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, 2023

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.)**

10260 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 a check mark whether the registrant 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 13, 2023, there were 29,828,891 shares of the registrant's common stock outstanding.

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Special Note Regarding Forward-Looking Statements

This 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*:*

- the clinical trial plans and timelines for larsucosterol;
- potential uses and benefits of larsucosterol to treat alcohol-associated hepatitis (also called "alcoholic hepatitis" or "AH"), non-alcoholic steatohepatitis, or other conditions;
- the results and timing of clinical trials;
- 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 plans to meet with the FDA and other regulatory agencies to review the results of our Phase 2b AHFIRM trial and to discuss the Phase 3 registration trial design in the first quarter of 2024;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our products, product candidates and technologies, including larsucosterol, POSIMIR, and our SABER, CLOUD and ORADUR technologies;
- the potential milestone and royalty payments we may receive from Innocoll Pharmaceuticals Limited related to POSIMIR, earn-out payments we may receive from Indivior UK Limited related to the commercialization of PERSERIS, and 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 "Risk Factors" section and "Overview" section of this Management's Discussion and Analysis of Financial Condition and Results of Operations. 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 Securities and Exchange Commission.

PART I. FINANCIAL INFORMATION

tem 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,985	$ 43,483
Accounts receivable, net	883	3,423
Inventories, net	2,521	2,113
Prepaid expenses and other current assets	1,391	2,375
Total current assets	43,780	51,394
Property and equipment, net	127	188
Operating lease right-of-use assets	4,374	1,943
Goodwill	6,169	6,169
Long-term restricted investments	150	150
Other long-term assets	128	256
Total assets	$ 54,728	$ 60,100
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,314	$ 3,106
Accrued liabilities	8,539	7,896
Deferred revenue, current portion	178	—
Term loan, current portion, net	18,700	21,170
Operating lease liabilities, current portion	1,527	1,832
Warrant liabilities	6,494	—
Total current liabilities	36,752	34,004
Operating lease liabilities, non-current portion	2,927	260
Other long-term liabilities	643	851
Commitments and contingencies		
Stockholders' equity:		
Common stock	23	23
Additional paid-in capital	601,960	586,357
Accumulated other comprehensive loss	(12)	(13)
Accumulated deficit	(587,565)	(561,382)
Stockholders' equity	14,406	24,985
Total liabilities and stockholders' equity	$ 54,728	$ 60,100

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,	
	2023	2022	2023	2022
Collaborative research and development and other revenue	$ 506	$ 10,585	$ 1,657	$ 11,686
Product revenue, net	1,238	1,392	4,222	4,282
Total revenues	1,744	11,977	5,879	15,968
Operating expenses:				
Cost of product revenues	312	345	1,059	1,073
Research and development	7,199	9,881	23,738	26,909
Selling, general and administrative	3,790	3,883	11,712	11,570
Total operating expenses	11,301	14,109	36,509	39,552
Loss from operations	(9,557)	(2,132)	(30,630)	(23,584)
Other income (expense):				
Interest and other income	653	284	1,681	465
Change in fair value of warrant liabilities	7,016	—	8,601	—
Interest and other expenses	(700)	(623)	(2,175)	(1,745)
Issuance cost for warrants	(427)	—	(1,627)	—
Loss on issuance of warrants	—	—	(2,033)	—
Other income (expense), net	6,542	(339)	4,447	(1,280)
Net loss	(3,015)	(2,471)	(26,183)	(24,864)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	(6)	17	1	2
Total comprehensive loss	$ (3,021)	$ (2,454)	$ (26,182)	$ (24,862)
Net loss per share				
Basic	$ (0.11)	$ (0.11)	$ (1.04)	$ (1.09)
Diluted	$ (0.14)	$ (0.11)	$ (1.07)	$ (1.09)
Weighted-average shares used in computing net loss per share				
Basic	27,211	22,777	25,175	22,773
Diluted	27,511	22,777	25,433	22,773

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 Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Balance at December 31, 2021	22,768	$ 23	$ 583,818	$ (10)	$ (526,049)	$ 57,782
Issuance of common stock upon exercise of stock options	1	—	8	—	—	8
Stock-based compensation expense from stock options and ESPP shares	—	—	678	—	—	678
Net loss	—	—	—	—	(10,842)	(10,842)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	(19)	—	(19)
Balance at March 31, 2022	22,769	$ 23	$ 584,504	$ (29)	$ (536,891)	$ 47,607
Issuance of common stock upon exercise of stock options	7	—	27	—	—	27
Stock-based compensation expense from stock options and ESPP shares	—	—	617	—	—	617
Net loss	—	—	—	—	(11,551)	(11,551)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes				4	—	4
Balance at June 30, 2022	22,776	$ 23	$ 585,148	$ (25)	$ (548,442)	$ 36,704
Issuance of common stock upon equity financings, net of issuance costs of $506	3	—	25	—	—	25
Stock-based compensation expense from stock options and ESPP shares			579			579
Net loss	—	—	—	—	(2,471)	(2,471)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	—	—	—	17	—	17
Balance at September 30, 2022	22,779	$ 23	$ 585,752	$ (8)	$ (550,913)	$ 34,854

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,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (26,183)	$ (24,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of fixed assets	112	—
Depreciation and accretion	154	109
Stock-based compensation	1,923	1,874
Amortization of debt issuance cost	345	358
Net amortization on investments	81	16
Changes in operating lease liabilities	(69)	(55)
Change in fair value of warrant liabilities	(8,601)	—
Loss on issuance of warrants	2,033	—
Issuance cost for warrants	427	
Changes in assets and liabilities:		
Accounts receivable	2,540	3,248
Inventories	(409)	(399)
Prepaid expenses and other assets	1,000	1,630
Accounts payable	(1,792)	828
Accrued liabilities	2,172	(516)
Deferred revenue	178	(98)
Total adjustments	94	6,995
Net cash used in operating activities	(26,089)	(17,869)
Cash flows from investing activities		
Purchases of property and equipment	(52)	(93)
Proceeds from sales of fixed assets	—	—
Purchases of available-for-sale securities	(80)	—
Proceeds from maturities of available-for-sale securities	—	18,453
Net cash (used in) provided by investing activities	(132)	18,360
Cash flows from financing activities		
Payments on equipment financing obligations	(1)	(1)
Payments on term loan principal	(2,857)	—
Net proceeds from issuances of common stock pursuant to the 2021 Sales Agreement	658	—
Net proceeds from issuance of common stock upon exercise of stock options and from the ESPP	23	60
Proceeds from issuances of warrants and common stock in the February 2023 registered direct offering	10,000	—
Net proceeds from issuances of warrants and common stock in the July 2023 registered direct offering	13,900	—
Net cash provided by financing activities	21,723	59
Net decrease in cash, cash equivalents, and restricted cash	(4,498)	550
Cash, cash equivalents, and restricted cash, beginning of the period (1)	43,633	49,994
Cash, cash equivalents, and restricted cash, end of the period (1)	$ 39,135	$ 50,544

(1) Includes restricted cash of $150,000 included in long term restricted investments the condensed balance sheets at September 30, 2023 and December 31, 2022, respectively.

The accompanying notes are an integral part of these 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 committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. Larsucosterol (also known as "DUR-928"), 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 FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis ("NASH") is also being 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, 2023, the operating results and comprehensive loss, and stockholders’ equity for the three and nine months ended September 30, 2023 and 2022, and cash flows for the nine months ended September 30, 2023 and 2022. The balance sheet as of December 31, 2022 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, 2022 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.

Reverse Stock Split

On December 5, 2022, the Company effected a 1-for-10 reverse stock split of its outstanding common stock. The reverse stock split also affected the Company's outstanding stock options, purchase rights and equity incentive plans and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately.

For all financial statement periods presented, references to number of shares, net loss per share, stock price and exercise price have been conformed to reflect the effects of the Company’s 1-for-10 reverse stock split, effective December 5, 2022, unless otherwise specified herein.

Liquidity and Need to Raise Additional Capital

As of September 30, 2023, the Company had an accumulated deficit of $587.6 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 sheet as of September 30, 2023 and December 31, 2022 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. 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

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. If the Company is able to subsequently sell products made with raw materials that were previously written down, the Company will report an unusually high gross profit as there will be no or little associated cost of goods for these materials.

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

	September 30, 2023	December 31, 2022
Raw materials	$ 161	$ 168
Work in process	1,252	1,151
Finished goods	1,108	794
Total inventories	$ 2,521	$ 2,113

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, 2023, the weighted-average remaining lease term was 3.62 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 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 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, 2023 and 2022 are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
United States	$ 883	$ 10,433	$ 3,304	11,185
Europe	525	1,246	1,569	$ 3,851
Japan	124	136	406	502
Other	212	162	600	430
Total	$ 1,744	$ 11,977	$ 5,879	$ 15,968

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.

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 Statements of Operations and Comprehensive Loss.

Common Stock Warrants

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and 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. 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,	
	2023	2022	2023	2022
Basic loss per share computation:				
Net loss	$ (3,015)	$ (2,471)	$ (26,183)	$ (24,864)
Weighted average number of shares outstanding - basic	27,211	22,777	25,175	22,773
Net loss per share - basic	$ (0.11)	$ (0.11)	$ (1.04)	$ (1.09)
Diluted loss per share computation:				
Net loss	$ (3,015)	$ (2,471)	$ (26,183)	$ (24,864)
Change in fair value of warrant liabilities	738	—	996	—
Net loss adjusted for change in fair value of warrant liabilities	$ (3,753)	$ (2,471)	$ (27,179)	$ (24,864)
Weighted average shares used to compute basic net loss per share	27,211	22,777	25,175	22,773
Dilutive effect of pre-funded warrants	300	—	258	—
Weighted average shares used to compute diluted net loss per share	27,511	22,777	25,433	22,773
Net loss per share - diluted	$ (0.14)	$ (0.11)	$ (1.07)	$ (1.09)

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 share for the three and nine months ended September 30, 2023, respectively, as the effect would be anti-dilutive. Options to purchase approximately 2.6 million and 2.6 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, 2022, respectively, as the effect would be anti-dilutive. In addition, 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 4.0 million and 2.4 million shares were also outstanding during the three and nine months ended September 30, 2023, but were not included in the computation of diluted net loss per share because the effect would be anti-dilutive.

Recently Adopted Accounting Pronouncements

In August 2020, FASB issued Accounting Standards Update ("ASU") 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU- 2020-06"), which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher stockholder's rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective of modified retrospective basis. For smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption of the ASU is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company early adopted this standard on January 1, 2023 and the adoption did not have any effect on the financial statements as the Company did not have any such outstanding instruments as of January 1, 2023.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 (ASU 2016-13) "Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments." ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. This standard is effective for fiscal years beginning after December 15, 2022 for small reporting companies, including interim reporting periods within those years and must be adopted using a modified retrospective approach, with certain exceptions. Early adoption is permitted. The Company adopted the standard on January 1, 2023 and the adoption did not have a material effect on the financial statements.

Note 2. Strategic Agreements

The collaborative research and development and other revenues associated with the Company's collaborators or counterparties were $506,000 and $1.7 million for the three and nine months ended September 30, 2023, compared with $10.6 million and $11.7 million for the corresponding periods in 2022, respectively. The collaborative research and development and other revenues in the three and nine months ended September 30, 2022 included $8.0 million of patent milestone revenue and $2.0 million of first commercial sale milestone revenue related to POSIMIR. 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 (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.

Upon execution of the Innocoll Agreement, Innocoll paid the Company an initial nonrefundable, upfront fee of $4.0 million as well as a fee in the amount of $1.3 million primarily to cover the manufacturing supplies and excipients and certain equipment transferred to Innocoll pursuant to the terms of the Innocoll Agreement, and certain recently incurred Company expenses the parties negotiated for Innocoll to reimburse. The Innocoll Agreement includes customary representations and warranties on behalf of the Company and Innocoll, including representations as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The Innocoll Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

The Company also evaluated Innocoll's future purchases of an excipient from the Company and concluded that these purchases are option rights, and are at market rates, and do not constitute a material right performance obligation. As such, these future purchases have been excluded from the allocation of transaction price and the Company will account for them as separate contracts when and if Innocoll elects to issue purchase orders for the excipient.

During December 2021, the upfront fee of $4.0 million as well as a fee in the amount of $1.2 million to cover reimbursed expenses, the manufacturing supplies and excipients transferred to Innocoll pursuant to the terms of the Innocoll Agreement was recognized as revenue when the performance obligations were satisfied in December 2021 and $0.1 million was recorded as a net reduction in equipment in December 2021. At December 31, 2021, the Company included $5.3 million due from Innocoll in accounts receivable on its balance sheet; these funds were received in January 2022.

In August 2022, the Company was issued a new patent by the U.S. Patent and Trademark Office, extending U.S. patent coverage of POSIMIR to at least 2041, resulting in an $8.0 million milestone payment by Innocoll to the Company. In September 2022, Innocoll launched POSIMIR in the U.S., triggering a $2.0 million milestone payment to the Company for the first commercial sale of POSIMIR. Thus, the Company recognized $10.0 million of milestone revenue under the agreement with Innocoll during the three and nine months ended September 30, 2022. As the commercial launch of POSIMIR progresses, the Company will 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.

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 receives quarterly earn-out payments into 2026 that are 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, 2023 and 2022 related to earn-out revenues from PERSERIS have been immaterial and are included in collaborative research and development and other revenue.

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, 2023 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, 2023 and December 31, 2022 (in thousands):

	September 30, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 1,022	$ —	$ —	$ 1,022
Certificates of deposit	150	—	—	150
Commercial paper	34,742	—	(12)	34,730
	$ 35,914	$ —	$ (12)	$ 35,902
Reported as:				
Cash and cash equivalents	$ 35,764	$ —	$ (12)	$ 35,752
Long-term restricted investments	150	—	—	150
	$ 35,914	$ —	$ (12)	$ 35,902

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 633	$ —	$ —	$ 633
Certificates of deposit	150	—	—	150
Commercial paper	40,478	—	(13)	40,465
	$ 41,261	$ —	$ (13)	$ 41,248
Reported as:				
Cash and cash equivalents	$ 41,111	$ —	$ (13)	$ 41,098
Long-term restricted investments	150	—	—	150
	$ 41,261	$ —	$ (13)	$ 41,248

The following is a summary of the cost and estimated fair value of available-for-sale securities at September 30, 2023, by contractual maturity (in thousands):

	September 30, 2023	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 34,742	$ 34,730
Mature after one year through five years	150	150
	$ 34,892	$ 34,880

There were no securities that have had an unrealized loss for more than 12 months as of September 30, 2023.

As of September 30, 2023, 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, 2023 and 2022 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Fair value at beginning of period - February 2023 issuance	$ 10,448	$ —	$ —	$ —
Initial fair value at the original issuance date	—	—	12,033	—
Change in fair value during the period	(5,619)	—	(7,204)	—
Fair value of liability classified warrants exercised	(2,726)	—	(2,726)	—
Fair value at end of period - February 2023 issuance	$ 2,103	$ —	$ 2,103	$ —
Fair value at beginning of period - July 2023 issuance	$ —	$ —	$ —	$ —
Initial fair value at the original issuance date	5,788	—	5,788	—
Change in fair value during the period	(1,397)	—	(1,397)	—
Fair value of liability classified warrants exercised	—	—	—	—
Fair value at end of period - July 2023 issuance	$ 4,391	$ —	$ 4,391	$ —
Total Fair value at end of period	$ 6,494	$ —	$ 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.

The pre-funded warrants are accounted for as current liabilities on the balance sheet and are adjusted to estimated fair value at period end through “other income (expense)” on the statement of operations. The estimated fair value of the outstanding pre-funded warrants was $1.7 million, $1.4 million, $1.5 million and $747,000 as of February 8, 2023 (i.e., the issuance date), March 31, 2023, June 30, 2023 and September 30, 2023, respectively. 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)	March 31, 2023	June 30, 2023	September 30, 2023
Common stock price	$ 5.81	$ 4.53	$ 4.95	$ 2.49
Exercise price per share	$ 0.00001	$ 0.00001	$ 0.00001	$ 0.00001
Expected volatility	86.60%	86.20%	89.10%	89.50%
Risk-free interest rate	3.82%	3.65%	4.22%	4.65%
Contractual term (in years)	5.00	4.90	4.60	4.40
Expected dividend yield	—%	—%	—%	—%

The common warrants are accounted for as current liabilities on the balance sheet and are adjusted to estimated fair value at period end through “other income (expense)” on the statement of operations. The estimated fair value of the outstanding common warrants was $10.3 million, $8.2 million, $9.0 million and $1.4 million as of February 8, 2023 (i.e., the issuance date), March 31, 2023, June 30, 2023 and September 30, 2023, 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. In all cases, the Company took the likelihood of achieving certain clinical events and related impact on the Company's common stock price into account.

The exercise price for the common warrants was adjusted down from $5.00 per share to $4.89 per share as a result of an anti-dilution provision in the common warrants issued in the February 2023 financing that was triggered by the July 2023 financing.

	February 8, 2023 (issuance)	March 31, 2023	June 30, 2023	September 30, 2023
Common stock price	$ 5.81	$ 4.53	$ 4.95	$ 2.49
Exercise price per share	$ 5.00	$ 5.00	$ 5.00	$ 4.89
Expected volatility	86.60%	86.20%	89.10%	89.50%
Risk-free interest rate	3.82%	3.65%	4.22%	4.65%
Contractual term (in years)	5.00	4.90	4.60	4.40
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 sheet and are adjusted to estimated fair value at period end through “other income (expense)” on the statement of operations. The estimated fair value of the outstanding common warrants was $5.8 million and $4.4 million as of July 21, 2023 (i.e., the issuance date) and September 30, 2023, 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)	September 30, 2023
Common stock price	$ 3.05	$ 2.49
Exercise price per share	$ 4.89	$ 4.89
Expected volatility	88.60%	89.10%
Risk-free interest rate	4.18%	4.60%
Contractual term (in years)	5.00	4.80
Expected dividend yield	—%	—%

Note 4. Accrued Liabilities

Accrued liabilities as of September 30, 2023 and December 31, 2022 were comprised as follows (in thousands):

	September 30, 2023	December 31, 2022
Accrued compensation and benefits	$ 3,076	$ 3,970
Accrued clinical costs	1,828	1,966
Accrued contract research and manufacturing costs	2,182	861
Others	1,453	1,099
Total	$ 8,539	$ 7,896

Note 5. Stock-Based Compensation

As of September 30, 2023, 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,	
	2023	2022	2023	2022
Cost of product revenues	$ 4	$ 5	$ 13	$ 15
Research and development	306	292	899	918
Selling, general and administrative	351	281	1,011	941
Total stock-based compensation	$ 661	$ 578	$ 1,923	$ 1,874

As of September 30, 2023 and December 31, 2022, $14,000 and $16,000 of stock-based compensation cost were 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, 2023 and 2022:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Stock Options				
Risk-free rate	4.17%	2.7-3.2%	3.96-4.17%	1.8-3.2%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	7.5	7.3	7.0-7.5	7.0-7.3
Volatility	88%	85-86%	87-88%	83-86%

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Employee Stock Purchase Plan				
Risk-free rate	5.14%	1.49%	4.58-5.14%	0.04-1.49%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	0.5	0.5	0.5	0.5
Volatility	88%	80%	88-104%	56-80%

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 12.74% as of September 30, 2023) 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 $2.9 million in the three and nine months ended September 30, 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, 2023, 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 sheet as of September 30, 2023 and December 31, 2022 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, 2023, are as follows (in thousands):

Three months ended December 31, 2023	$	2,143
2024		8,571
2025		8,429
Total minimum payments		19,143
Less unamortized debt discount and accrued final payment		(443)
Carrying value of term loan, net		18,700

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)
Cupertino, CA	20,100 sq. ft.	Office and Laboratory	Lease expires 2024
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-assets with the associated interest component estimated by applying the effective interest method. Rent expenses under all operating leases were $492,000 and $1.4 million for the three and nine months ended September 30, 2023, respectively, and $478,000 and $1.4 million for the three and nine months ended September 30, 2022, respectively.

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

		Operating Leases
Three months ended December 31, 2023	$	496
2024		1,483
2025		1,401
2026		1,443
2027 and thereafter		659
	$	5,482

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, allows 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 may sell, subject to certain limitations, pursuant to a sales agreement dated July 30, 2021 with Cantor Fitzgerald & Co. (the "2021 Sales Agreement").

On December 5, 2022, the Company effected a 1-for-10 reverse stock split of its outstanding common stock. The reverse stock split also affected our outstanding stock options, purchase rights and equity incentive plans and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately.

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 included in loss on issuance of warrants on the statement of operations for the three months ended March 31, 2023 and nine months ended September 30, 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). 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 records these warrants as current liabilities on the balance sheet at fair value, with subsequent changes in their respective fair values recognized in the statement 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 statement 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 statement 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, the Company issued 924,000 shares to the holder. The Company recorded a gain of $3.5 million resulting from the exercise of the warrants in the accompanying statements of operations for the three and nine months ended September 30, 2023 and recorded $2.7 million in additional-paid-in capital upon the issuance of the shares on the balance sheet as of September 30, 2023.

At September 30, 2023, 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 $1.4 million, a decrease of $1.3 million from June 30, 2023; and updated the estimated fair value of the pre-funded warrants using the Black-Scholes option valuation model resulting in an updated estimated fair value of $747,000, a decrease of $738,000 from June 30, 2023. The gain of $2.1 million and $3.7 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 for the three and nine months ended September 30, 2023, respectively.

As of September 30, 2023, common warrants to purchase 600,000 shares of the Company's common stock and pre-funded warrants to purchase 300,000 shares of the Company's common stock were outstanding.

The common warrant liability and the pre-funded 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 statement of operations and comprehensive loss.

The Company also allocated the offering expenses of $1.2 million to warrant liabilities and expensed (within other expense, net) $1.2 million upon the closing of the February Offering.

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 sheet. 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 offering in the three months ended September 30, 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 September 30, 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 sheet at the estimated fair value, with subsequent changes in their respective estimated fair values recognized in the statement 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 fair value are recognized as a component of other income (expense) in the statement 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 fair value of these warrants as of the issuance date and as of September 30, 2023 were $5.8 million and $4.4 million, respectively. The gain of $1.4 million resulting from the change in the fair value of the liability for these warrants was recorded as a change in estimated fair value of warrant liabilities in the accompanying statements of operations for the three and nine months ended September 30, 2023.

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 statement of operations and comprehensive loss.

As of September 30, 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.

ATM Financings

During the three months ended September 30, 2023, the Company did not issue any shares pursuant to the 2021 Registration Statement and the 2021 Sales Agreement. During the nine months ended September 30, 2023, the Company raised net proceeds (net of commissions) of approximately $658,000 from the sale of 118,132 shares of the Company's common stock in the open market at a weighted average price of $5.68 per share pursuant to the 2021 Registration Statement and the 2021 Sales Agreement.

As of November 13, 2023, the Company had up to $223.5 million of the Company's securities available for sale under the 2021 Registration Statement, of which $73.5 million of the Company's common stock are available pursuant to the 2021 Sales Agreement.

Note 9. Subsequent Events

On November 7, 2023, the Company announced topline data from a double-blind, placebo-controlled Phase 2b clinical trial called AHFIRM (trial in AH to evaluate saFety and effIcacy of laRsucosterol treatMent). The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant between both doses of larsucosterol versus standard of care. The Company is evaluating the financial statement impact of the topline results of the AHFIRM trial in the fourth quarter of the fiscal year ending December 31, 2023.

From October 1, 2023 to November 13, 2023, the Company raised net proceeds (net of commissions) of approximately $803,000 from the sale of approximately 1.3 million shares of the Company's common stock in the open market at a weighted average price of $0.63 per share pursuant to the 2021 Registration Statement and the 2021 Sales Agreement.

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, 2023 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, 2022 filed with the Securities and Exchange Commission ("SEC") 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 reports filed 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 (also known as "DUR-928"), 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 a 28-Day and 90-Day historical mortality rate 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 efflcacy 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 June 2023 we announced that we had completed enrollment in the AHFIRM trial. 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, with reductions of 41% (p=0.070) in the 30 mg arm and 35% (p=0.126) in the 90 mg arm compared with standard of care ("SOC"). 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) for the 30 mg arm and 58% (p=0.008) for the 90 mg arm compared with SOC in the U.S. Larsucosterol was safe and well tolerated. There were fewer treatment-emergent adverse events ("TEAEs") in the larsucosterol arms compared with SOC. We intend to have an End of Phase 2 ("EOP2") meeting with FDA to discuss the trial results and the Phase 3 registration trial design in the first quarter of 2024. We have also investigated larsucosterol in patients with non-alcoholic steatohepatitis with encouraging results in a Phase 1b clinical trial and are considering further development of larsucosterol for this and other indications.

Building on our knowledge of epigenetic modulation, we have internally developed multiple novel small molecule DNMT inhibitors that exhibit broad spectrum activity against multiple hematologic and solid tumor types. These compounds display unique and desirable physiochemical properties and pharmacokinetic profiles, as well as favorable tolerability. We intend to select a product candidate by the end of 2023 to advance into clinical trials in cancer patients. Our goal is to be prepared to initiate clinical trials for this product candidate by the end of 2024.

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 U.S. 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 with Innocoll Pharmaceuticals Limited ("Innocoll"), pursuant to which the Company 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.

As a result of the assignment of certain patent rights, we also receive single digit sales-based earn-out payments from U.S. net sales of Indivior UK Limited's PERSERIS® (risperidone) drug for schizophrenia and single-digit royalties from net sales of Orient Pharma Co., Ltd.'s Methydur Sustained Release Capsules ("Methydur") for the treatment of attention deficit hyperactivity disorder in Taiwan. We also manufacture and sell ALZET® osmotic pumps used in laboratory research.

NOTE: POSIMIR® is a trademark of Innocoll Pharmaceuticals, Ltd. in the U.S. and a trademark of DURECT Corporation outside of the U.S. SABER® and ALZET® are trademarks of DURECT Corporation. 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. During the last two years, we generated collaborative research and development revenues from collaborative agreements with Innocoll and others.

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.

Operating Results

Since our inception in 1998, we have generally had a history of operating losses. At September 30, 2023, we had an accumulated deficit of $587.6 million. Our net losses were $3.0 million and $26.2 million for the three and nine months ended September 30, 2023 compared with $2.5 million and $24.9 million for the corresponding periods in 2022. 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 in the near future to decrease compared to the third quarter of 2023 as we complete the AHFIRM trial and evaluate our research and development spending plans. We expect our selling, general and administrative expenses in the near future to be comparable to the third quarter of 2023. We expect to incur continuing losses and negative cash flows from operations for the foreseeable future.

Recent Developments

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. The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant between both doses of larsucosterol versus standard of care. We intend to have an EOP2 meeting with FDA to discuss the trial results and the Phase 3 registration trial design in the first quarter of 2024.

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 estimates and assumptions relate to revenue recognition, prepaid and accrued contract research expenses, and stock-based compensation. 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, 2022.

Results of Operations

Three and nine months ended September 30, 2023 and 2022

Collaborative research and development and other revenue

We recognize revenue from collaborative research and development activities and service contracts. Collaborative research and development and other revenue primarily represents reimbursement of qualified expenses related to collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies, and revenue from the recognition of upfront fees and milestone payments in connection with our collaborative or license agreements.

We expect our collaborative research and development and other revenue to fluctuate in future periods pending our efforts to enter into potential new collaborations, and any royalty or earn-out revenue recognized from collaborators or counterparties.

The collaborative research and development and other revenue associated with our major collaborators or counterparties were $506,000 and $1.7 million for the three and nine months ended September 30, 2023, compared with $10.6 million and $11.7 million for the corresponding periods in 2022. The collaborative research and development and other revenues in the three and nine months ended September 30, 2022 included $8.0 million of patent milestone revenue and $2.0 million of first commercial sale milestone revenue under the agreement with Innocoll. 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 with respect to Methydur net sales.

Product revenue

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 $1.2 million and $4.2 million for the three and nine months ended September 30, 2023 compared with $1.4 million and $4.3 million for the corresponding periods in 2022. The decreases in the three and nine months ended September 30, 2023 were primarily attributable to lower revenue from our ALZET mini pump product line as a result of lower units sold and lower revenue from certain excipients that are included in Methydur and in an animal health product compared to the corresponding periods in 2022.

Cost of product revenues

Cost of product revenues was $312,000 and $1.1 million for the three and nine months ended September 30, 2023 compared with $345,000 and $1.1 million for the corresponding periods in 2022. Cost of product revenues in the three months ended September 30, 2023 decreased compared to the corresponding period in 2022 primarily due to lower units sold from our ALZET product line. Cost of product revenues in the nine months ended September 30, 2023 are comparable to the corresponding period in 2022. Stock-based compensation expense recognized related to cost of product revenues was $4,000 and $13,000 for the three and nine months ended September 30, 2023 compared to $5,000 and $15,000 for the corresponding periods in 2022.

As of September 30, 2023, we had 9 manufacturing employees compared with 10 as of September 30, 2022. 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 $7.2 million and $23.7 million for the three and nine months ended September 30, 2023 compared to $9.9 million and $26.9 million for the corresponding periods in 2022. We incurred lower research and development costs associated with larsucosterol and the depot injectable programs, partially offset by higher research and development costs associated with other research programs in the three and nine months ended September 30, 2023 compared to the corresponding periods in 2022, as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $306,000 and $899,000 for the three and nine months ended September 30, 2023 compared to $292,000 and $918,000 for the corresponding periods in 2022. As of September 30, 2023, we had 38 research and development employees compared with 43 as of September 30, 2022. We expect research and development expenses in the near future to decrease compared to the third quarter of 2023 as we complete the AHFIRM trial and evaluate our research and development spending plans.

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Larsucosterol	$ 6,391	$ 9,321	$ 21,081	$ 24,683
Depot injectable programs	—	367	319	1,173
Others	808	193	2,338	1,053
Total research and development expenses	$ 7,199	$ 9,881	$ 23,738	$ 26,909

Larsucosterol

Our research and development expenses for larsucosterol were $6.4 million and $21.1 million in the three and nine months ended September 30, 2022 compared to $9.3 million and $24.7 million for the corresponding periods in 2022. The decreases in the three and nine months ended September 30, 2023 were primarily due to lower clinical trial related expenses as we completed patient follow-up in the AHFIRM trial, lower contract manufacturing expenses and lower employee-related costs for this drug candidate compared with the corresponding periods in 2022.

Depot injectable programs

Our research and development expenses for depot injectable programs were zero and $319,000 in the three and nine months ended September 30, 2023 compared to $367,000 and $1.2 million for the corresponding periods in 2022. The decreases in the three and nine months ended September 30, 2023 were primarily due to lower employee-related costs and lower outside expenses for these programs compared with the corresponding periods in 2022.

Other DURECT research programs

Our research and development expenses for all other programs were $808,000 and $2.3 million in the three and nine months ended September 30, 2023 compared to $193,000 and $1.1 million for the corresponding periods in 2022. The increases in the three and nine months ended September 30, 2023 were primarily due to higher employee-related costs and higher outside expenses associated with these programs compared with the corresponding periods in 2022.

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, 2022.

Selling, general and administrative. Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation costs associated with finance, 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 $3.8 million and $11.7 million in the three and nine months ended September 30, 2023 compared to $3.9 million and $11.6 million for the corresponding periods in 2022. The decrease in the three months ended September 30, 2023 was primarily due to lower general legal expenses and lower recruiting expenses compared to the corresponding period in 2022. The increase in the nine months ended September 30, 2023 was primarily due to higher market research expenses, higher audit related expenses as well as higher employee expenses compared to the corresponding period in 2022. Stock-based compensation expense recognized related to selling, general and administrative personnel was $351,000 and $1.0 million for the three and nine months ended September 30, 2023 compared to $281,000 and $941,000 for the corresponding periods in 2022.

We had 25 selling, general and administrative employees as of September 30, 2023 compared with 26 as of September 30, 2022. We expect selling, general and administrative expenses in the near future to be comparable to the third quarter of 2023.

Other income (expense). Other income was $6.5 million and $4.4 million in the three and nine months ended September 30, 2023 compared to other expense of $339,000 and $1.3 million for the corresponding periods in 2022.

Interest and other income was $653,000 and $1.7 million in the three and nine months ended September 30, 2023 compared to $284,000 and $465,000 for the corresponding periods in 2022. The increases in the three and nine months ended September 30, 2023 were primarily due to higher interest rates associated with our cash, cash equivalents and investments compared with the corresponding periods in 2022.

Interest and other expenses were $700,000 and $2.2 million in the three and nine months ended September 30, 2023 compared to $623,000 and $1.7 million for the corresponding periods in 2022. The increases in the three and nine months ended September 30, 2023 were primarily due to higher interest rates on our term loan compared with the corresponding periods in 2022.

Other income (expenses) for the three months ended September 30, 2023 also includes approximately $427,000 of issuance costs of common warrants and common stock that were issued in July 2023 in connection with a registered direct offering, which were offset by a $7.0 million non-cash gain associated with the change in fair value of the liability-classified warrants issued in connection with registered direct offerings that were made in February 2023 and July 2023 as well as the alternative cash exercise of common warrants associated with the February 2023 registered direct offering that occurred in the period. Other income (expenses) for the nine months ended September 30, 2023 also includes $1.6 million of issuance costs of these warrants as well as approximately $2.0 million

non-cash loss on the issuance of these warrants, which was offset by approximately $8.6 million in non-cash gain associated with the change in fair value of the February 2023 and July 2023 liability-classified warrants and the alternative cashless exercise of the warrants in the period.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $39.1 million at September 30, 2023 compared to cash, cash equivalents, and investments of $43.6 million at December 31, 2022. These balances include $150,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of September 30, 2023 and December 31, 2022. 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 approximately $22.7 million of net proceeds received from the registered direct offerings in February 2023 and in July 2023, net proceeds of $658,000 from the sale of our common stock in the open market pursuant to the 2021 Sales Agreement (as defined and 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. Unless we secure additional equity or debt financing, of which there can be no assurance, we may not be able to continue operations.

Cash Flows

We used $26.1 million of cash in operating activities for the nine months ended September 30, 2023 compared to $17.9 million for the corresponding period in 2022. The increase in cash used in operating activities was primarily due to lower payments from our collaborators. The cash used in operations was primarily to fund operations as well as our working capital requirements, partially offset by the changes in accounts receivable, accounts payable and accrued liabilities.

We used $132,000 of cash in investing activities for the nine months ended September 30, 2023 compared to $18.4 million provided by investing activities for the corresponding period in 2022. The decrease in cash provided by investing activities was primarily due to a decrease in proceeds from maturities of available-sale-securities for the nine months ended September 30, 2023 compared with the corresponding period in 2022.

We received $21.7 million of cash from financing activities for the nine months ended September 30, 2023 compared to $59,000 for the corresponding period in 2022. The increase in cash received from financing activities was primarily due to cash proceeds received from the offerings that were completed in February 2023 and in July 2023 and from the sale of our common stock in the open market under the 2021 Sales Agreement, partially offset by principal payments on the term loan with Oxford Finance LLC ("Oxford Finance") during the nine months ended September 30, 2023.

We anticipate that cash used in operating activities in the near future will increase compared to the third quarter of 2023 due to changes in working capital related to payments for accrued research and development expenses for larsucosterol and prepaid insurance premiums.

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, terminated our registration statement filed in August 2018 (File No. 333-226518) and 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 may sell, subject to certain limitations, pursuant to a sales agreement dated July 30, 2021 with Cantor Fitzgerald (the “2021 Sales Agreement”). The 2021 Sales Agreement replaced a prior 2015 Sales Agreement. From October 1, 2023 to November 13, 2023, we raised net proceeds (net of commissions) of approximately $803,000 from the sale of our common stock in the open market under the 2021 Sales Agreement.

As of November 13, 2023, we had up to $223.5 million of our securities available for sale under the 2021 Registration Statement, of which $73.5 million of our common stock are available pursuant to the 2021 Sales Agreement.

Any material sales in the public market of our common stock, under the 2021 Sales Agreement or otherwise under the 2021 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 may be used for working capital and general business requirements. The term loan repayment schedule provided initially for interest only payments for the first 18 months, followed by consecutive monthly payments of principal and interest in arrears starting on March 1, 2018 and continuing through the maturity date of August 1, 2020. Following five amendments, we make interest only payments under the amended Loan Agreement until June 1, 2023 and the final maturity date of the loan is September 1, 2025. The Loan Agreement provides for a floating interest rate (7.95% initially and 12.74% as of September 30, 2023) 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 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. Our debt repayment obligations under the Loan Agreement, as amended, 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 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 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 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 classified as a current liability on our balance sheet as of September 30, 2023 and December 31, 2022 due to the timing of repayment obligations and due to recurring losses, liquidity concerns and a subjective acceleration clause in the Loan Agreement.

Going Concern

As of September 30, 2023, we had approximately $39.1 million in cash, cash equivalents and investments compared with $43.6 million as of December 31, 2022. In February 2023, we received approximately $8.8 million in net proceeds (net of placement agent fees and other offering expenses) from a registered direct offering. In June 2023, we raised net proceeds (net of commissions) of approximately $658,000 from the sale of our common stock in the open market under the 2021 Sales Agreement. In July 2023, we received approximately $13.9 million in net proceeds (net of placement agent fees and other offering expenses) from a registered direct offering.

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 of our recurring losses from operations, negative cash flows from operating activities and need to raise additional capital, our independent registered public accounting firm included an explanatory paragraph in its report on our audited financial statements for the year ended December 31, 2022 related to our going concern evaluation.

In September 2023, we signed an extension to a facility lease that extended the lease term to February 2027. Otherwise, there were no significant changes in our commercial commitments and contractual obligations during the nine months ended September 30, 2023 as compared with the information presented in our Annual Report on Form 10-K for the year ended December 31, 2022.

tem 3. Quantitative and Qualitative Disclosures about Market Risk

As of September 30, 2023, our exposure to market risk has not changed materially since December 31, 2022. 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, 2022, filed with the SEC on March 8, 2023.

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, 2022, 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, 2022, 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, 2022 and with any risk factors we may include in subsequent periodic filings with the SEC.

Risks Related To Our Business

We are dependent on the success of larsucosterol and the path to regulatory approval is uncertain; we cannot be certain that it will receive regulatory approval or be commercialized

Our business depends substantially on the successful development of larsucosterol, which has completed multiple clinical trials, including a Phase 2b clinical trial (AHFIRM) in patients with severe AH, topline results of which were announced in November 2023. The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant between both doses of larsucosterol versus SOC. Accordingly, future clinical trials may be required to establish clinically and statistically significant proof of efficacy, and sufficient evidence of safety to support regulatory approval. We plan to meet with FDA regarding the next steps for advancing larsucosterol in AH. We will have to interact with the FDA and other regulatory agencies regarding important aspects of the program, potentially including the size and design of clinical trials, the specific primary and secondary endpoints for the clinical trials, inclusion and exclusion criteria, stopping rules, duration of follow up, size of the safety databases, statistical analysis plans and other matters. There is no assurance that future clinical trials will establish efficacy of larsucosterol to treat AH or will not result in unanticipated side effects. If larsucosterol fails to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon development of larsucosterol, which would materially harm our business.

Larsucosterol may not be eligible to receive regulatory approval from the FDA or comparable foreign authorities and begin commercialization for a number of years, if ever. This uncertainty may make it difficult to predict the timing or expense required to obtain regulatory approval for larsucosterol. If we are unable to reach an agreement with the FDA or other regulatory agencies regarding next steps for larsucosterol's clinical development, we may curtail or limit our development activities for this product candidate. Even if we ultimately receive regulatory approval for larsucosterol, we or our potential future partners, if any, may be unable to commercialize it successfully for a variety of reasons. These include, for example, the future availability of alternative, potentially superior or less expensive treatments, lack of cost-effectiveness, the lack of favorable access and/or commercial pricing, the cost or technical challenges of manufacturing the product on a commercial scale and competition with other treatments. The success of larsucosterol may also be limited by the prevalence and severity of any adverse side effects, including mortality.

The FDA or other regulatory agencies may require more information or clinical studies for our product candidates, and our product candidates may never be approved

The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant between both doses of larsucosterol versus SOC. The failure to adequately demonstrate the safety and effectiveness of larsucosterol to the satisfaction of the FDA and other regulatory agencies will result in delays to the regulatory approval or non-approvability of larsucosterol. Future clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for larsucosterol or may require such significant numbers of patients or additional costs to make it impractical to satisfy the regulatory agency's requirements, and thus larsucosterol may not be approved for marketing. During the review process, the FDA or other regulatory agencies may request additional information regarding the efficacy or safety of larsucosterol and providing such additional information could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval or lead our Company to abandon the development of larsucosterol. Additionally, the FDA, or other regulatory agencies, may also request more information regarding the chemistry, manufacturing or controls related to larsucosterol, and answering such questions could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval or abandonment of larsucosterol. Even if larsucosterol receives FDA or other regulatory agency approval, the regulatory agency may require that we conduct additional clinical or non-clinical studies after such approval, place limitations on the use of our products in applicable labels, require marketing under a Risk Evaluation and Mitigation Strategy program, include commercially unattractive

language in the approved product label, delay approval to market our products or limit the indicated use of our products, which may harm our business and results of operations.

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 and our other product candidates, funding and establishing additional clinical- and commercial-scale manufacturing arrangements and facilities.

Presently, we do not have sufficient cash resources to meet our plans for the next twelve months from the issuance of this quarterly report. 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, 2022. We will require additional financing to fund our operations or we will have to significantly curtail 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. 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 our operations, resulting in delays in the development of larsucosterol and other product candidates 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 preclinical studies and clinical trials;
- 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 funding to complete a Phase 3 trial of larsucosterol, if required by the FDA. 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 contract with third parties for the manufacture of larsucosterol and expect to continue to do so for any required additional clinical trials as well as the commercialization of larsucosterol. Our reliance on third parties increases the risk that submissions

for regulatory approval of larsucosterol may be delayed or that we will not have sufficient quantities of larsucosterol available at an acceptable cost, which could delay, prevent or impair our development and commercialization efforts of larsucosterol

We currently rely on third-party contractors to manufacture, package, label and distribute clinical supplies of injectable larsucosterol, and we expect to establish supply agreements for commercial quantities of larsucosterol following approval for marketing by applicable regulatory authorities. We also expect to rely on third-party contractors to manufacture larsucosterol for use in future clinical trials. As of the filing date of this Quarterly Report on Form 10-Q, our third-party manufacturer has not established a final process for the commercial supply of injectable larsucosterol and neither we nor our third-party manufacturer have completed stability testing required to submit and obtain regulatory approval for the use of larsucosterol in the treatment of AH. Reliance on third-party contractors entails risks including, but not limited to:

- our inability to identify and negotiate manufacturing and supply agreements with suitable manufacturers;
- delays in the development of manufacturing process technologies and stability testing;
- our inability to control manufacturing process development and its timing;
- manufacturing delays if our third-party contractors give greater priority to the supply of other products over larsucosterol or otherwise do not satisfactorily perform according to the terms of our agreements with such contractors;
- possible terminations or nonrenewals of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- possible breaches by third-party contractors of our agreements with such contractors;
- failures by third-party contractors to comply with applicable regulatory requirements;
- possible mislabeling of clinical supplies, which could result in the supply of incorrect dose amounts or the improper identification of the active drug and/or placebo;
- the possibility that clinical supplies will not be delivered to clinical sites on time, leading to clinical trial interruptions, or that drug supplies will not be distributed to commercial vendors in a timely manner, resulting in lost sales; or
- possible misappropriations of our proprietary information, including our trade secrets and know-how.

Additionally, we may incur delays in the regulatory submissions or approval of larsucosterol due to manufacturing process development and stability testing, or from the need to identify or qualify alternative third-party manufacturers. Our current and anticipated future dependence upon third parties for the manufacturing of larsucosterol may adversely affect our future profit margins and our ability to commercialize any of our products that receive marketing approval on a timely and competitive basis.

Safety data and indications of activity from completed Phase 1 and 2 clinical trials of larsucosterol may not predict safety, activity or therapeutic efficacy in future trials

Safety data and indications of activity from completed Phase 1 and 2 clinical trials of larsucosterol, or from geographic or other subset analyses of the AHFIRM trial, may ultimately not be correlated with treatment or improvement in the associated disease, and there is a risk that larsucosterol may not demonstrate therapeutic efficacy in larger placebo-controlled trials. For example, the AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant between both doses of larsucosterol versus SOC. The failure of larsucosterol to show efficacy in one indication may negatively affect its perceived value in other indications, and the emergence of safety signals in ongoing or future clinical trials would significantly harm our business.

From time to time, we may publicly disclose preliminary or “topline” data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report, including the preliminary Phase 2b clinical data for AHFIRM reported in November 2023, may differ from, and may not be indicative of, future results of the same clinical trials, or different conclusions or considerations may qualify such topline results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available and negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular

program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed.

Future clinical trials for larsucosterol may be delayed and may not demonstrate efficacy or safety

Future trials of larsucosterol in patients with AH are subject to potential delays for several reasons, including without limitation:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our pre-clinical studies or clinical trials;
- failure to agree with FDA or other regulatory agencies regarding the trial design, including without limitation inclusion and exclusion criteria or primary and secondary endpoints;
- failure to reach, or delays in reaching, an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to obtain institutional review board, or the IRB, approval at each site;
- delays, suspension, or termination of clinical trials by the IRB responsible for overseeing the trial at a particular trial site;
- slower than expected rates of recruitment of patients or failure to recruit a sufficient number of patients;
- delays in manufacturing or delivery of drug product to clinical trial sites;
- patients dropping out of the trial after enrollment or withdrawing consent;
- clinical sites deviating from trial protocol, dropping out of a trial, or failing to comply with regulatory requirements;
- government, IRB, or other regulatory delays or “clinical holds” requiring suspension or termination of the trials;
- COVID, flu or other diseases having an adverse effect on patients’ willingness to participate in a trial; and
- protocol amendments.

There can also be no assurance that biological activity demonstrated in previous animal disease models or earlier clinical trials of larsucosterol will also be seen in future clinical trials, or that any clinically relevant biological activity will be observed, or that enrollment rates in future trials will be favorable or that these additional trials will not identify safety issues. Failure of future trials to achieve desired results in their anticipated timeframe could negatively impact our business and ability to raise additional capital.

Moreover, success in future research, preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and non-clinical testing. Any future clinical trial process may fail to demonstrate that our potential drug candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a drug candidate and may delay development of other potential drug candidates. Any delay in, or termination of, future non-clinical testing or clinical trials will delay the filing of any future investigational new drug application and new drug application with the FDA or the equivalent applications with pharmaceutical regulatory authorities outside the United States and, ultimately, our ability to commercialize any potential drugs and generate product revenues. The results of AHFIRM, including the topline data from our AHFIRM Phase 2b trial, may not be indicative of future results.

Risks Related To Our Common Stock

Our stock price has in the past and may in the future not meet the minimum bid price for continued listing on Nasdaq. Our ability to continue operations or to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from Nasdaq

In several instances in the past, including as recently as February 9, 2022, we received written notifications from Nasdaq informing us that because the closing bid price of our common stock was below $1.00 for 30 consecutive trading days (the “Minimum Closing Bid Price Requirement”), our shares no longer complied with the Minimum Closing Bid Price Requirement for continued listing on Nasdaq under Nasdaq Marketplace Rules. Each time, we were given a period of 180 days from the date of the notification and in one case an extra 180-day period to regain compliance with Nasdaq’s listing requirements by having the closing bid price of our common stock listed on Nasdaq be at least $1.00 for at least 10 consecutive trading days.

While we have regained compliance within the applicable time periods in the past, if our shares again no longer comply with the Minimum Closing Bid Price Requirement for continued listing on the Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2) and we do not regain compliance within the applicable 180-day time period, Nasdaq will notify us that our securities will be subject to delisting. For example, on November 7, 2023, the closing bid price of our common stock was below $1.00. One strategy to regain compliance in such circumstances would be to implement a reverse stock split. For example, we implemented such a strategy to regain compliance with the Minimum Closing Bid Price Requirement when we completed a 1-for-10 reverse stock split on December 5, 2022 (the "Stock Split"). We could also appeal Nasdaq's determination to delist our securities to a Hearings Panel. During any appeal process, shares of our common stock would continue to trade on the Nasdaq Capital Market.

There can be no assurance that we will regain compliance with the requirements for listing our common stock on the Nasdaq Capital Market. Delisting from Nasdaq would constitute an event of default under our loan facility with Oxford, entitling Oxford to accelerate our obligations under such facility, among other actions. Under such circumstances, we could be required to renegotiate the repayment terms of our loan facility, on terms which would not be as favorable to our Company as our current terms, or we could be required to take other actions, such as discontinuing some or all of our operations, selling assets, or other action. Delisting could also adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Additionally, there can be no assurance that the Stock Split will result in a per-share market price that will maintain compliance with the Minimum Closing Bid Price Requirement, that will attract institutional investors or investment funds or that such share price will satisfy investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not improve. Further, if the market price of our common stock declines, the percentage decline may be greater than would have occurred in the absence of a reverse stock split.

Investors may experience substantial dilution of their investment

In order to raise capital and for other purposes, we may in the future offer and issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock, and the price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share at which investors in our common stock bought their shares. In July 2021, we filed the 2021 Registration Statement to sell up to $250 million of securities from time to time in one or more public offerings, including up to $75.0 million of shares of common stock through the 2021 Sales Agreement. Any sales in the public market of our common stock, under the 2021 Sales Agreement, in offerings under our shelf registration statement or otherwise, could adversely affect prevailing market prices for our common stock. Through several financings between 2019 and 2022, and through our 2015 Sales Agreement, 2018 Sales Agreement and 2021 Sales Agreement with Cantor Fitzgerald during this period, we have raised an aggregate of $79.5 million. On February 3, 2023, we consummated a registered direct offering financing pursuant to which we sold an aggregate of 1,700,000 shares of our common stock, pre-funded warrants to purchase up to 300,000 shares of our common stock and common warrants to purchase up to 2,000,000 shares of our common stock. Each share of common stock and accompanying common warrant and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $5.00 per share and accompanying warrant or, in the case of pre-funded warrants, $4.99999 per pre-funded warrant and accompanying common warrant. In June 2023, we raised net proceeds (net of commissions) of approximately $658,000 from the sale of our common stock in the open market under the 2021 Sales Agreement. Additionally, on July 19, 2023, we consummated a registered direct offering financing pursuant to which we sold an aggregate of 2,991,027 shares of our common stock and common warrants to purchase up to 2,991,027 shares of our common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $5.015 per share and accompanying warrant. Investors could experience substantial dilution of their investment as a result of subsequent exercises of the outstanding warrants. In November 2023, we raised net proceeds (net of commissions) of approximately $803,000 from the sale of our common stock in the open market under the 2021 Sales Agreement. As of November 13, 2023, we had up to 223.5 million of our securities available for sale under the 2021 Registration Statement, of which $73.5 million of our common stock are available pursuant to the 2021 Sales Agreement.

In addition, as of September 30, 2023, 816,347 shares of our common stock were issuable upon exercise of stock options outstanding under our stock option plans at a weighted average exercise price of $9.44 per share, 4,197,120 additional shares of common stock were reserved for potential future issuance under our stock option plan, and an aggregate of 60,479 shares of common stock were reserved for potential future issuance under our 2000 Employee Stock Purchase Plan. At September 30, 2023, we had 150,000,000 authorized shares of common stock and, as such, we have the ability to issue significantly more shares and options in the future, which would result in substantial dilution to our stockholders, including investors in this offering.

The price of our common stock may be volatile

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

Price declines in our common stock have in the past and could in the future result from general market and economic conditions and a variety of other factors, including:

- adverse results (including adverse events or failure to demonstrate safety, efficacy or statistical significance) or delays in our clinical and non-clinical trials of larsucosterol or other product candidates;
- announcements of FDA non-approval of our product candidates, approvals with narrow indications, commercially limiting labels, clinical holds or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies or law enforcement agencies with respect to our products and product candidates, clinical trials, manufacturing processes, accounting practices or sales and marketing activities, or those of our third-party collaborators;
- announcements of technological innovations, patents, product approvals, sales performance or new products by our competitors;
- failure of third-party collaborators to continue development or successful commercialization of the respective products and product candidates they are developing or commercializing;
- failure by our commercial licensee (Innocoll) to successfully manufacture and store adequate supplies, and/or to achieve sales expectations and successfully commercialize POSIMIR;
- regulatory, judicial and patent developments in the United States and foreign countries;
- any lawsuit or arbitration involving us or our products and product candidates including intellectual property infringement or product liability suits;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning our strategic alliances or termination of such alliances or acquisitions or dispositions;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts, misstatements or mischaracterizations in analyst reports or dropping or lack of analyst coverage;
- negative press coverage or online or social media misinformation about the Company or its partners or their respective products or personnel;
- deviations in our operating results from the estimates of analysts;
- sales of our common stock by our executive officers or directors or sales of substantial amounts of common stock by us or others;
- potential failure to meet continuing listing standards from The Nasdaq Capital Market;
- loss or disruption of facilities due to natural disasters;
- acceleration of our debt obligations due to a determination by our lender that a material adverse change has occurred;
- changes in accounting principles; or
- loss of any of our key scientific or management personnel.

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has periodically experienced extreme price and volume fluctuations. For example, the COVID-19 pandemic, pronouncements by the Federal Reserve, inflation, outbreaks of war such as between Russia and Ukraine or Israel and Hamas, oil price volatility and other factors have caused broad stock market and industry fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

In the past, following periods of volatility in the market price of a particular company’s securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive, particularly if we were to lose the lawsuit and have to pay damages, and divert management’s attention and our Company’s resources.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the fiscal quarter ended September 30, 2023, 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, except as described in the table below:

Name and Title	Date Adopted	Character of Trading Arrangement[(1)]	Aggregate Number of Shares of Common Stock to be Purchased or Sold Pursuant to Trading Arrangement	Duration	Other Material Terms	Date Terminated
James E. Brown *President, Chief Executive Officer and Director*	June 14, 2023	Rule 10b5-1 Trading Arrangement	Up to 80,000 shares to be Sold[(2)]	15 months	N/A	August 14, 2023[(3)]

(1) Except as indicated by footnote, each trading arrangement marked as a "Rule 10b5-1 Trading Arrangement" is intended to satisfy the affirmative defense of Rule 10b5-1(c), as amended (the "Rule").

(2) No securities were purchased or sold during the duration of the Rule 10b5-1 Plan.

(3) For additional details about the material terms of this arrangement, refer to the description under the heading "Insider Adoption or Termination of Trading Arrangements" contained in Part II, Item 5. Other Information of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, which is incorporated herein by reference.

tem 6. Exhibits

Exhibit Number	Exhibit Name
4.1	Form of Warrant (July 2023) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 21, 2023).
10.1	Securities Purchase Agreement, dated July 19, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 21, 2023).
10.2*	Sixth amendment to Lease between the Company and De Anza Enterprises LLC dated as of September 6, 2023.
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, 2023, formatted in Inline XBRL: (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations, (iii) Condensed Statements of Comprehensive Income, (iv) Condensed Statements of Changes in Stockholders' Equity, (v) Condensed Statements of Cash Flows and (vi) Notes to Condensed 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.

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, 2023

By: /S/ TIMOTHY M. PAPP

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

Date: November 14, 2023