 6, 2025.

Item 5. Other Information

The information set forth below "Item 1.02. Termination of a Material Definitive Agreement" of Part II, Item 5 of this Quarterly Report on Form 10-Q is provided in lieu of filing such information on a Current Report on Form 8-K under Item 1.02 Termination of a Material Definitive Agreement.

Item 1.02. Termination of a Material Definitive Agreement

On November 8, 2024, we received a notice of termination of the Innocoll Agreement, dated December 21, 2021, as amended on September 19, 2022, by and between the Company and Innocoll. Innocoll terminated the Innocoll Agreement for convenience pursuant to Section 10.2(a) of the Innocoll Agreement, effective May 6, 2025 (the "Termination Date"). Pursuant to the Innocoll Agreement, the Company granted Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize in the United States, POSIMIR®, the Company's FDA-approved post-surgical pain product, with respect to all uses and applications in humans. For further description of the Innocoll Agreement, see Note 2 "Strategic Agreements—Agreement with Innocoll" to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q.

Prior to the Termination Date, Innocoll will work with the Company to fulfill the respective rights and obligations of each party in accordance with the terms and conditions of the Innocoll Agreement, including the transfer of data and know-how related to POSIMIR. As a result of the termination of the Innocoll Agreement, the Company will not be entitled to receive any further royalties or milestone payments due after the Termination Date unless such royalties or milestone payments were accrued prior to the Termination Date. The Company is evaluating next steps with respect to the commercialization of POSIMIR.

Insider Adoption or Termination of Trading Arrangements

During the fiscal quarter ended September 30, 2024, none of our directors or officers informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

tem 6. Exhibits

Exhibit Number	Exhibit Name
3.1*	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company.
10.1+	Form of Employee Restricted Stock Unit Award Agreement for use with the DURECT Corporation 2000 Stock Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 30, 2024)
10.2+	DURECT Corporation 2000 Stock Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 26, 2024)
10.3++*	Amendment No. 1 to Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated July 2, 2015.
10.4++*	Amendment No. 2 to Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated March 6, 2018.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Exchange Act as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in Inline XBRL: (i) Condensed Unaudited Balance Sheets, (ii) Condensed Unaudited Statements of Operations and Comprehensive Loss, (iii) Condensed Unaudited Statements of Changes in Stockholders' Equity, (iv) Condensed Unaudited Statements of Cash Flows and (v) Notes to Condensed Unaudited Financial Statements, tagged as blocks of text and including detailed tags.
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL (included as Exhibit 101).

* Filed herewith.
** Furnished, not filed.
+ Indicates a management contract or compensatory plan or arrangement.
++ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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.

DURECT CORPORATION

By: /S/ JAMES E. BROWN
James E. Brown
Chief Executive Officer

Date: November 14, 2024

By: /S/ TIMOTHY M. PAPP
Timothy M. Papp
Chief Financial Officer
(Principal Accounting Officer)

Date: November 14, 2024

Exhibit 3.1

CERTIFICATE OF AMENDMENT TO THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
DURECT CORPORATION

The undersigned, James E. Brown, hereby certifies that:

1. He is the President and Chief Executive Officer of Durect Corporation, a Delaware corporation (the "Corporation").

2. The original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on February 6, 1998 under the name "Durect Therapeutics Corporation."

3. The first paragraph of Article IV, Paragraph (A) of the Corporation's Amendment to its Amended and Restated Certificate of Incorporation, is amended and restated in its entirety to read as follows:

"(A) The Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Corporation is authorized to issue is Three Hundred and Sixty Million (360,000,000) shares, each with a par value of $0.0001 per share. Three Hundred and Fifty Million (350,000,000) shares shall be Common Stock and Ten Million (10,000,000) shares shall be Preferred Stock."

4. This Certificate of Amendment to the Corporation's Amended and Restated Certificate of Incorporation has been duly adopted by this Corporation's board of directors and stockholders in accordance with the provisions of the Corporation's Amended and Restated Certificate of Incorporation and with Section 242 of the General Corporation Law of the State of Delaware.

5. All other provisions of the Corporation's Amended and Restated Certificate of Incorporation shall remain in full force and effect.

6. This Certificate of Amendment to the Corporation's Amended and Restated Certificate of Incorporation herein certified shall become effective immediately upon filing with the Office of the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment to the Corporation's Amended and Restated Certificate of Incorporation at Cupertino, California on September 25, 2024.

/S/ JAMES E. BROWN
James E. Brown
President and Chief Executive Officer

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [* * *], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.3

AMENDMENT NO. 1 TO EXCLUSIVE LICENSE AGREEMENT

THIS AMENDMENT No. 1 TO EXCLUSIVE LICENSE AGREEMENT is entered into on July 2, 2015 (the "Effective Date of the Amendment"), by and between DURECT Corporation ("Company") and Virginia Commonwealth University Intellectual Property Foundation ("VCUIPF").

WHEREAS, Company and VCUIPF are parties to an Exclusive License Agreement dated December 5, 2012 (the "Agreement"), and

WHEREAS, the parties now wish to amend the Agreement as provided for herein.

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Amendment, the parties do hereby agree as follows:

1. Appendix A of the Agreement is hereby amended by deleting it in its entirety and replacing it with the Appendix A attached hereto and made a part hereof.

2. All capitalized terms not otherwise defined in this Amendment shall have the same meanings that are ascribed to them in the Agreement.

3. Except as expressly amended by this Amendment, the Agreement shall remain unchanged and continue in full force and effect as provided therein. This Amendment and the Agreement constitute the complete, final and exclusive understanding and agreement of the parties with respect to the subject matter of the Agreement, and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the parties respecting the subject matter of the Agreement. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment in duplicate originals by their authorized officers as of the Effective Date of the Amendment.

DURECT CORPORATION	VIRGINIA COMMONWEALTH UNIVERSITY INTELLECTUAL PROPERTY FOUNDATION
By: /S/ STEVE HELMER	By: /S/ IVELINA METCHEVA
Name: Steve Helmer	Name: Ivelina Metcheva Phd, MBA
Title:VP, Chief Patent Counsel	Title: President
Date: July 2, 2015	Date: July 1, 2015

APPENDIX A
LICENSED PATENT RIGHTS

U.S. Patent Applications:

Provisional Serial No. 60/621,537, filed October 25, 2004	Nuclear Oxysterol, Potent Regulator Of Cholesterol Homeostasis, For Therapy Of Hypercholesterolemia, Hyperlipidemia, and Atherosclerosis
Non-Provisional Serial No. 11/739,330, filed April 26, 2007	Nuclear Sulfated Oxysterol, Potent Regulator Of Cholesterol Homeostasis, For Therapy Of Hypercholesterolemia, Hyperlipidemia, and Atherosclerosis
Provisional Serial No. 61/154,063, filed February 20, 2009	5-Cholesten-3b , 25-diol 3-sulfate (25HC3S), an authentic PPARy agonist and LXR antagonist, or the therapy of inflammatory diseases
Non-Provisional Serial No. 12/708,803, filed February 19, 2010	Nuclear Sulfated Oxysterol, Potent Regulator Of Lipid Homeostasis, For Therapy Of Hypercholesterolemia, Hypertriglycerides, Fatty Liver Diseases, and Atherosclerosis
Provisional Serial No. 61/472,293, filed April 6, 2011	Hydroxysteroid sulfotransferase (SULT2B1b) for therapy of hyperlipidemia and fatty liver diseases
Non-Provisional Serial No. 13/441,241, filed April 6, 2012	Sulfated Oxysterol and Oxysterol Sulfation by Hydroxysterol Sulfotransferase Promote Lipid Homeostasis and Liver Proliferation
Provisional Serial No. 61/604,711, filed February 29, 2012	Sulfated oxysterol, 25HC3S and oxysterol sulfation by hydroxysterol sulfotransferase (SULT2Blb) promote liver proliferation: therapy for cirrhosis, injury, recovery following hepatectomy, and other applications
Provisional Serial No. 61/623,203, filed April 12, 2012 Provisional Serial No. 61/623,414, filed April 12, 2012	A Novel Cholesterol Metabolite, 5-Cholesten, 3-,25-diol, Disulfate (25HCDS) for Therapy of Metabolic Disorders, Hyperlipidemia, Fatty Liver Disease, Diabetes and Atherosclerosis
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VCU Invention Disclosures

VCU Invention Disclosure No.	Title
REN-04-072, disclosed September 24, 2004	Nuclear oxysterol, potent regulator of cholesterol hemeostasis, for therapy of hypercholesterolemia, hyperlipidemia, and atherosclerosis
REN-08-078, disclosed December 15, 2008	5-Cholesten-3b, 25-diol 3-sulfate (25HC3S), an authentic PPARγ agonist and LXR antagonist, for the therapy of inflammatory diseases, such as inflammatory bowel diseases, fat liver diseases, and atheroclerotic diseases
REN-11-030, disclosed April 5, 2011	Hydroxysteroid sulfotransferase (SULT2B1b) for therapy of hyperlipidemia and fatty liver diseases
REN-11-93, disclosed November 7, 2011	Sulfated oxysterols, 25HC3S and 25HCDS, and oxysterol sulfation by hydroxysterol sulfotransferase (SULT2B1b) promote liver proliferation: therapy for cirrhosis, injury, and recovery following hepatectomy
REN-11-94, disclosed November 7, 2011	A novel cholesterol metabolite, 5-cholesten, 3-,25-diol, disulfate (25HCDS) for therapy of metabolic disorders, hyperlipidemia, diabetes, fat liver diseases, and atherosclerosis
REN-12-025, disclosed March 26, 2012	A Novel Cholesterol Metabolite, 5-Cholesten, 3-,25-diol, Disulfate (25HCDS) for Therapy of Metabolic Disorders, Hyperlipidemia, Diabetes, Fat Liver Diseases, and Atherosclerosis
REN-12-061, disclosed June 21, 2012	Novel Oxysterol, 5-Cholesten 3,27-diol 27-Glucuronide, for Therapy of Hypertriglyceridemia
REN-12-075	Low Levels of Oxysterol Sulfates, 25-,24, and 27(26)-hydroxycholesterol Sulfates, as biomarkers for diagnosis of lipid metabolic disorders, nonalcoholic fatty liver diseases
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CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [* * *], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.4

AMENDMENT NO. 2 TO EXCLUSIVE LICENSE AGREEMENT

THIS AMENDMENT No. 2 TO EXCLUSIVE LICENSE AGREEMENT is entered into on March 6, 2018 (the "Effective Date of the Amendment"), by and between DURECT Corporation ("Company") and Virginia Commonwealth University Intellectual Property Foundation ("VCUIPF").

WHEREAS, Company and VCUIPF are parties to an Exclusive License Agreement dated December 5, 2012, as amended (the "Agreement"), and
WHEREAS, the parties now wish to further amend the Agreement as provided for herein.
NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Amendment, the parties do hereby agree as follows:

1. ***Appendix A of the Agreement is hereby amended by deleting it in its entirety and replacing it with the Appendix A attached hereto and made a part hereof.***

2. Section 1.10 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following: "IMPROVEMENT(S)" means [* * *].

3. Section 1.26 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following: "SRA" means the Sponsored Research Agreement by and between VCU and LICENSEE, effective May 7, 2012, as amended."

4. Sections 2.3(b), (c) and (d) of the Agreement are hereby amended by [* * *].

5. All capitalized terms not otherwise defined in this Amendment shall have the same meanings that are ascribed to them in the Agreement.

6. Except as expressly amended by this Amendment, the Agreement shall remain unchanged and continue in full force and effect as provided therein. This Amendment and the Agreement constitute the complete, final and exclusive understanding and agreement of the parties with respect to the subject matter of the Agreement, and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the parties respecting the subject matter of the Agreement. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment in duplicate originals by their authorized officers as of the Effective Date of the Amendment.

DURECT CORPORATION

By: /S/ JAMES E. BROWN
Name: James E. Brown, D.V.M
Title: CEO
Date: March 6, 2018

VIRGINIA COMMONWEALTH UNIVERSITY

INTELLECTUAL PROPERTY FOUNDATION

By: /S/ IVELINA METCHEVA
Name: Ivelina Metcheva Phd, MBA
Title: President
Date: March 8, 2018

APPENDIX A

LICENSED PATENT RIGHTS

Patents and Applications:

Nuclear Sulfated Oxysterol, Potent Regulator of Cholesterol Homeostasis, for Therapy of Hypercholesterolemia, Hyperlipidemia, and Atherosclerosis

Country	Sub Case	Case Type	Status	App. No.	Filing Date	Patent No.	Issue Date
US		PRI	Inactive	60/621,537	25-Oct-2004		
US	0	ORD	Published	11/739,330	24-Apr-2007		
US	00	PRO	Inactive	61/154,063	20-Feb-2009		
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
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US	1	CIP	Granted	12/708,803	19-Feb-2010	8,399,441	19-Mar-2013
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]	[* * *]		

Sulfated Oxysterol and Oxysterol Sulfation by Hydroxysterol Sulfotransferase Promote Lipid Homeostasis and Liver Regeneration

Country	Sub Case	Case Type	Status	App. No.	Filing Date	Patent No.	Issue Date
US		ORD	Granted	13/441,241	06-Apr-2012	9,034,859	19-May-2015
US	0	PRO	Inactive	61/604,711	29-Feb-2012		
US	00	PRO	Inactive	61/472,293	06-Apr-2011		
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A Novel Cholesterol Metabolite, 5-cholesten, 3B- 25- diol, disulfate (25HCDS) for Therapy of Metabolic Disorders, Hylerlipidemia, Diabetes, Fatty Liver Diseases, and Atherosclerosis

Country	Sub Case	Case Type	Status	App. No.	Filing Date	Patent No.	Issue Date
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US	01	PRO	Inactive	61/623,203	12-Apr-2012		
US	02	PRO	Inactive	61/623,414	12-Apr-2012		
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VCU Invention Disclosures

VCU Invention Disclosure No.	Title
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REN-08-078F	5-Cholesten-3b, 25-diol 3-sulfate (25HC3S), an authentic PPARy agonist and LXR antagonist, for the therapy of inflammatory diseases, such as inflammatory bowel diseases, fat liver diseases, and atheroclerotic diseases
REN-11-030	Hydroxysteroid sulfotransferase (SULT2B1b) for therapy of hyperlipidemia and fatty liver diseases
REN-11-93	Sulfated oxysterols, 25HC3S and 25HCDS, and oxysterol sulfation by hydroxysterol sulfotransferase (SULT2B1b) promote liver proliferation: therapy for cirrhosis, injury, and recovery following hepatectomy
REN-11-94	A novel cholesterol metabolite, 5-cholesten, 3-,25-diol, disulfate (25HCDS) for therapy of metabolic disorders, hyperlipidemia, diabetes, fat liver diseases, and atherosclerosis
REN-12-025	A Novel Cholesterol Metabolite, 5-Cholesten, 3-,25-diol, Disulfate (25HCDS) for Therapy of Metabolic Disorders, Hyperlipidemia, Diabetes, Fat Liver Diseases, and Atherosclerosis
REN-12-061	Novel Oxysterol, 5-Cholesten 3,27-diol 27-Glucuronide, for Therapy of Hypertriglyceridemia
REN-12-075	Low Levels of Oxysterol Sulfates, 25-,24, and 27(26)-hydroxycholesterol Sulfates, as biomarkers for diagnosis of lipid metabolic disorders, nonalcoholic fatty liver diseases

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Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James E. Brown, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DURECT Corporation for the quarter ended September 30, 2024;

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

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

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

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (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.

November 14, 2024

/S/ JAMES E. BROWN

James E. Brown
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy M. Papp, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DURECT Corporation for the quarter ended September 30, 2024;

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

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

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

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (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.

November 14, 2024

/S/ TIMOTHY M. PAPP

Timothy M. Papp
Chief Financial Officer
(Principal Accounting 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 of DURECT Corporation (the "Company") on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James E. Brown, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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.

November 14, 2024

/S/ JAMES E. BROWN

James E. Brown
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of DURECT Corporation (the "Company") on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy M. Papp, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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.

November 14, 2024

/S/ TIMOTHY M. PAPP

Timothy M. Papp
Chief Financial Officer
(Principal Accounting Officer)