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 June 30, 2020

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 **Preferred Share Purchase Rights**	**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 July 31, 2020, there were 200,576,707 shares of the registrant's Common Stock outstanding.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2020 (unaudited)	December 31, 2019 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,446	$ 34,924
Short-term investments	32,699	29,750
Accounts receivable (net of allowances of $109 at June 30, 2020 and $34 at December 31, 2019)	1,997	2,313
Inventories, net	3,460	3,383
Prepaid expenses and other current assets	3,481	1,459
Total current assets	60,083	71,829
Property and equipment, net	476	469
Operating lease right-of-use assets	5,372	6,066
Goodwill	6,399	6,399
Long-term restricted investments	150	150
Other long-term assets	283	1,107
Total assets	$ 72,763	$ 86,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,015	$ 2,109
Accrued liabilities	3,692	6,284
Contract research liabilities	2,572	3,653
Deferred revenue, current portion	—	22,679
Operating lease liabilities, current portion	2,073	2,043
Total current liabilities	10,352	36,768
Deferred revenue, non-current portion	812	812
Operating lease liabilities, non-current portion	3,827	4,517
Term loan, non-current portion, net	20,539	20,262
Other long-term liabilities	891	801
Commitments and contingencies		
Stockholders' equity:		
Common stock	19	19
Additional paid-in capital	521,064	512,046
Accumulated other comprehensive income (loss)	71	(3)
Accumulated deficit	(484,812)	(489,202)
Stockholders' equity	36,342	22,860
Total liabilities and stockholders' equity	$ 72,763	$ 86,020

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

DURECT CORPORATION

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

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Collaborative research and development and other revenue	$ 23,347	$ 1,639	$ 23,317	$ 3,139
Product revenue, net	2,497	2,346	5,302	4,977
Total revenues	25,844	3,985	28,619	8,116
Operating expenses:				
Cost of product revenues	964	879	2,196	2,015
Research and development	6,686	6,598	14,403	12,849
Selling, general and administrative	3,439	3,278	6,879	6,732
Total operating expenses	11,089	10,755	23,478	21,596
Income (Loss) from operations	14,755	(6,770)	5,141	(13,480)
Other income (expense):				
Interest and other income	135	177	393	386
Interest expense	(552)	(634)	(1,144)	(1,263)
Net other expense	(417)	(457)	(751)	(877)
Net income (loss)	$ 14,338	$ (7,227)	$ 4,390	$ (14,357)
Net change in unrealized gain (loss) on available-for-sale securities, net of reclassification adjustments and taxes	89	(3)	74	(7)
Total comprehensive income (loss)	$ 14,427	$ (7,230)	$ 4,464	$ (14,364)
Net income (loss) per share				
Basic	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)
Diluted	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)
Weighted-average shares used in computing net income (loss) per share				
Basic	196,866	164,359	196,306	163,219
Diluted	207,477	164,359	206,111	163,219

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 Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	195,257	$ 19	$ 512,046	$ (3)	$ (489,202)	$ 22,860
Issuance of common stock upon exercise of stock options	577	—	761	—	—	761
Stock-based compensation expense from stock options and ESPP shares	—	—	416	—	—	416
Net loss	—	—	—	—	(9,948)	(9,948)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(15)	—	(15)
Balance at March 31, 2020	195,834	$ 19	$ 513,223	$ (18)	$ (499,150)	$ 14,074
Issuance of common stock upon equity financings, net of issuance costs of $192	2,610	—	6,202	—	—	6,202
Issuance of common stock upon exercise of stock options, ESPP purchases and other	1,119	—	1,145	—	—	1,145
Stock-based compensation expense from stock options and ESPP shares	—	—	494	—	—	494
Net income	—	—	—	—	14,338	14,338
Unrealized gain on available-for-sale securities, net of tax	—	—	—	89	—	89
Balance at June 30, 2020	199,563	$ 19	$ 521,064	$ 71	$ (484,812)	$ 36,342
Balance at December 31, 2018	162,060	$ 16	$ 488,608	$ —	$ (468,624)	$ 20,000
Issuance of common stock upon equity financings, net of issuance costs of $129	243	—	61	—	—	61
Stock-based compensation expense from stock options and ESPP shares	—	—	437	—	—	437
Fully vested options issued to settle accrued liabilities	—	—	994	—	—	994
Net loss	—	—	—	—	(7,130)	(7,130)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(4)	—	(4)
Balance at March 31, 2019	162,303	$ 16	$ 490,100	$ (4)	$ (475,754)	$ 14,358
Issuance of common stock upon equity financings, net of issuance costs of $127	29,571	3	15,316	—	—	15,319
Issuance of common stock upon ESPP purchases	57	—	27	—	—	27
Stock-based compensation expense from stock options and ESPP shares	—	—	420	—	—	420
Net loss	—	—	—	—	(7,227)	(7,227)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(3)	—	(3)
Balance at June 30, 2019	191,931	$ 19	$ 505,863	$ (7)	$ (482,981)	$ 22,894

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

DURECT CORPORATION

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

	Six months ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net income (loss)	$ 4,390	$ (14,357)
Adjustments to reconcile net income (loss) to net cash used in by operating activities:		
Depreciation and amortization	139	153
Stock-based compensation	906	860
Amortization of debt issuance cost	225	179
Net amortization on investments	(76)	24
Changes in operating lease liabilities	34	79
Changes in assets and liabilities:		
Accounts receivable	316	(385)
Inventories	(74)	(246)
Prepaid expenses and other assets	(1,198)	910
Accounts payable	(94)	423
Accrued and other liabilities	(2,448)	896
Contract research liabilities	(1,081)	(201)
Deferred revenue	(22,679)	—
Total adjustments	(26,030)	2,692
Net cash used in operating activities	(21,640)	(11,665)
Cash flows from investing activities		
Purchases of property and equipment	(146)	(81)
Purchases of available-for-sale securities	(28,156)	(49)
Proceeds from maturities of available-for-sale securities	25,357	1,693
Net cash (used in) provided by investing activities	(2,945)	1,563
Cash flows from financing activities		
Payments on equipment financing obligations	(1)	(5)
Net proceeds from issuances of common stock	8,108	15,406
Net cash provided by financing activities	8,107	15,401
Net increase (decrease) in Cash, cash equivalents, and restricted cash	(16,478)	5,299
Cash, cash equivalents, and restricted cash, beginning of the period (1)	35,074	31,794
Cash, cash equivalents, and restricted cash, end of the period (1)	$ 18,596	$ 37,093
Supplementary disclosure of non-cash financing information		
Fully vested options issued to settle accrued liabilities	$ —	$ 994
Operating lease right-of-use assets obtained in exchange for operating lease obligations (2)	$ —	$ 7,329

(1) Includes restricted cash of $150,000 (in long term restricted investments) included in the condensed balance sheet at June 30, 2020 and December 31, 2019.
(2) Amounts for the six months ended June 30, 2019 include the transition adjustment for the adoption of Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842).

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 with research and development programs broadly falling into two categories: (i) new chemical entities derived from the Company's Epigenetics Regulator Program, in which the Company attempts to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) proprietary pharmaceutical programs, in which the Company applies its formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which the Company aims to improve through a new formulation. The Company has several products under development by itself and with third party collaborators. The Company also manufactures and sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, the Company conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

Basis of Presentation

These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (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 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 June 30, 2020, the operating results and comprehensive income (loss), and stockholders' equity for the three and six months ended June 30, 2020, and cash flows for the six months ended June 30, 2020 and 2019. The balance sheet as of December 31, 2019 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, 2019 filed with the SEC.

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

Liquidity and Need to Raise Additional Capital

As of June 30, 2020, the Company had an accumulated deficit of $484.8 million as well as negative cash flows from operating activities for the six months ended June 30, 2020.

The Company historically has had negative cash flows from operating activities and expects its negative cash flows to continue. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidates. Management's plans in order to meet its operating cash flow requirements include seeking additional collaborative agreements for certain of its programs and achieving milestone and other payments under its collaboration and licensing agreements 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.

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 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 associated cost of goods for these materials.

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

	June 30, 2020 (unaudited)	December 31, 2019
Raw materials	$ 279	$ 282
Work in process	1,541	1,537
Finished goods	1,640	1,564
Total inventories	$ 3,460	$ 3,383

Revenue Recognition

The Company enters into license and collaboration agreements under which the Company may receive upfront license fees, research funding and contingent milestone payments and royalties.

Product Revenue, Net

The Company sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products.

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: Consistent with industry practice, the Company generally offers customers a limited right of return for products that have been purchased from the Company. The Company estimates the amount of its product sales that may be 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 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 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 and commercial milestone payments; payments for manufacturing supply services the Company provides 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, which are classified as royalty 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. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the standalone selling price, which 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 non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaborative research and development revenues and net income (loss) in the period of adjustment.

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. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaborative research and development revenues and net income (loss) in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of 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. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded in collaborative research and development revenue when the customer obtains control of the goods, which is upon delivery.

Royalties and Earn-outs: For arrangements that include sales-based royalties or earn-outs, including milestone payments based on 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 any material royalty revenue resulting from the Company's collaborative arrangements or material earn-out revenue from the Company's patent purchase agreement with Indivior.

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 the location of the customer) for the three and six months ended June 30, 2020 and 2019 are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
United States	$ 24,503	$ 2,860	$ 25,614	$ 5,354
Europe	668	556	1,753	1,383
Japan	251	314	525	736
Other	422	255	727	643
Total	$ 25,844	$ 3,985	$ 28,619	$ 8,116

Comprehensive Income (Loss)

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

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding. Diluted net income (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 income (loss) per share were as follows (in thousands except per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Numerators:				
Net income (loss)	$ 14,338	$ (7,227)	$ 4,390	$ (14,357)
Denominator:				
Weighted average shares used to compute basic net income (loss) per share	196,866	164,359	196,306	163,219
Dilutive common shares from stock options and ESPP	10,611	—	9,805	—
Weighted average shares used to compute diluted net loss per share	207,477	164,359	206,111	163,219
Net income (loss) per share:				
Basic	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)
Diluted	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)

Options to purchase approximately 4.4 million and 7.2 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2020, respectively, as the effect would be anti-dilutive. Options to purchase approximately 29.8 million and 30.0 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2019, respectively, as the effect would be anti-dilutive.

Recent Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update ("ASU") No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 (ASU 2018-18)*. ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the counterparty is a customer for a distinct good or service (i.e. a unit of account). For units of account that are in the scope of ASC 606, all of the guidance in ASC 606 should be applied, including the guidance on recognition, measurement, presentation and disclosure. ASU 2018-18 also adds a reference in Topic 808 to the unit of account guidance in ASC 606 and requires that it be applied only to assess whether transactions in a collaborative arrangement are in the scope of ASC 606. ASU 2018-18 will preclude entities from presenting amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer as revenue from contracts with customers. ASU 2018-18 is effective for the Company for all interim and annual reporting periods beginning after December 15, 2019. The adoption of this standard did not have a material effect on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those years. The adoption of this standard did not have a material effect on the Company's financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, (ASU 2017-04)*. ASU 2017-04 eliminated Step 2 from the goodwill impairment test. Instead, under the amendments in ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU 2017-04 is effective for all interim and annual reporting periods beginning after December 15, 2019. The adoption of this standard did not have a material effect on the Company's financial statements.

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, 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 is in the process of assessing the impact of adopting of this standard on its financial statements.

Note 2. Strategic Agreements

The collaborative research and development and other revenues associated with the Company's collaborators or counterparties are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Collaborator/Counterparty				
Gilead (1)	$ 23,144	$ 1,452	$ 22,876	$ 2,704
Others (2)	203	187	441	435
Total collaborative research and development and other revenue	$ 23,347	$ 1,639	$ 23,317	$ 3,139

(1) The Company signed a license agreement with Gilead on July 19, 2019 and received a nonrefundable upfront license fee and a milestone payment totaling $35.0 million in 2019 which was being recognized as revenue as the Company's obligation was being satisfied (see Agreement with Gilead Sciences, Inc.) In June 2020, the Company received notice that Gilead was terminating the License Agreement and a related R&D agreement between Gilead and the Company. As a result, the Company recognized as revenue all of the remaining upfront fee and milestone payment during the three and six months ended June 30, 2020 that had previously been deferred as there were no remaining substantive performance obligations to be provided to Gilead by the Company as of June 30, 2020. Amounts recognized as revenue during the three and six months ended June 30, 2019, related entirely to the Company's reimbursable collaborative research and development services performed under the Company's agreement with Gilead.

(2) Includes: (a) amounts related to earn-out revenue from Indivior UK Limited (Indivior) with respect to PERSERIS net sales; (b) feasibility program(s); and (c) research and development activities funded by Santen pharmaceutical Co. Ltd. (Santen). Note that in January 2018, the Company was notified by Santen that due to a shift in near term priorities, Santen had elected to reallocate research and development resources and put the Company's program on pause until further notice. While the main program is on pause, the parties are working together on a limited set of research and development activities funded by Santen.

Agreement with Gilead Sciences, Inc.

On July 19, 2019, the Company entered into a license agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("Gilead"). Pursuant to the Gilead Agreement, the Company granted Gilead the exclusive worldwide rights to develop and commercialize a long-acting injectable HIV product utilizing DURECT's SABER® technology. Gilead also received exclusive access to the SABER platform for HIV and Hepatitis B Virus (HBV) and the exclusive option to license additional SABER-based products directed to HIV and HBV.

Under the terms of the Gilead Agreement, Gilead made an upfront payment to DURECT of $25 million, and in October 2019, the Company also received a $10 million milestone payment from Gilead for further development of the product candidate.

The upfront and milestone consideration of $35 million received in 2019 was being recognized as revenue as the Company's performance obligations were being satisfied using the cost-to-cost input method, which the Company believed best depicted the transfer of control to the customer.

In June 2020, the Company was notified that Gilead was terminating the Gilead Agreement and a related R&D agreement between Gilead and the Company. As a result, we recognized $23.1 million as revenue during the three and six months ended June 30, 2020, which represents all of the remaining upfront fee and milestone payment that had previously been deferred as there were no remaining substantive performance obligations to be provided to Gilead by the Company as of June 30, 2020.

The following table provides a summary of collaborative research and development revenue recognized under the Gilead Agreement (in thousands).

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Recognition of upfront and milestone consideration	$ 23,144	$ —	$ 22,679	$ —
Research and development expenses reimbursable by Gilead	—	1,452	197	2,704
Total collaborative research and development revenue	$ 23,144	$ 1,452	$ 22,876	$ 2,704

Patent Purchase Agreement with Indivior

On September 26, 2017, the Company entered into a Patent Purchase Agreement (the "Indivior Agreement") with Indivior. Pursuant to the Indivior Agreement, the Company assigned to Indivior certain patent rights including granted patents extending through at least 2026. The Indivior Agreement contains customary representations, warranties and indemnities of the parties. Amounts recognized in the three and six months ended June 30, 2020 and 2019 related to earn-out revenues from PERSERIS have been immaterial and are included in collaborative research and development and other revenue.

Agreement with Santen Pharmaceutical Co., Ltd.

On December 11, 2014, the Company and Santen Pharmaceutical Co., Ltd. (Santen) entered into a definitive agreement (the Santen Agreement). Pursuant to the Santen Agreement, the Company granted Santen an exclusive worldwide license to the Company's proprietary SABER formulation platform and other intellectual property to develop and commercialize a sustained release product utilizing the Company's SABER technology to deliver an ophthalmology drug. Santen controls and funds the development and commercialization program, and the parties established a joint management committee to oversee, review and coordinate the development activities of the parties under the Santen Agreement.

In connection with the Santen agreement, Santen agreed to pay the Company an upfront fee of $2.0 million in cash and to make contingent cash payments to the Company of up to $76.0 million upon the achievement of certain milestones, of which $13.0 million are development-based milestones and $63.0 million are commercialization-based milestones including milestones requiring the achievement of certain product sales targets (none of which has been achieved as of June 30, 2020). Santen will also pay for certain Company costs incurred in the development of the licensed product. If the product is commercialized, the Company would also receive a tiered royalty on annual net product sales ranging from single-digit to the low double digits, determined on a country-by-country basis. In January 2018, the Company was notified by Santen that due to a shift in near term priorities, Santen elected to reallocate research and development resources and put the Company's program on pause until further notice. While the main program is on pause, the parties are working together on a limited set of research and development activities funded by Santen. As of June 30, 2020, the cumulative aggregate payments received by the Company under this agreement were $3.3 million.

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, 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 June 30, 2020 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 June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 935	$ —	$ —	$ 935
Certificates of deposit	150	—	—	150
Commercial paper	27,151	7	(3)	27,155
Municipal bonds	16,053	39	—	16,092
Corporate debt	6,019	28	—	6,047
	$ 50,308	$ 74	$ (3)	$ 50,379
Reported as:				
Cash and cash equivalents	$ 17,530	$ —	$ (1)	$ 17,529
Short-term investments	32,628	74	(2)	32,700
Long-term restricted investments	150	—	—	150
	$ 50,308	$ 74	$ (3)	$ 50,379

	December 31, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 524	$ —	$ —	$ 524
Certificates of deposit	150	—	—	150
Commercial paper	47,221	1	(4)	47,218
U.S. Government agencies	4,500	1	—	4,501
Corporate debt	9,869	1	(2)	9,868
	$ 62,264	$ 3	$ (6)	$ 62,261
Reported as:				
Cash and cash equivalents	$ 32,364	$ —	$ (3)	$ 32,361
Short-term investments	29,750	3	(3)	29,750
Long-term restricted investments	150	—	—	150
	$ 62,264	$ 3	$ (6)	$ 62,261

The following is a summary of the cost and estimated fair value of available-for-sale securities at June 30, 2020, by contractual maturity (in thousands):

	June 30, 2020	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 49,373	$ 49,444
	$ 49,373	$ 49,444

There were no securities that have had an unrealized loss for more than 12 months as of June 30, 2020.

As of June 30, 2020, 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.

Note 4. Stock-Based Compensation

As of June 30, 2020, the Company has three stock-based compensation plans. The stock-based compensation cost that has been included in the statements of comprehensive loss is shown as below (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Cost of product revenues	$ 27	$ 22	$ 52	$ 43
Research and development	249	172	460	346
Selling, general and administrative	216	228	394	470
Total stock-based compensation	$ 492	$ 422	$ 906	$ 859

As of June 30, 2020 and 2019, $13,000 and $10,000 of stock-based compensation cost was capitalized in inventory on the Company's balance sheets, 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 six months ended June 30, 2020 and 2019:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Stock Options				
Risk-free rate	0.5%	1.9-2.5%	0.5-1.4%	1.9-2.7%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	7.0-7.3	7.5-10.0	7.0-7.3	7.5-10.0
Volatility	86-87%	79-83%	84-87%	79-86%

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Employee Stock Purchase Plan				
Risk-free rate	0.1%	2.4%	0.1-1.6%	2.4-2.5%
Expected dividend yield	—	—	—	—
Expected life of option (in years)	0.5	0.5	0.5	0.5
Volatility	124%	78%	105-124%	60-78%

Note 5. Term Loan

In July 2016, the Company entered into a $20.0 million secured single-draw term loan with Oxford Finance LLC (Oxford Finance). The Company and Oxford Finance entered into three subsequent amendments to the Loan Agreement in February 2018, November of 2018 and December 2019, for which the Company paid Oxford Finance loan modification fees of $100,000, $900,000 and $825,000 respectively. As amended, the Loan Agreement provides for interest only payments for the first 18 months, followed by consecutive monthly payments of principal and interest in arrears starting on December 1, 2021 and continuing through the maturity date of the term loan of May 1, 2024. The Loan Agreement provides for a floating interest rate (7.95% initially and 7.47% as of June 30, 2020) 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 sheet 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 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 2016 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.

The fair value of the term loan approximates the carrying value. Future maturities and interest payments due under the term loan as of June 30, 2020, are as follows (in thousands):

Six months ended December 31, 2020	$ 929
2021	3,172
2022	9,381
2023	8,644
2024	4,717
Total minimum payments	26,843
Less amount representing interest	(5,119)
Gross balance of term loan	21,724
Less unamortized debt discount	(1,185)
Carrying value of term loan, net	20,539
Less term loan, current portion, net	—
Term loan, non-current portion, net	$ 20,539

As of June 30, 2020, the Company was in compliance with all material covenants under the Loan Agreement and there had been no material adverse change.

Note 6. Commitments

Operating Leases

The Company has lease arrangements for its facilities in California and Alabama as follows.

Location	Approximate Square Feet	Operation	Expiration
Cupertino, CA	30,149 sq. ft.	Office, Laboratory and Manufacturing	Lease expires 2024 (with an option to renew for an additional five years)
Cupertino, CA	20,100 sq. ft.	Office and Laboratory	Lease expires 2024 (with an option to renew for an additional five years)
Vacaville, CA	24,634 sq. ft.	Manufacturing	Lease expires 2023
Birmingham, AL	21,540 sq. ft.	Office, Laboratory and Manufacturing	Lease expires 2021 (with two options to renew the lease term for an additional five years each after the current lease expires)

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. Rent expense under all operating leases was $564,000 and $1.1 million for the three and six months ended June 30, 2020, respectively, compared to $564,000 and $1.1 million for the corresponding periods in 2019.

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

	Operating Leases
Six months ended December 31, 2020	$ 1,105
2021	2,126
2022	1,991
2023	1,970
Thereafter	275
	$ 7,467

Note 7. Stockholders' Equity

In August 2018, the Company filed a shelf registration statement on Form S-3 with the SEC (the "2018 Registration Statement") (File No. 333-226518), which upon being declared effective in October 2018, terminated the Company's registration statement filed in November 2015 (File No. 333-207776) and allowed the Company to offer up to $175.0 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 November 3, 2015 with Cantor Fitzgerald & Co. (the "2015 Sales Agreement").

During the three and six months ended June 30, 2020, the Company raised net proceeds (net of commissions) of approximately $6.2 million from the sale of 2,610,375 shares of the Company's common stock in the open market at a weighted average price of $2.45 per share, pursuant to the 2015 Sales Agreement.

During the three months ended June 30, 2019, the Company raised net proceeds (net of commissions) of approximately $355,000 from the sale of 571,700 shares of the Company's common stock in the open market at a weighted average price of $0.64 per share, pursuant to the 2015 Sales Agreement. During the six months ended June 30, 2019, the Company raised net proceeds (net of commissions) of approximately $538,900 from the sale of 814,450 shares of the Company's common stock in the open market at a weighted average price of $0.68 per share, pursuant to the 2015 Sales Agreement.

As of July 31, 2020, the Company had up to approximately $147.6 million of the Company's securities available for sale under the 2018 Registration Statement, of which approximately $62.7 million of the Company's common stock are available pursuant to the 2015 Sales Agreement.

Note 8. Subsequent Event

In July 2020, the Company raised net proceeds (net of commissions) of approximately $2.2 million from the sale of 1,007,392 shares of the Company's common stock in the open market at a weighted average price of $2.30 per share, pursuant to the 2015 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 six months ended June 30, 2020 should be read in conjunction with our annual report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission and "Risk Factors" section included elsewhere in this Form 10-Q. 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 report, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "could," "potentially" and similar expressions are forward-looking statements. Such forward-looking statements 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, for example, statements about:

- the clinical trial plans for DUR-928;
- potential uses and benefits of DUR-928 to treat alcoholic hepatitis (AH), non-alcoholic steatohepatitis (NASH), COVID-19 patients with acute liver or kidney injury, or other conditions, including acute kidney injury (AKI), and nonalcoholic fatty liver disease;
- potential regulatory filings for or approval of DUR-928, POSIMIR, or any of our or any third parties' other product candidates;
- the potential earn-out payments we may receive from Indivior related to the commercialization of PERSERIS and milestone and royalty payments we may receive from Santen or Orient Pharma;
- the progress of our third-party collaborations, including estimated milestones;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our product candidates and technologies, including POSIMIR and our SABER and ORADUR technologies;
- responsibilities of our third-party collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators' plans with respect to our product candidates and continued development of our product candidates;
- our responsibilities to our third-party collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products or product candidates;
- our ability to protect intellectual property, including intellectual property licensed to our collaborators;
- market opportunities for product candidates in our product development pipeline;
- the progress and results of our research and development programs and our evaluation of additional development programs;
- requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;
- the results and timing of clinical trials, the ability to enroll patients in clinical trials in a timely and cost-effective manner, the likelihood of future clinical trial results being similar to results from previous trials, including for DUR-928, the possible commencement of future clinical trials and announcements of the findings of our clinical trials;
- 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, DEA, EMEA and other government regulation on our business;
- uncertainties associated with obtaining, asserting and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with the product candidates we develop and/or license to third-party collaborators;
- the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;
- the possibility that we may develop additional manufacturing capabilities;
- 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 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, and our need or desire for additional financing, including potential sales under our shelf registration statement;
- our expectations regarding research and development expenses, and selling, general and administrative expenses;
- the composition of future revenues; and
- accounting policies and estimates.

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.

Overview

We are a biopharmaceutical company with research and development programs broadly falling into two categories: (i) new chemical entities derived from our Epigenetic Regulator Program, in which we attempt to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) proprietary pharmaceutical programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve through a new formulation. We also manufacture and sell osmotic pumps used in laboratory research, and design, develop and manufacture a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products.

Our product pipeline currently consists of multiple investigational drug candidates in development. DURECT's lead candidate, DUR-928 is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival. It is in Phase 2 development for alcoholic hepatitis (AH) and acute liver or kidney injury in COVID-19 patients and Phase 1 for nonalcoholic steatohepatitis (NASH). DURECT's proprietary drug delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage development program in this category is POSIMIR® (bupivacaine extended-release solution), an investigational analgesic product intended to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

NOTE: POSIMIR®, SABER®, CLOUD®, ORADUR™, ALZET® and LACTEL® are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners.

A central aspect of our business strategy involves advancing multiple product opportunities at one time, which is enabled by leveraging our resources with those of corporate collaborators. Thus, certain of our programs are currently licensed to corporate collaborators on terms which typically call for our collaborator to fund all or a substantial portion of future development costs and pay us milestone payments based on specific development or commercial achievements plus royalties on product sales. At the same time, we have retained the rights to other programs, which are the basis of potential future collaborations and which over time may provide a pathway for us to develop our own commercial, sales and marketing organization.

Additional details of these programs and related strategic agreements are contained in our annual report on Form 10-K for the year ended December 31, 2019 and in Note 2 of the financial statements included in Item 1 above.

Recent Developments

The COVID-19 global pandemic poses a significant life-threatening and economic risk throughout the world. The rapid spread of the disease has resulted in a pandemic with millions of confirmed cases and causing hundreds of thousands of deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into Acute Respiratory Distress Syndrome (ARDS), multi-organ failure, and death. Many of these patients experience a rapid elevation of inflammation-inducing signaling molecules (cytokine storm) that trigger acute injuries in multiple organs including the liver and the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed COVID-19, 62% of patients presented with at least one elevated liver enzyme. In another study, 36.6% of 5,449 patients admitted with COVID-19 had or developed AKI. A range of vaccine and many other therapeutic candidates are under development.

In response to this global pandemic, we have initiated recruiting patients for a double-blind, placebo-controlled, multi-center, proof-of-concept Phase 2 study to evaluate the safety and efficacy of DUR-928 in COVID-19 patients with acute liver or kidney injury. In addition, as we continue to actively advance all of our research and development programs, we are assessing on an ongoing basis the impact of COVID-19 on our clinical trials, product candidate testing, expected timelines and costs.

COVID-19 has also had a negative impact on our business. In light of recent developments relating to the COVID-19 global pandemic, the focus of healthcare providers and hospitals is on the prioritization of healthcare resources toward fighting the virus and clinical site initiations. As a result, patient enrollment and activities that require visits to clinical sites, including data monitoring, have been and may continue to be delayed. We are also evaluating the impact of the COVID-19 on orders for our ALZET and LACTEL product lines, where we have seen decreases in sales volumes and requests for changes in payment terms. In addition, in response to the spread of COVID-19, we closed our principal executive office for a period of time, although our employees continue to work from home, and, in keeping with social distancing requirements, we have limited the number of staff in our facilities. This partial disruption, although temporary, may impact our operations and overall business by delaying the progress of our research and development programs, including our planned preclinical studies and clinical trials. The impact of COVID-19 is evolving rapidly and its future effects are uncertain. Given the uncertainty of the situation, the duration of the disruption and related financial impact cannot be reasonably estimated at this time. We will continue to evaluate the impact of the COVID-19 pandemic on our business and expect to reevaluate the timing of our anticipated preclinical and clinical objectives as we learn more and the impact of COVID-19 on our industry becomes clearer.

Epigenetic Regulator Program and New Chemical Entities

Epigenetic regulation involves biochemical modification of either DNA itself or proteins that are intimately associated with DNA. These modifications lead to changes in gene expression that facilitate downstream biological effects.

DURECT's Epigenetic Regulator Program involves a multi-year collaborative effort with the Department of Internal Medicine at Virginia Commonwealth University (VCU), the VCU Medical Center and the McGuire VA Medical Center. The knowledge base supporting this program is a result of more than 30 years of lipid research by Shunlin Ren, M.D., Ph.D., Professor of Internal Medicine at the VCU Medical Center. The lead compound from this program, DUR-928, is an endogenous, orally bioavailable, small molecule that modulates the gene expression of various nuclear receptors that play important regulatory roles in lipid homeostasis, inflammation, and cell survival. Under a license with VCU, we hold the exclusive royalty-bearing worldwide right to develop and commercialize DUR-928 and related molecules discovered in the program.

The biological activity of DUR-928 has been demonstrated in over a dozen different animal disease models involving three animal species. Some of these models represent acute organ injuries (e.g., endotoxin shock, acute oxidative stress, ischemic-reperfusion injury in the kidney and brain) and several represent chronic metabolic disorders involving hepatic lipid accumulation and dysfunction (e.g., NASH and NAFLD).

Our major product research and development efforts for DUR-928 are set forth in the following table:

Summary of DUR-928 Clinical Trials

Indication	Preclinical	Phase 1	Phase 2	Design / Timing	Patient Population
Alcoholic Hepatitis (Injectable)				Planned Phase 2b trial initiation 2H 2020. If robust mortality benefit is shown, could lead to accelerated regulatory path.	>117,000 annual U.S. hospitalizations[1]
COVID-19 with Acute Liver or Kidney Injury				Ongoing Phase 2 double-blind, placebo-controlled, multi-center safety and efficacy trial, n=80.	TBD
NASH (Oral)				Topline Phase 1b data, n=65: Significant reductions in liver enzymes, liver imaging, serum lipids. Additional data analysis ongoing.	9-16 million in the U.S.[2]

(1) US Department of Health and Human Services' Healthcare Cost and Utilization Project reports https://hcupnet.ahrq.gov (accessed Sept 2019). (2) Estes C, et al. Hepatology, 2018;67:123-133.

In pharmacokinetic and toxicology studies conducted in mice, hamsters, rats, rabbits, dogs, minipigs and monkeys, DUR-928 has been found to be tolerable and safe by all routes of administration tested to date. These results support the use of DUR-928 in the completed, ongoing and planned human safety, pharmacokinetics (PK), proof-of-concept, and efficacy trials. The chronic toxicity of DUR-928 was further assessed in a 6-month oral study in rats and in a 9-month oral study in dogs. These studies were completed successfully and support long duration human clinical trials of DUR-928.

Acute Organ Injury Program with Injectable DUR-928

Market Opportunity. Alcoholic hepatitis (AH) is an acute form of alcoholic liver disease (ALD) associated with long-term heavy intake of alcohol, and often occurs after a recent period of increased alcohol consumption. AH is typically characterized by recent onset jaundice and hepatic failure. An analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients, showed the overall mortality from AH was 26% at 28 days. According to the most recent data provided by the Agency for Healthcare Research and Quality (AHRQ), a part of the US Department of Health and Human Services (HHS), there were 117,000 hospitalizations for patients with alcoholic hepatitis in 2016. From a recent publication analyzing the mortality and costs associated with alcoholic hepatitis, the cost per patient is estimated at over $50,000 in the first year. ALD is one of the leading causes of liver transplants in the US, each of which cost over $800,000. The rapid spread of the COVID-19 has resulted in a pandemic with millions of confirmed cases and causing hundreds of thousands of deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into Acute Respiratory Distress Syndrome (ARDS), multi-organ failure, and death. Many of these patients experience a rapid elevation of inflammation-inducing signaling molecules (cytokine storm) that trigger acute injuries in multiple organs including the liver and the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed COVID-19, 20% of patients presented with at least one elevated liver enzyme. In another study, 37% of 5,449 patients admitted with COVID-19 had or developed AKI. There are various forms of acute organ injury affecting the liver, the kidney or other organs for which we are or may seek to develop DUR-928.

Clinical Program. In 2019, we completed a Phase 2a clinical trial evaluating intravenously infused DUR-928 in patients with moderate and severe AH. This was an open label, dose escalation (30, 90 and 150 mg), multi-center U.S. study, originally designed to

be conducted in two sequential parts. Part A included patients with moderate AH and Part B included patients with severe AH. Severity of AH was determined by the Model of End-Stage Liver Disease (MELD) scores, a common scoring system to assess the severity and prognosis of AH patients; moderate was defined as MELD 11-20 and severe as MELD 21-30.

In this Phase 2a trial, dose escalation was permitted following review of safety and pharmacokinetic (PK) results of the prior dose level by a Dose Escalation Committee (DEC). The target number of patients for the study was 4 per dose group. Final enrollment included 19 patients with moderate and severe AH, who were administered DUR-928 intravenously at three different doses. Eight patients (four moderate and four severe) were dosed at 30mg, seven patients (three moderate and four severe) were dosed at 90mg and four patients (all severe) were dosed at 150mg. After being discharged on day two, one patient did not return for the scheduled day seven and day 28 follow-up visits; therefore Lille, bilirubin and MELD data reported below are based on 18 patients. The objectives of this study included assessment of safety, PK and pharmacodynamic (PD) signals, including liver biochemistry, biomarkers, and prognostic scores, including the Lille score, following DUR-928 treatment.

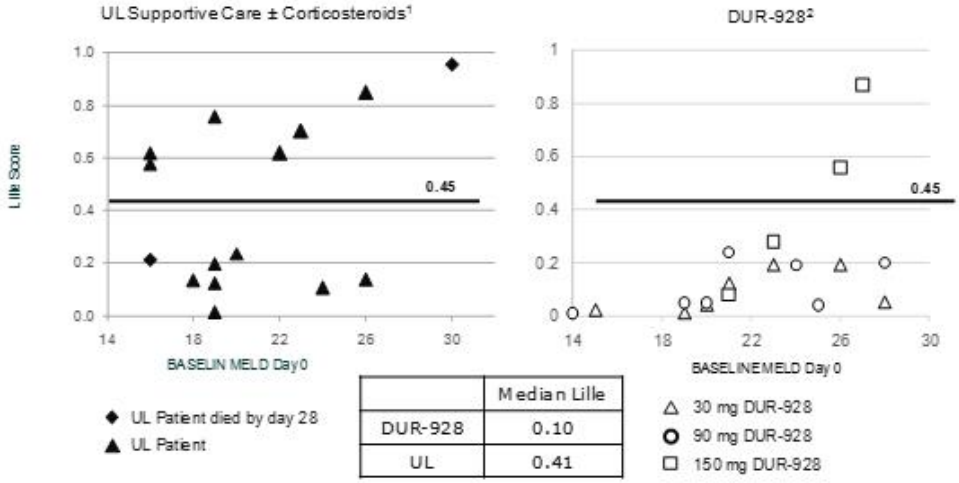
In November 2019, the results from our Phase 2a clinical trial of DUR-928 in alcoholic hepatitis (AH) were presented as a late-breaking oral presentation at The Liver Meeting®. The study results were also selected for inclusion in the 'Best of The Liver Meeting' summary slide presentation in the alcohol-related liver disease category.

All 19 patients treated with DUR-928 in this trial survived the 28-day follow-up period and there were no drug-related serious adverse events. Fifteen of the 19 patients had Maddrey's Discriminant Function scores of 32 or greater, indicating that they had severe AH. Patients treated with DUR-928 had a statistically significant reduction from baseline in bilirubin at day 7 and 28 and MELD at day 28. Lille scores were also statistically significantly lower than those from a well-matched group of patients in a contemporary ongoing trial as well as several published historical controls. 74% of all DUR-928 treated patients and 67% of those with severe AH were discharged from the hospital within four days of receiving a single dose of DUR-928.

Lille

Lille scores are used in clinical practice to help determine the prognosis and response of AH patients after seven days of treatment. The lower the Lille score, the better the prognosis. Patients with a Lille score below 0.45 have a six-month survival rate of 85% compared to those with Lille scores above 0.45, who have only a 25% six-month survival rate.[1] The chart below shows the Lille scores for individual AH patients treated with DUR-928 plotted as a function of their baseline MELD scores. In our study, the median Lille score for patients treated with DUR-928 was 0.10. The median Lille score among a cohort of 15 patients treated with standard of care at the University of Louisville (UL) was 0.41 (shown as historical control).

The chart below shows individual patient Lille scores plotted as a function of their baseline MELD scores.



	Median Lille
DUR-928	0.10
UL	0.41

1) *Our advisor, Dr. Craig McClain from the University of Louisville (UL), shared anonymized data from his study, in which 15 AH patients with initial MELD scores ranging from 15-30 received either supportive care alone (n=8 moderate AH patients) or supportive care with corticosteroids (n=7 severe AH patients). Two of the UL control patients died by day 28.*
2) *One patient in the DUR-928 group did not return for the day 7 or 28 visit. All 19 patients, including this one, treated with DUR-928 in this trial survived the 28-day follow-up period.*
3) *Lille scores in the DUR-928 group were significantly lower than that of the UL patients (p=0.01; Wilcoxon's Rank Sum Test).*

[1] *Louvet A et al. Hepatology 2007; 45: 1348-54.*

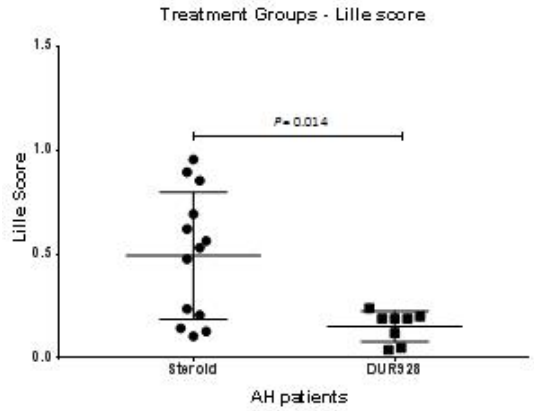
As shown below, 100% of patients in the 30 mg and 90 mg DUR-928 dosing groups were treatment responders based on their Lille scores. 89% of the overall DUR-928 patient population were treatment responders based on Lille. Patients with severe AH, as defined by Maddrey's Discriminant Function ≥32 or MELD 21-30, and baseline serum bilirubin above 8 mg/dL, had similarly high response rates to DUR-928 treatment.

AH Patient Category		n[1]	Responders (Lille<0.45)	Lille Median (Quartile)
All Patients[2]		18	89%	0.10 (0.04, 0.20)
30 or 90 mg DUR-928[3]		14	100%	0.05 (0.04, 0.19)
DF≥32 (SAH)[2, 4]		15	87%	0.19 (0.05, 0.22)
30 or 90 mg DUR-928[3]		11	100%	0.12 (0.05, 0.19)
MELD 21-30[2]		12	83%	0.19 (0.11, 0.25)
30 or 90 mg DUR-928[3]		8	100%	0.19 (0.10, 0.19)
Baseline bilirubin >8mg/dl[2]		11	82%	0.10 (0.05, 0.20)
30 or 90 mg DUR-928[3]		8	100%	0.10 (0.05, 0.19)

1) *One patient did not return for Day 7 and 28 visits;*
2) *Including patients receiving 30, 90 and 150 mg of DUR-928;*
3) *Excluding patients receiving 150 mg of DUR-928.*
4) *Maddrey's Discriminant Function (MDF or DF) is calculated using the patient's prothrombin time and serum bilirubin level. DF was introduced in 1978 as a predictor of significant mortality risk for AH patients. A DF≥32 identified AH patients with a 30-day mortality rate of ≥50%.*

The Lille scores of patients treated with DUR-928 in this trial were also significantly lower than several selected published historical studies *(Hepatology 2007, 45:1348-1354; Gut 2011, 60:255-260)*, in which patients had similar baseline bilirubin, albumin, creatinine, prothrombin time and DF scores, and were treated with standard of care with or without corticosteroids. Of course, due to the historical nature of these studies, such comparisons should be taken cautiously.

A sub-group analysis was conducted to compare severe AH patients in the 30 mg and 90 mg dosing groups (n=8) with well-matched severe AH patients (n=13) who received corticosteroids for 28 days in a contemporaneous study at the University of Louisville (UL). Patients shown below in the UL steroid group had a mean baseline MELD of 24.46 and mean baseline Maddrey's DF score of 62.98. The 8 patients in the DUR-928 group had baseline mean MELD of 24.50 and mean baseline Maddrey's DF score of 61.25. All patients treated with DUR-928 survived the 28-day follow up period, while 3 patients in the UL steroid group died within the first 28 days.

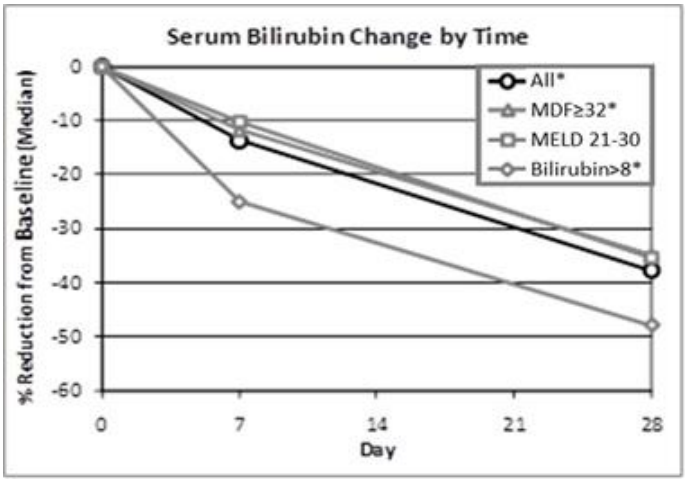


The steroid group in the above graph includes the 7 severe AH patients treated with steroids from the UL group shown in the MELD vs Lille graph above plus an additional 6 severe AH patients subsequently treated in the UL study.

Bilirubin

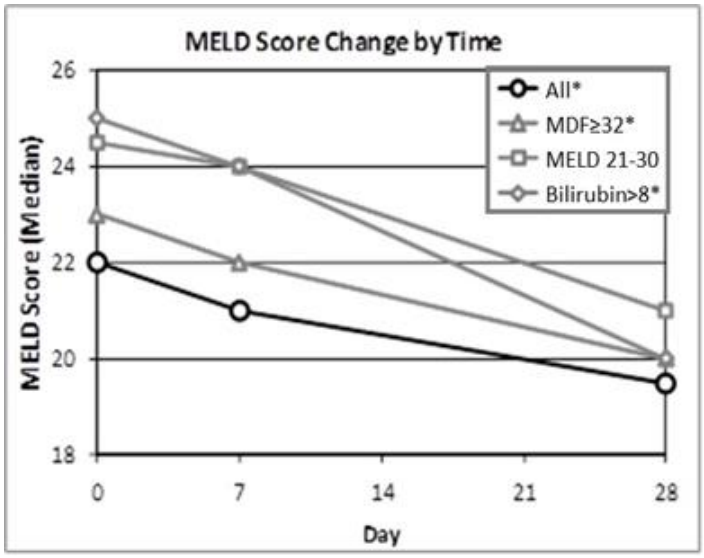
Bilirubin is formed by the breakdown of red blood cells in the body. The level of total bilirubin in the blood is an indication of how the liver is functioning. High bilirubin levels are associated with liver dysfunction and disease. In this trial, patients treated with

DUR-928 had a significant early reduction from baseline in bilirubin by day 7. Patients with more elevated bilirubin at baseline (serum bilirubin >8 mg/dL) had a median reduction from baseline of 25% by day 7 and 48% by day 28.



**p<0.05 compared to baseline (Wilcoxon's Signed Rank Test)*

MELD is another common scoring system used to assess the severity and prognosis of AH patients. Patients with MELD scores of 11-20 are classified as having moderate AH and patients with MELD scores of 21-30 are classified as having severe AH. As with Lille scores, the lower the MELD score, the better the prognosis for the AH patient. In this study (shown in the chart below), the median reduction from baseline in MELD among all DUR-928 treated patients was >2 points and among those with baseline bilirubin levels >8 mg/dL was 5 points by day 28.



**p<0.05 compared to baseline (Wilcoxon's Signed Rank Test)*
MELD is calculated based on (a) bilirubin, (b) serum creatinine (sCr), and (c) International Normalized Ratio (INR), which is a measure of prothrombin time.

Safety and Pharmacokinetics

In the Phase 2a study, DUR-928 was well tolerated at all doses tested. There were no drug-related serious adverse events and only three adverse events designated as possibly related to DUR-928: one occurrence of moderate generalized pruritus, one mild rash and one grade two alkaline phosphatase. There were no discontinuations, early withdrawals or termination of study drug or study

participation due to adverse events. All patients treated with DUR-928 survived through the 28-day follow-up period. Drug exposures were dose proportional and were not affected by the severity of the disease.

We are working with the FDA and our advisors to finalize the design of a multi-center, international, randomized, double blind, placebo-controlled Phase 2b clinical trial of DUR-928 in severe AH patients. Patients in the trial will be randomized to receive 30 mg of DUR-928, 90 mg of DUR-928 or placebo. The primary endpoint will be survival rate for patients treated with DUR-928 compared to those treated with placebo. Further details of the trial design, including the size of the trial and other trial parameters will be provided at a future date. We expect to initiate the trial in the second half of 2020, subject to potential delays due to COVID-19.

Phase 1 trials of DUR-928 administered through injection have supported the development of DUR-928 in AH. The initial Phase 1 trial in healthy subjects was a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and PK of intramuscular (IM) injected DUR-928. The 24-subject study (16 healthy volunteers on the drug and 8 on placebo) of four escalating dose levels resulted in dose proportional systemic exposure of DUR-928 with peak plasma concentrations greater than 1000-fold higher than endogenous levels. DUR-928 was well-tolerated at all dose levels, with no serious treatment-related adverse events reported. We also conducted a multiple-dose study involving 10 healthy subjects, in which participants received IM-injected DUR-928 for 5 consecutive days (8 subjects on the drug, 2 on placebo) using the next to highest dose from the single dose study. No serious treatment related adverse events were reported, no subjects withdrew from the study, no accumulation in plasma concentrations were observed with repeat dosing, and the pain scores and injection site reactions were minimal. We also conducted a single-ascending dose intravenous (IV) infusion study with 16 healthy subjects and observed no treatment-related serious adverse events. The systemic exposure following IV infusion was dose proportional.

A Phase 1 drug-drug interaction study conducted in healthy subjects demonstrated that neither orally administered nor intravenously injected DUR-928 at doses tested affected the safety and PK of midazolam, a drug metabolized by CYP3A4, which is one of the important enzymes associated with clinically relevant drug-drug interactions.

We have also conducted a Phase 1b study with injected DUR-928 in patients with impaired kidney function (stage 3 and 4 chronic kidney disease (CKD)) and matched control subjects (MCS), matched by age, body mass and gender with normal kidney function. This study was a single-site, open-label, single-ascending-dose study in two successive cohorts (first a low dose of 30 mg and then a high dose of 120 mg) evaluating safety and PK of intramuscular injected DUR-928. The low dose cohort consisted of 6 patients with CKD and 3 MCS; the high dose cohort consisted of 5 CKD patients and 3 MCS. In this trial, DUR-928 was well tolerated among all subjects and the PK parameters between the kidney function impaired patients and the MCS were comparable. The results of this Phase 1b trial were presented at Kidney Week 2018 in San Diego.

COVID-19 with DUR-928

Market Opportunity. Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus (SARS-COV-2) infection. The rapid spread of the disease has resulted in a pandemic with millions of confirmed cases and causing hundreds of thousands of deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into Acute Respiratory Distress Syndrome (ARDS), multi-organ failure, and death. Many of these patients experience a rapid elevation of inflammation-inducing signaling molecules (cytokine storm) that trigger acute injuries in multiple organs including the liver and the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed hospitalized COVID-19, 62% of patients presented with at least one elevated liver enzyme. In another study, 36.6% of 5,449 patients admitted with COVID-19 had or developed AKI.

Clinical Program. We have begun to recruit patients for a randomized, double-blind, placebo-controlled, multi-center Phase 2 study to evaluate the safety and efficacy of DUR-928 in hospitalized COVID-19 infected patients with acute liver or kidney injury. This Phase 2, randomized, double-blind, placebo-controlled, multi-center study is designed to evaluate safety and efficacy of DUR-928 in COVID-19 patients with acute liver or kidney injury. The primary efficacy endpoint is a composite of survival and being free of acute organ failure (free of mechanical ventilation, free of liver failure events and free of renal replacement therapy) at day 28.

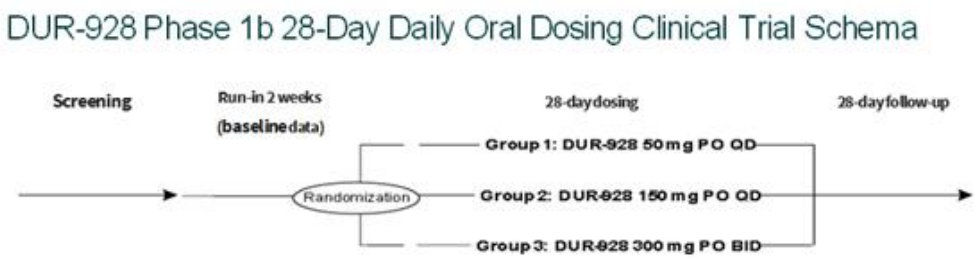
A total of approximately 80 patients are planned to be enrolled into two study treatment groups in a 3:1 (DUR-928:placebo) ratio. Patients will receive a dose of 150 mg of DUR-928 or placebo by intravenous infusion on day 1 and day 4 in combination with standard of care therapy, which will be determined by the principal investigator (PI) at each clinical trial site. Patients will be followed for 60 days. Should any drug product be determined by the FDA to be safe and effective for the treatment of COVID-19 while the trial is ongoing, such treatments may be offered, at each PI's discretion, to any remaining and future patients in this trial.

Chronic Liver Disease Program with Orally Administered DUR-928

Market Opportunity. Non-alcoholic fatty liver disease (NAFLD) is the most common form of chronic liver disease in both children and adults. It is estimated that NAFLD affects approximately 30% to 40% of adults and 10% of children in the United States. Non-alcoholic steatohepatitis (NASH), a more severe and progressive form of NAFLD, is one of the most common chronic liver diseases worldwide, with an estimated prevalence of 3-5% globally. No drug is currently approved for treatment of NAFLD or NASH. Moreover, alcoholic fatty liver disease (AFLD), including its more advanced stage, alcoholic steatohepatitis (ASH), develops in approximately 90% of individuals who drink more than 60 grams/day of alcohol, but may occur in individuals who drink less, and

is a major contributor to the global burden of liver cirrhosis. In addition to these liver diseases, there are a number of orphan liver diseases for which we may seek to develop DUR-928.

Clinical Program. We recently conducted a Phase 1b randomized and open-label clinical study in the U.S. to evaluate safety, pharmacokinetics and signals of biological activity of DUR-928 in NASH patients with stage 1-3 fibrosis. DUR-928 (at doses of 50 mg QD, 150 mg QD and 300 mg BID) was administered orally for 28 days with 20 patients or more per dose group for a total of 65 patients in the trial as shown below. Key endpoints included safety and PK, clinical chemistry and biomarkers (e.g., ALT, AST, GGT, triglycerides, Non-HDL-C, CK-18s, inflammatory cytokines) as well as liver fat content by imaging and liver stiffness (e.g. MRI-PDFF and FibroScan®).



In May 2020, we reported positive topline results from this Phase 1b clinical study of orally administered DUR-928 in NASH patients.

A total of 65 patients completed the study, in which DUR-928 was orally administered daily for 4 weeks at 50 mg (n=23), 150 mg (n=21), or 600 mg (300 mg BID (n=21)) and followed up for an additional 4 weeks. Both the 50 mg and 600 mg dose groups showed a statistically significant median reduction at day 28 from baseline of serum alanine aminotransferase (ALT) levels at -16% and -17%, respectively. The 600 mg dose group also showed statistically significant median reductions at day 28 from baseline of serum aspartate aminotransferase (AST) (-18%) and gamma-glutamyl transferase (GGT) (-8%), and the 50 mg dose group had a statistically significant reduction at day 28 from baseline in liver stiffness as measured by Fibroscan (-10%).

Patients in the 50 mg or 150 mg dose groups also had statistically significant median reduction at day 28 from baseline of serum triglycerides (-13% in the 50 mg group) or LDL-C (-11% in the 150mg group). Patients with elevated baseline triglycerides (≥200 mg/dL; n=16) across all dose groups had a median reduction at day 28 from baseline of -24% ($p < 0.01$).

At day 28, 43% of patients in all three dose groups showed ≥ 10% liver fat reduction from baseline as measured by magnetic resonance imaging - proton density fat fraction (MRI-PDFF). In this subgroup, there was a significant reduction from baseline in median liver fat content (-18%, -19%, and -23%, in the 50 mg, 150 mg and 600 mg groups respectively). The reduction of liver fat content was accompanied by a significant median reduction from baseline of serum ALT (-21%, -19%, and -32%, in the 50 mg, 150 mg and 600 mg groups respectively).

DUR-928 was well tolerated at all three doses evaluated. There were no serious adverse events reported during the study. Pharmacokinetic (PK) parameters after repeat dosing were comparable to those after a single dose (from a prior study), indicating no accumulation after repeat dosing.

Results, including biomarker data, are still being analyzed. DURECT plans to present additional results and data analyses at a future scientific meeting.

Topline Data Summary (Day 28 vs Baseline)

Median at Day 28 ** p < 0.05* *** p < 0.01* **** p < 0.001*		All Subjects			Patients with ≥ 10% Reduction in MRI-PDFF		
		50 mg QD *(n=21-23)*	**150 mg QD** *(n=20-21)*	**300 mg BID** *(n=20-21)*	**50 mg QD** *(n=9)*	**150 mg QD** *(n=8)*	**300 mg BID** *(n=9)*
Liver Enzymes	**ALT**	**-16%***	-10%	**-17%*****	**-21%****	**-19%***	**-32%*****
	AST	-14%	-9%	**-18%****	**-24%****	-21%	**-39%*****
	GGT	-6%	-1%	**-8%***	**-13%*****	**-16%***	-14%
Imaging	**MRI-PDFF**	-7%	-7%	-4%	**-18%*****	**-19%*****	**-23%*****
	FibroScan	**-10%****	-9%	-1%	-7%	**-9%****	-9%
Serum Lipids	**LDL-C**	-6%	**-11%***	-7%	-7%	-11%	**-8%***
	Non-HDL-C	-8%	-5%	-1%	-10%	**-8%***	**-12%***
	Triglycerides	**-13%***	-3%	-2%	-9%	0%	-8%
	24% reduction in serum triglycerides in patients with elevated baseline triglycerides (≥200 mg/dL; n=16) across all dose groups at day 28 from baseline (p <0.01)						

***ALT** (alanine aminotransferase); **AST** (aspartate aminotransferase); **GGT** (gamma-glutamyl transferase); **LDL-C** (Low-Density Lipoprotein – Cholesterol); **Non-HDL-C** (Total cholesterol excluding High-Density Lipoprotein-Cholesterol); **QD** (once a day); **BID** (twice a day); **MRI-PDFF** (Magnetic Resonance Imaging - Proton Density Fat Fraction) is a non-invasive measure of the proportion of liver tissue which is composed of fat; **FibroScan** is a specialized ultrasound machine that measures the stiffness of liver tissue.*

We have completed multiple Phase I trials in healthy subjects with orally administered DUR-928. These included single-ascending-dose and multiple-ascending-dose studies as well as a food effect study. In all of these studies DUR-928 was well-tolerated at all dose levels, with no serious treatment-related adverse events reported. Dose related increases in plasma concentrations were observed and no accumulation in plasma concentrations or food effects were observed with repeat dosing.

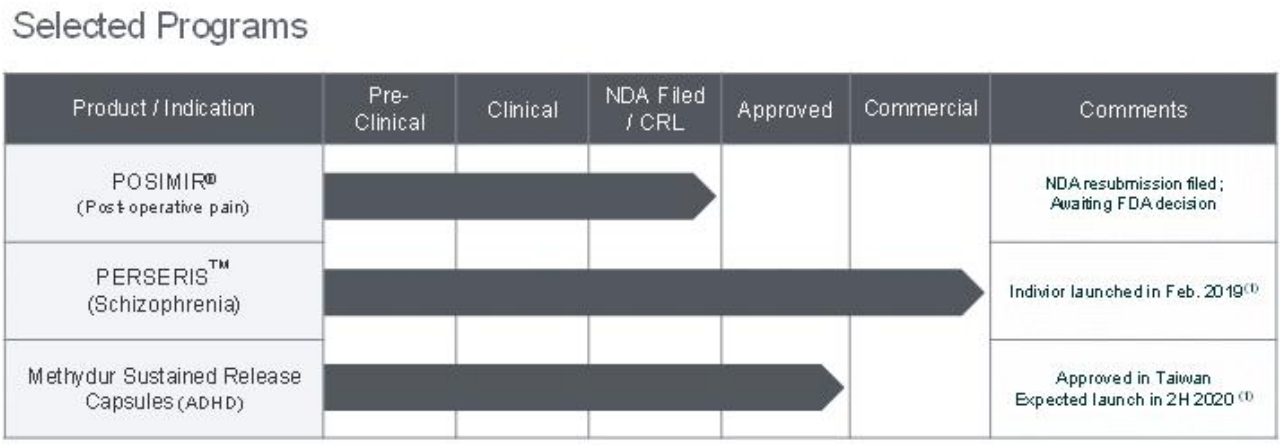
We also conducted a Phase 1b trial in cirrhotic and non-cirrhotic NASH patients and matched control subjects (MCS) (matched by age, body mass index and gender with normal liver function) utilizing orally administered DUR-928. This was an open-label, single-ascending-dose safety and PK study conducted in Australia in two successive dose cohorts (first a low dose of 50 mg and then a high dose of 200 mg). Both cohorts consisted of 10 NASH patients and 6 MCS. Data from this study was presented at the International Liver Congress™ 2017 organized by the European Association for the Study of the Liver (EASL) in Amsterdam on April 22, 2017. All patients and MCS in this study tolerated DUR-928 well. One patient (with a prior history of arrhythmia and an ongoing viral infection) in the high dose cohort experienced a serious adverse event (shortness of breath), which occurred without unusual biochemical changes and resolved without intervention but was considered possibly treatment related by the physician due to its temporal association with dosing. In both low and high dose cohorts, the PK parameters were comparable between the NASH patients and the MCS. In addition, the systemic exposure following the low and high doses of DUR-928 was dose dependent.

While this study was not designed to assess efficacy, we observed statistically significant reductions from baseline of several biomarkers after both doses of DUR-928. A single oral dose of DUR-928 significantly reduced the levels of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, hsCRP, and IL-18 in these subjects. The mean decrease of full-length CK-18 (a generalized cell death marker) at the measured time point of greatest effect (12 hours after dosing) was 33% in the low dose cohort and 41% in the high dose cohort. The mean decrease of cleaved CK-18 (a cell apoptosis marker) at the measured time point of greatest effect (12 hours after dosing) was 37% in the low dose cohort and 47% in the high dose cohort. The mean reduction of total bilirubin (a liver function marker) at the measured time point of greatest effect (12 hours after dosing) was 27% in the low dose cohort and 31% in the high dose cohort. The mean decrease of high sensitivity C-Reactive Protein (hsCRP) (a marker of inflammation) at the measured time point of greatest effect (24 hours after dosing) was 8% in the low dose cohort and 13% in the high dose cohort. The mean decrease of IL-18 (an inflammatory mediator) at the measured time point of greatest effect (8 hours after dosing) was 4% in the low dose cohort and 8% in the high dose cohort.

Collectively, the biological signals observed in NASH patients plus results from our animal and cell culture studies suggest potential therapeutic activity of DUR-928 for patients with liver diseases. However, additional studies are required to evaluate the safety and efficacy of DUR-928, and there is no assurance that these biomarker, clinical chemistry and liver imaging effects will be associated with clinically relevant benefits, or that DUR-928 will demonstrate safety or efficacy in treating liver diseases in our ongoing or future trials.

We are conducting a Phase 1b safety, PK and PD studies of orally administered DUR-928 in patients with chronic liver disease and cirrhosis whose liver function is impaired (Child-Pugh Class B and C) to support potential inclusion of patients with advanced fibrosis (f4) in future clinical trials.

Additional Proprietary Pharmaceutical Programs



(1) DURECT to receive earn-outs or royalties based on net sales of Indivior and Methydur. PERSERIS prescribing information, including BOXED WARNING and Medication Guide visit www.perseris.com.

POSIMIR® (bupivacaine extended-release solution)

POSIMIR is our investigational post-operative pain relief depot product that utilizes our patented SABER® technology. POSIMIR is designed to be administered directly into the surgical site to deliver bupivacaine for up to three days after surgery, which we believe coincides with the time period of the greatest need for post-surgical pain control in most patients.

Status. In April 2013, we submitted an NDA as a 505(b)(2) application, which relied in part on the FDA's findings of safety and effectiveness of a reference drug. In February 2014, we received a Complete Response Letter (CRL) from the FDA. Based on the CRL and subsequent communications with the FDA, we conducted a new Phase 3 clinical trial (the PERSIST trial) consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery to further evaluate the benefits and risks of POSIMIR. In October 2017, we reported that the PERSIST trial did not meet its primary efficacy endpoint. While results trended in favor of POSIMIR versus the comparator, they did not achieve statistical significance. After carefully reviewing the existing POSIMIR data and evaluating the feedback we had received from the FDA, including the CRL and other correspondence, we submitted a full response to the CRL to the FDA in June 2019 seeking FDA approval of POSIMIR. In October 2019, the FDA notified the Company that its resubmission for POSIMIR would be discussed at a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). At a meeting of the FDA's Anesthetic and Analgesic Drug Products Advisory Committee in January 2020, six advisory committee members voted to recommend that the efficacy, safety, and overall risk-benefit profile of

POSIMIR support approval, while six did not support approval based on the information presented. Although the FDA considers the recommendations of the AADPAC, the recommendations by the panel are non-binding. The final decision regarding pending regulatory actions for a product is made by the FDA. Since the Advisory Committee meeting, we have responded to several requests for additional information from the FDA. While the original user fee goal date for our POSIMR application was in December 2019, no subsequent date has been assigned.

In total, we have completed 16 clinical studies in the POSIMIR program, in seven different surgical procedures, including inguinal hernia repair, shoulder surgery (primarily subacromial decompression), appendectomy, abdominal hysterectomy, open laparotomy, laparoscopic cholecystectomy, and laparoscopic colectomy. The incision lengths treated ranged from a few centimeters for laparoscopic portals, to open laparotomy incisions of up to 35 cm. The seriousness of the surgery ranged from day surgery hernia repair in relatively healthy patients to major abdominal surgery for colon cancer in elderly patients with substantial co-morbidity who were often hospitalized for a week or more. The safety experience from this variety of procedures and patients was designed to allow for extrapolation of the safety and efficacy data to a broad surgical population. Our POSIMIR clinical development program has been devised to establish the safety and efficacy of POSIMIR for the treatment of post-surgical pain for up to 3 days. POSIMIR has not been approved by the FDA for marketing in the U.S. for any indication.

Market Opportunity. According to data published by the Center for Disease Control and Prevention, there are approximately 72 million ambulatory and inpatient surgical procedures performed annually in the U.S. Insufficient postoperative pain control remains a significant problem, with studies indicating that roughly 65% of patients experience moderate-to-extreme pain after surgery. The current standard of care for post-surgical pain includes a variety of opiate and non-opiate analgesics and muscle relaxants. While systemic opioids can effectively reduce post-surgical pain, they commonly cause side effects including drowsiness, constipation, nausea and vomiting, and cognitive impairment. Post-surgical pain also can be treated effectively with local anesthetics; however, their usefulness often is limited by their short duration of action**.**

PERSERIS™(risperidone)

In September 2017, we entered into an agreement with Indivior, 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 an upfront non-refundable payment to DURECT of $12.5 million. Indivior also paid a $5 million milestone payment to DURECT in August 2018 following the FDA approval of PERSERIS. Under the terms of the agreement with Indivior, DURECT receives quarterly earn-out payments that are based on a single digit percentage of U.S. net sales of PERSERIS into 2026. Indivior commercially launched PERSERIS in the U.S. in February 2019.

ORADUR-ADHD Program

In collaboration with Orient Pharma, we developed a drug candidate based on our ORADUR technology for the treatment of ADHD. This drug candidate is intended to provide once-a-day dosing. In August 2009, we entered into a development and license agreement, as amended, with Orient Pharma, a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan, under which we granted to Orient Pharma development and commercialization rights in certain defined Asian and South Pacific countries to ORADUR-Methylphenidate ER. We retain rights to North America, Europe and all other countries not specifically licensed to Orient Pharma.

In September 2018, Orient Pharma informed us that it had obtained marketing authorization for Methydur Sustained Release Capsules from the Ministry of Health and Welfare in Taiwan. Methydur Sustained Release Capsules are indicated for the treatment of ADHD and will be available in three strengths (22 mg, 33 mg and 44 mg) in Taiwan. Orient Pharma also has stated that it expects to make Methydur Sustained Release Capsules commercially available in Taiwan in 2020, while seeking a partner in China and pursuing regulatory approvals in selected other countries in Southeast Asia where it has commercialization rights and a commercialization presence. We will receive a single digit royalty on sales of Methydur Sustained Release Capsules by Orient Pharma and retain rights to this product in markets not specifically licensed to Orient Pharma.

Drug Delivery Technologies and Programs

Our drug delivery technologies are designed to deliver the right drug to the right place, in the right amount and at the right time to treat a variety of chronic, acute and episodic diseases and conditions. We aim to improve therapy for a given disease or patient population by controlling the rate and duration of drug administration. In addition, if advantageous for the therapy, our technologies can target the delivery of the drug to its intended site of action.

Our technologies are suitable for providing long-term drug therapy because they can often store highly concentrated, stabilized drugs in a small volume and protect the drug from degradation by the body. This, in combination with the ability to continuously deliver desired doses of a drug, can extend the therapeutic value of a wide variety of drugs, including, in some cases, those which would otherwise be ineffective, too unstable, too potent or cause adverse side effects. In some cases, delivering the drug directly to the intended site of action can improve efficacy while minimizing unwanted side effects elsewhere in the body, which often limit the long-term use of many drugs. Our technologies may thus provide better therapy for chronic diseases or conditions, or for certain acute conditions where longer drug dosing is required or advantageous, by replacing multiple injection therapy or oral dosing, improving

drug efficacy, reducing side effects and ensuring dosing compliance. Our technology may thereby improve patients' quality of life by eliminating more repetitive treatments, reducing dependence on caregivers and allowing patients to lead more independent lives.

We currently have several active drug delivery technology platforms:

The SABER and CLOUD Bioerodible Injectable Depot Systems

Our bioerodible injectable depot systems include our SABER and CLOUD platform technologies. SABER uses a high viscosity base component, such as sucrose acetate isobutyrate (SAIB), to provide controlled release of a drug. When the high viscosity SAIB is formulated with drug, biocompatible excipients and other additives, the resulting formulation is easily injectable with standard syringes and needles. After injection of a SABER formulation, the excipients diffuse away over time, leaving a viscous depot which provides controlled sustained release of drug. CLOUD is a class of bioerodible injectable depot technology which generally does not contain SAIB but includes various other release rate modifying excipients and/or bioerodible polymers to achieve the delivery of drugs for periods of days to months from a single injection.

The SABER technology is the basis of POSIMIR (described above). The SABER technology is also utilized in our ophthalmic program with Santen Pharmaceutical Co., Ltd. (Santen), as well as in feasibility programs.

The SABER technology is also the basis for SucroMate™ Equine, an injectable animal health drug utilizing our SABER technology to deliver the peptide deslorelin. This was the first FDA approved SABER injectable product when it was launched in 2011 by CreoSalus, Inc.

The ORADUR Sustained Release Gel Cap Technology

We believe that our ORADUR sustained release technology can transform short-acting oral capsule dosage forms into sustained release oral products. Products based on our ORADUR technology can take the form of an easy to swallow capsule that uses a high-viscosity base component such as sucrose acetate isobutyrate (SAIB) to provide controlled release of active ingredients for an extended period of time. Oral dosage forms based on the ORADUR gel-cap may also have the added benefit of being less prone to abuse (e.g., by crushing and then snorting, smoking, injecting or extracting by mixing with alcohol or water). These properties have the potential to make ORADUR-based products an attractive option for pharmaceutical companies that seek to develop abuse-deterrent oral products.

The ORADUR technology is the basis of our ORADUR-Methylphenidate ER program (described above).

Product Revenues

We also currently generate product revenue from the sale of the following three products:

- ALZET® osmotic pumps which are used for animal research;
- LACTEL® biodegradable polymers which are used by our customers as raw materials in their pharmaceutical and medical products; and
- to a much lesser extent, certain key excipients that are included in Methydur and one excipient that is included in a currently marketed animal health product.

Because we consider our core business to be developing and commercializing pharmaceuticals, we do not intend to significantly increase our investments in or efforts to sell or market any of our existing product lines. However, we expect that we will continue to make efforts to increase our revenue related to collaborative research and development by entering into additional research and development agreements with third-party collaborators to develop product candidates based on our drug delivery technologies.

Operating Results

Since our inception in 1998, we have had a history of operating losses. At June 30, 2020, we had an accumulated deficit of $484.8 million. Our net income was $14.3 million and $4.4 million for the three and six months ended June 30, 2020, resulting from recognition of $23.1 million previously deferred revenue related to the upfront and milestone payments in connection with an agreement for which we received notice of termination from Gilead in June 2020. Such revenue is non-recurring and has no cash flow impact on the Company during the three and six month periods ended June 30, 2020. Our net loss was $7.2 million and $14.4 million for the three and six months ended June 30, 2019. Our 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 increase compared to the second quarter of 2020 as we experience higher research and development expenses related to DUR-928. We expect selling, general and administrative expenses in the near future to be comparable to the second quarter of 2020. We do not anticipate meaningful revenues from our products in development, should they be approved, for at least the next twelve months. Therefore, we expect to incur continuing losses and negative cash flows from operations for the foreseeable future. Depending on whether we enter into additional collaborative agreements in the near term and the extent to which we earn milestone revenues, we may be required to raise additional capital through a variety of sources.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with 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, the recoverability of our long-lived assets, including goodwill and other intangible assets, accrued liabilities, contract research liabilities, inventories and stock-based compensation. Actual amounts could differ significantly from these estimates. There have been no material changes to our other critical accounting policies and estimates other than the accounting policies related to collaborative research and development expenses as compared to the disclosures in our annual report on Form 10-K for the year ended December 31, 2019.

Collaborative Research and Development Revenues

We enter into license agreements which are within the scope of ASC 606, under which we license certain rights to our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; reimbursement of development costs incurred by us under approved work plans; development, regulatory and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; sales-based milestones and royalties on net sales of licensed products. Each of these payments results in collaborative research and development revenues, except for revenues from royalties or earn-outs on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we perform 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) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. We expect 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate 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 us 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 we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaborative research and development revenues and net income (loss) in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded in collaborative research and development revenues when the customer obtains control of the goods, which is upon delivery.

Royalties and Earn-outs: For arrangements that include sales-based royalties or earn-outs, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize 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, we have not recognized any material royalty revenue resulting from our collaborative arrangements or any material earn-out revenue from our patent purchase agreement with Indivior.

Results of Operation

Three and Six months ended June 30, 2020 and 2019

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities and service contracts. Collaborative research and development revenue primarily represent 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 agreements.

We expect our collaborative research and development and other revenue in the near future to decrease compared to the second quarter of 2020 largely as a result of the recognition of the remaining deferred revenue of $23.1 million from the upfront fee and a milestone payment associated with the Gilead agreement in the second quarter of 2020. We expect our collaborative research and development and other revenue to fluctuate in future periods depending on the success of our efforts to enter into potential new collaborations, our existing third party collaborators' commitment to and progress in the research and development programs, and any royalty or earn-out revenue recognized from collaborators or counterparties.

The collaborative research and development and other revenues associated with the Company's collaborators or counterparties were $23.3 million for both the three and six months ended June 30, 2020, compared to $1.6 million and $3.1 million for the corresponding periods in 2019. These revenues were primarily related to revenue recognized associated with the Company's license and feasibility agreements.

The collaborative research and development and other revenues associated with our collaborators or counterparties are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Collaborator/Counterparty				
Gilead (1)	$ 23,144	$ 1,452	$ 22,876	$ 2,704
Others (2)	203	187	441	435
Total collaborative research and development and other revenue	$ 23,347	$ 1,639	$ 23,317	$ 3,139

(1) We signed a license agreement with Gilead on July 19, 2019 and received a nonrefundable upfront license fee and a milestone payment totaling $35.0 million in 2019 which was being recognized as revenue as our obligation was being satisfied using the cost-to-cost input method (see Note 2. Agreement with Gilead Sciences, Inc.). In June 2020, we received notice that Gilead was terminating the License Agreement and a related R&D agreement between Gilead and us. As a result, we recognized as revenue all of the remaining upfront fee and milestone payment during the three and six months ended June 30, 2020 that had previously been deferred as there were no remaining substantive performance obligations to be provided to Gilead by the Company as of June 30, 2020. Amounts recognized as revenue during the three and six months ended June 30, 2019, related entirely to our reimbursable collaborative research and development services performed under our agreement with Gilead.

(2) Includes: (a) amounts related to earn-out revenue from Indivior UK Limited (Indivior) with respect to PERSERIS net sales; (b) feasibility program(s); and (c) research and development activities funded by Santen pharmaceutical Co. Ltd. (Santen). Note that in January 2018, we were notified by Santen that due to a shift in near term priorities, Santen had elected to reallocate research and development resources and put our program on pause until further notice. While the main program is on pause, the parties are working together on a limited set of research and development activities funded by Santen.

Product revenue

A portion of our revenues is derived from product sales, which include our ALZET mini pump product line, our LACTEL biodegradable polymer product line and certain excipients that are included in Methydur and in a currently marketed animal health product. Net product revenues were $2.5 million and $5.3 million in the three and six months ended June 30, 2020, respectively, compared with $2.3 million and $5.0 million for the corresponding periods in 2019. The increases in the three and six months ended June 30, 2020 were primarily attributable to higher revenue from our LACTEL product line as a result of higher units sold, partially

offset by lower revenue from our ALZET mini pump product line as a result of lower units sold compared to the corresponding periods in 2019.

COVID-19 may have an adverse impact on the economies and financial markets of many countries, resulting in a severe and prolonged global economic downturn that could affect demand for our ALZET and LACTEL product lines. We expect that our product revenues may decline in the coming months as a result of the COVID-19 pandemic, as customers for our ALZET and LACTEL product lines may be limiting or reducing their operations or requesting changes to payment terms.

Cost of product revenues

Cost of product revenues was $964,000 and $2.2 million for the three and six months ended June 30, 2020, respectively, compared with $879,000 and $2.0 million for the corresponding periods in 2019. The increases in the three and six months ended June 30, 2020 were primarily due to higher cost of goods sold related to our LACTEL product line arising from higher units sold compared to the corresponding periods in 2019. Stock-based compensation expense recognized related to cost of product revenues was $27,000 and $52,000 for the three and six months ended June 30, 2020, respectively, compared to $22,000 and $43,000 for the corresponding periods in 2019.

We had 21 manufacturing employees as of June 30, 2020 compared with 20 as of June 30, 2019. We expect the number of employees involved in manufacturing will remain comparable in the near future.

Research and development

Research and development expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost 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 $6.7 million and $14.4 million for the three and six months ended June 30, 2020, respectively, compared to $6.6 million and $12.8 million for the corresponding periods in 2019. The increase in the three months ended June 30, 2020 was primarily attributable to higher research and development costs associated with DUR-928, the depot injectable programs and other research programs, partially offset by lower research and development costs associated with the Gilead program and POSIMIR compared to the corresponding period in 2019, as more fully discussed below. The increase in the six months ended June 30, 2020 was primarily attributable to higher research and development costs associated with DUR-928, POSIMIR, the depot injectable programs and other research programs, partially offset by lower research and development costs associated with the Gilead program compared to the corresponding period in 2019, as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $249,000 and $460,000 for the three and six months ended June 30, 2020, respectively, compared to $172,000 and $346,000 for the corresponding periods in 2019. As of June 30, 2020, we had 46 research and development employees compared with 43 as of June 30, 2019. We expect research and development expenses in the near future to increase compared to the second quarter of 2020 as we expect to incur higher research and development expenses for DUR-928.

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
DUR-928	$ 5,286	$ 3,989	$ 10,363	$ 8,185
POSIMIR	608	1,298	2,328	2,020
Gilead	376	1,085	831	2,169
Depot injectable programs	276	145	456	326
Others	140	81	425	149
Total research and development expenses	$ 6,686	$ 6,598	$ 14,403	$ 12,849

DUR-928

Our research and development expenses for DUR-928 were $5.3 million and $10.4 million in the three and six months ended June 30, 2020, respectively, compared to $4.0 million and $8.2 million for the corresponding periods in 2019. The increase in the three months ended June 30, 2020 was primarily due to higher contract manufacturing expenses and higher employee related costs for this drug candidate compared with the corresponding period in 2019. The increase in the six months ended June 30, 2020 was primarily due to higher clinical trial expenses, higher contract manufacturing expenses and higher employee related costs for this drug candidate compared with the corresponding period in 2019.

It is too early to assess the full impact of the COVID-19 outbreak on our business, including our planned DUR-928 Phase 2b trial in alcoholic hepatitis and our Phase 2 trial in COVID-19 patients, but COVID-19 may affect our ability to initiate and/or complete recruitment and data analysis for our clinical trials, including DUR-928 trials, in our planned timeframe.

POSIMIR

Our research and development expenses for POSIMIR were $608,000 and $2.3 million in the three and six months ended June 30, 2020, respectively, compared to $1.3 million and $2.0 million for the corresponding periods in 2019. The decrease in the three months ended June 30, 2020 was primarily due to lower consulting related expenses for this drug candidate compared with the corresponding period in 2019. The increase in the six months ended June 30, 2020 was primarily due to higher consulting related expenses for this drug candidate, largely related to the FDA Advisory Committee meeting in January 2020, compared with the corresponding period in 2019.

It is possible that the COVID-19 outbreak will impact the timing of FDA's review of the POSIMIR NDA.

Gilead Program

Our research and development expenses for the Gilead program were $376,000 and $831,000 in the three and six months ended June 30, 2020, respectively, compared to $1.1 million and $2.2 million for the corresponding periods in 2019. The decreases in the three and six months ended June 30, 2020 were primarily due to lower employee-related costs and outside costs devoted to the program compared with the corresponding periods in 2019. In June 2020, Gilead provided notice that, effective as of December 22, 2020, it is terminating the Gilead Agreement and a related R&D agreement between Gilead and us.

Depot injectable programs

Our research and development expenses for depot injectable programs were $276,000 and $456,000 in the three and six months ended June 30, 2020, respectively, compared to $145,000 and $326,000 for the corresponding periods in 2019. The increases in the three and six months ended June 30, 2020 were primarily due to higher employee-related costs and higher outside expenses for these programs compared with the corresponding periods compared with the corresponding periods in 2019.

Other DURECT research programs

Our research and development expenses for all other programs were $140,000 and $425,000 in the three and six months ended June 30, 2020, respectively, compared to $81,000 and $149,000 for the corresponding periods in 2019. The increases in the three and six months ended June 30, 2020 was primarily due to higher employee-related costs associated with these programs compared with the corresponding periods in 2019.

The duration of development of our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete are speculative and subjective due to the numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation, the uncertainties of future preclinical and clinical study results, uncertainties related to the COVID-19 outbreak, the uncertainties with our collaborators' commitment to and progress in the programs and the 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 estimated costs of the efforts necessary to complete the research and development programs. For additional information regarding these risks and uncertainties, see "Risk Factors" below.

Selling, general and administrative. Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost 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 $3.4 million and $6.9 million in the three and six months ended June 30, 2020, respectively, compared to $3.3 million and $6.7 million for the corresponding periods in 2019. The increases in 2020 were due to higher employee related costs for selling, general and administrative personnel. Stock-based compensation expense recognized related to selling, general and administrative personnel was $216,000 and $394,000 for the three and six months ended June 30, 2020, respectively, compared to $228,000 and $470,000 for the corresponding periods in 2019.

We had 26 selling, general and administrative employees as of June 30, 2020 compared with 22 employees as of June 30, 2019. We expect selling, general and administrative expenses in the near future to be comparable to the second quarter of 2020.

Other income (expense). Interest and other income was $135,000 and $393,000 for the three and six months ended June 30, 2020, respectively, compared to $177,000 and $386,000 for the corresponding periods in 2019. The decrease in interest and other income in the three months ended June 30, 2020 compared with the corresponding period in 2019 was primarily the result of lower interest income generated as a result of lower interest rates associated with our cash and investments. The increase in interest and other income in the six months ended June 30, 2020 compared with the corresponding period in 2019 was primarily the result of higher interest income generated as a result of a higher average balance of cash and investments.

Interest and other expense was $552,000 and $1.1 million for the three and six months ended June 30, 2020, respectively, compared to $634,000 and $1.3 million for the corresponding periods in 2019. The decreases in interest and other expense in the three and six months ended June 30, 2020 were primarily due to lower interest rates associated with the term loan with Oxford Finance compared with the corresponding periods in 2019.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $51.3 million at June 30, 2020 compared to $64.8 million at December 31, 2019. These balances include $150,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of June 30, 2020 and December 31, 2019. The decrease in cash, cash equivalents and investments during the six months ended June 30, 2020 was primarily the result of cash used in ongoing operating expenses and interest payments, partially offset by cash received from the exercise of stock options and payments received from collaboration partners and customers.

We used $21.6 million of cash in operating activities in the six months ended June 30, 2020 compared to $11.7 million used for the corresponding period in 2019. The cash used for operations was primarily to fund operations as well as our working capital requirements, partially offset by the changes in account receivable, prepaid expenses and other assets, and accrued and other liabilities.

We used $2.9 million of cash in investing activities for the six months ended June 30, 2020 compared to $1.6 million provided by investing activities for the corresponding period in 2019. The increase in cash used from investing activities was primarily due to an increase in purchases of available-for-sale securities for the six months ended June 30, 2020 compared to the corresponding period in 2019. We anticipate incurring capital expenditures of approximately $200,000 in 2020 to purchase research and development and other capital equipment.

We received $8.1 million of cash from financing activities for six months ended June 30, 2020 compared to $15.4 million for the corresponding period in 2019. The decrease in cash received from financing activities was primarily due to lower net proceeds received from issuances of common stock and from exercise of stock options in the six months ended June 30, 2020 compared with the corresponding period in 2019.

We anticipate that cash used in operating activities in the near future will increase compared to the second quarter of 2020 as we experience higher research and development expenses related to DUR-928.

In August 2018, we filed a shelf registration statement on Form S-3 with the SEC (the “2018 Registration Statement”) (File No. 333-226518), which upon being declared effective in October 2018, terminated our registration statement filed in November 2015 (File No. 333-207776) and allowed us to offer up to $175.0 million of securities from time to time in one or more public offerings, inclusive of up to $75.0 million of our common stock which the Company may sell, subject to certain limitations, pursuant to a sales agreement dated November 3, 2015 with Cantor Fitzgerald & Co. (the “2015 Sales Agreement”).

During the three and six months ended June 30, 2020, the Company raised net proceeds (net of commissions) of approximately $6.2 million from the sale of 2,610,375 shares of the Company’s common stock in the open market at a weighted average price of $2.45 per share, pursuant to the 2015 Sales Agreement.

As of July 31, 2020, the Company had up to approximately $147.6 million of the Company’s securities available for sale under the 2018 Registration Statement of which approximately $62.7 million of the Company’s common stock are available pursuant to the 2015 Sales Agreement.

Any material sales in the public market of our common stock, under the 2015 Sales Agreement or otherwise under the 2018 Registration Statement, could adversely affect prevailing market prices for our common stock.

During the six months ended June 30, 2020, there were no significant changes in our commercial commitments and contractual obligations as compared with the information presented in our Annual Report on Form 10-K for the year ended December 31, 2019.

The COVID-19 pandemic is impacting our business in several ways. Sales of our ALZET product line were negatively impacted in the first half of 2020 by COVID-19 and the future impact on sales of our ALZET and LACTEL product lines are uncertain. For DUR-928, we may experience delays in the start of the Phase 2b clinical trial in patients with AH and in the recruitment of patients in our COVID-19 trial, and some patients who completed dosing of the Phase 1b clinical trial in NASH were

not able to complete their follow up visits. We are also incurring additional expenses to initiate and conduct a clinical trial of DUR-928 in COVID-19 patients. These losses, delays and additional expenses will increase our cash burn and extend the period before which we may be able to raise additional capital based on additional clinical trial results. Additional volatility in capital markets and/or clinical trial delays resulting from the impacts of COVID-19 may also limit our ability to raise capital on acceptable terms, if at all.

We believe that our existing cash, cash equivalents and investments and anticipated revenues will be sufficient to fund our planned operations, existing debt and contractual commitments and planned capital expenditures through at least the next 12 months from the date the financial statements are filed. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Additionally, we do not expect to generate significant revenues from our pharmaceutical product candidates currently under development for at least the next twelve months, if at all. Depending on whether we enter into additional collaborative agreements in the near term and the extent to which we earn milestone revenues, we may be required to raise additional capital through a variety of sources, including:

- the public equity markets;
- private equity financings;
- collaborative arrangements; and/or
- public or private debt.

There can be no assurance that we will enter into additional collaborative agreements, will earn milestone revenues or that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, any 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).

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.

We are experiencing certain operational and other challenges as a result of the COVID-19 global pandemic, which could delay or halt our research and development programs or clinical programs. See Recent Developments and Item 1A - Risk Factors for further discussion of the current and expected impact on our business and programs.

Off-Balance Sheet Arrangements

As of June 30, 2020, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

Item 3. Quantitative and Qualitative Disclosures about Market Risk

During the six months ended June 30, 2020, there have been no significant changes in market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Item 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 Rule 13a-15(e)) as of the end of the period covered by this Form 10-Q. Based on that evaluation, the Company's principal executive and principal financial officers concluded that 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 has materially affected, or is 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.

In addition to the other information in this Form 10-Q, a number of factors may affect our business and prospects. These factors include but are not limited to the following, which you should consider carefully in evaluating our business and prospects. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects may be materially and adversely affected.

Risks Related To Our Business

We are dependent on the success of DUR-928 and we cannot be certain that it will receive regulatory approval or be commercialized

Our business depends substantially on the successful development of DUR-928, which recently completed a Phase 1b clinical trial in NASH and a Phase 2a clinical trial in AH, and is currently recruiting patients for a Phase 2 clinical trial in COVID-19 patients. The NASH clinical trial was designed to evaluate safety, pharmacokinetics and various pharmacodynamic signals, the AH trial was designed to determine the safety, pharmacokinetics and pharmacodynamic signals of DUR-928 in AH patients following treatment, and the trial in patients with COVID-19 is designed to evaluate safety and efficacy, as well as pharmacokinetics and pharmacodynamic signals. Future clinical trials will need to establish clinically and statistically significant proof of efficacy, and/or sufficient evidence of safety to support additional clinical trials and ultimately regulatory approval. DUR-928 will require additional development, including more clinical trials as well as further preclinical studies, including those designed to evaluate its dosage, dosing regimen, toxicology, carcinogenicity, pharmacokinetics and other non-clinical parameters, as well as regulatory clearances before it can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because DUR-928 fails to be shown to be safe and effective or because we have inadequate financial or other resources to advance DUR-928 through the pre-clinical and clinical development and approval processes. We consider DUR-928 to be our lead and most important asset. If DUR-928 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 DUR-928, any of which would materially harm our business. In evaluating DUR-928 in patients with COVID-19, a recently identified and not well understood pathology associated with severe morbidity and mortality, there is a risk that we may not be able to demonstrate efficacy in that patient population, a risk that we may not be able to recruit sufficient patients in a timely and cost-effective manner and a risk of treatment emergent events that may harm the drug's safety profile and could require the expenditure of substantial resources and funds.

We do not anticipate that DUR-928 will be eligible to receive regulatory approval from the FDA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for DUR-928, 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 availability of alternative, potentially superior or less expensive treatments or vaccines, 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 drugs or vaccines. The success of DUR-928 may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize DUR-928, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline.

Early indications of activity from Phase 1 and 2 clinical trials of DUR-928 may not predict therapeutic efficacy

Although Phase 1 and Phase 2 clinical trials of DUR-928 have shown positive initial data in AH patients, including reductions in bilirubin and MELD scores from baseline and promising Lille scores, and demonstrated that DUR-928 can lead to the reduction of from baseline in liver enzymes, imaging and serum lipids as well as certain biomarkers, such as statistically significant reductions from baseline in the levels of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, high sensitivity C-Reactive Protein (hsCRP) and IL-18 in NASH patients, and non-statistically significant reductions in CK-18 and bilirubin in CKD patients, such initial results, indications of activity and biomarker changes may ultimately not be correlated with treatment or improvement in the associated disease, and there is a risk that DUR-928 may not demonstrate therapeutic efficacy in larger controlled trials, despite encouraging initial data and improvements in biomarker levels in smaller, early trials. The failure of DUR-928 to show efficacy in one indication may negatively affect its perceived value in other indications, or the emergence of safety signals in ongoing or future clinical trials, would significantly harm our business.

Open-label trials of DUR-928 in NASH and AH have inherent limitations

The recently completed NASH and AH trials of DUR-928 are open-label trials with no control groups. Open label trials have inherent risk of bias given that the patients and physicians know that they received active study drug, which can lead to placebo effects. Trials without control groups have an inherent risk in that the comparisons used to determine the study drug's effect and side effect profile are based on comparisons with baseline (pre-treatment) levels (for blood chemistry and biomarker endpoints) and/or

with historical controls, which may not have been conducted under similar enough conditions to make accurate comparisons and/or draw accurate conclusions from those comparisons. Any initial data collected from these open-label trials also cannot be meaningfully analyzed or relied upon until after the completion of the trials due to the limited number of patients involved, open-label nature and lack of control groups. Additionally, larger controlled clinical trials will be required to evaluate the safety and efficacy of DUR-928 to treat any indication, including AH, NASH, AKI, CKD and COVID-19. There can be no assurance that ongoing or future studies will demonstrate the safety or efficacy of DUR-928 in a statistically significant or clinically meaningful manner.

The outbreak of the novel coronavirus disease, COVID-19, has and will adversely impact our business

On March 11, 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, COVID-19, as a global pandemic, which continues to spread throughout the United States and around the world. Starting in March 17, 2020, the health officers of all San Francisco Bay Area counties issued shelter-in-place orders, which directed all businesses in the San Francisco Bay Area to cease non-essential operations at physical locations in the counties, and these orders have continued in varying terms since. While we are currently considered to be an essential business and our operations have only been partially affected by these orders, it is too early to assess the full impact of the COVID-19 outbreak on our business, including our planned DUR-928 Phase 2b trial in alcoholic hepatitis and our ongoing Phase 2 trial in COVID-19 patients with acute liver or kidney injury, and COVID-19 may affect our ability to initiate and/or complete recruitment and data analysis for our clinical trials in a commercially reasonable timeframe. In addition, COVID-19 may have an adverse impact on the economies and financial markets of many countries, resulting in a severe and prolonged global economic downturn that could affect demand for our ALZET and LACTEL product lines and POSIMIR, if approved, and impact our operating results. We also need to raise additional capital to provide sufficient funding to continue our product development efforts, including clinical trials. COVID-19 initially had an adverse impact on the capital markets and could again, which would make it more difficult for companies such as ours to access capital. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints, the ability to collect, ship and analyze biological samples from clinical trial patients due to concerns about potential contamination of samples and/or exposure of clinical staff to patients with the COVID-19;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

Ongoing and planned clinical trials for DUR-928 may be delayed and may not demonstrate efficacy or safety in the indications tested

The COVID-19 pandemic has and may continue to delay full data analysis and results reporting for our recently completed NASH trial. We have initiated recruiting patients for a double-blind, placebo-controlled, multi-center, Phase 2 study to evaluate the safety and efficacy of DUR-928 in COVID-19 patients with acute liver or kidney injury; given the number of other trials being conducted for vaccines and therapeutic treatments for COVID-19, there is a risk that recruiting clinical trial sites and patients for this trial may be challenging, take a longer period of time than anticipated or may not even be achievable. We are planning a double blind, multi-center Phase 2b clinical trial to evaluate intravenously infused DUR-928 in patients with severe AH and anticipate initiating that trial in the second half of 2020, subject to potential delays resulting from COVID-19 or the time to obtain FDA comments and feedback, timing of entering contracts with clinical sites and contract research organizations, obtaining institutional review board approvals and delays in other activities that need to be put in place prior to clinical trial initiation. We had previously stated that,

assuming reasonable enrollment rates, we anticipated that top-line data would be available from this trial in 2022. Given uncertainty related to the timing of initiation of the trial due to COVID-19-related impacts on clinical trial sites and the FDA, and finalization of the trial design, we will provide a revised estimate of the timing of top-line data from this trial at a future date. There can be no assurance that the trial will commence or enroll as anticipated if at all, and delays in commencement or enrollment could add to the costs and expenses of this trial and harm our business. With respect to the above clinical trials, there can be no assurance that biological activity demonstrated in previous animal disease models or earlier clinical trials will also be seen in these additional patients in ongoing trials or future clinical trials, or that any clinically relevant biological activity will be observed, or that enrollment rates will be favorable or that these additional trials will not identify safety issues. Failure of these trials to achieve desired results in their anticipated timeframes would negatively impact our business and ability to raise additional capital.

DUR-928 is in the early stages of development for COVID-19 patients with acute liver or kidney injury, and development of DUR-928 as a COVID-19 therapy will require extensive testing and funding.

Because DUR-928, as a product candidate for COVID-19 therapy, is in the early stages of development, it will require extensive clinical testing. In addition, in order to fully develop this product candidate, we will need significant additional funding. To date, we have not yet developed any drug candidates designed to combat infectious diseases and the COVID-19 trial involves very high risk patients. There can be no assurance that we will be able to successfully develop a therapy to treat any patients with COVID-19, and even if successful, to do so during this pandemic, or be able to secure the additional funding required to fully develop DUR-928 for patients with COVID-19.

We may not advance clinical trials of DUR-928 for COVID-19 if the COVID-19 disease outbreak subsides or a successful vaccine is developed and deployed.

Disease outbreaks are unpredictable. For example, the SARS virus disappeared about four months after it caused a global panic. In the event that COVID-19 has a shorter term disease cycle than currently anticipated or if an effective vaccine is developed that obviates the need for therapeutics or the virus' current prevalence substantially diminishes, we may be forced to abandon or delay the clinical trial and development of DUR-928 for COVID-19 due to a lack of patients or funding.

The path to regulatory approval of DUR-928 is uncertain

We are currently developing DUR-928 in several indications, including AH, COVID-19 and NASH. In these indications, there are no currently approved drugs (although in COVID-19, there is at least one drug approved by the FDA on an emergency basis). Accordingly, we will have to interact with the FDA and other regulatory agencies regarding important aspects of the clinical development program, including the size 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. This uncertainty may make it difficult to predict the timing or expense required to obtain regulatory approval for DUR-928. We also may need to revise our clinical development plans after trials have commenced or been completed, which could add to the time and expense associated with the clinical development of DUR-928. If we are unable to reach agreement with the FDA or other regulatory agencies regarding clinical development plans for DUR-928, we may curtail or limit our development activities for this product candidate.

New chemical entities derived from our Epigenetic Regulator Program, which is in the early stages of development, may require more time and resources for development, testing and regulatory approval than our Drug Delivery Program product candidates, and may not result in any approval or viable commercial products

Our Epigenetic Regulator Program is in the early and mid-stages of development, involves a novel therapeutic approach and new chemical entities, requires significant further research and development and regulatory approvals and is subject to the risks of failure inherent in the development of products based on innovative approaches. New chemical entities derived from our Epigenetic Regulator Program are molecules that have not previously been approved and marketed as therapeutics, unlike product candidates in our drug delivery programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve through a new formulation. As a result, the product candidates from our Epigenetic Regulator Program may face greater risk of unanticipated safety issues or other side-effects, or may not demonstrate efficacy. Further, the regulatory pathway for our new chemical entities may be more demanding than that for product candidates under our drug delivery programs, for which we may be able to leverage existing data under Section 505(b)(2) of the Food, Drug, and Cosmetic Act to reduce development risk, time and cost. For example, we have yet to fully define the therapeutic dose and/or dosing regimen in any indication for DUR-928, the first drug candidate in our Epigenetic Regulator Program.

Prospects for POSIMIR are uncertain following the failure of the PERSIST trial to achieve its primary efficacy endpoint and the termination of our agreement with Sandoz

The failure of the PERSIST trial for POSIMIR to achieve its primary efficacy endpoint may reduce the prospects of obtaining FDA approval for POSIMIR. In January 2019, Sandoz elected to terminate our licensing agreement for POSIMIR, as a result of which we will not receive any milestone or royalty payments from Sandoz and we or a potential future partner will be responsible for commercialization of POSIMIR in the United States, if approved. We intend to seek a new collaboration partner for POSIMIR in the

United States, but there is no assurance we will be successful in that effort or that any terms offered will be attractive to the Company. We may elect to terminate development of POSIMIR at any time. If we elect to continue to develop POSIMIR, we may be required to make a larger investment than previously planned, which would limit the funds available for other product development activities or require us to raise additional capital.

The FDA may not agree with our response to its Complete Response Letter (CRL) to the NDA submission for POSIMIR

After carefully reviewing the existing POSIMIR data and evaluating the feedback we have received from the FDA, including the CRL and other correspondence, we submitted to FDA a response to the CRL. After accepting the response to the CRL, the FDA notified the Company that its resubmission for POSIMIR would be discussed at a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). The meeting was held on January 16, 2020, which occurred after our user fee goal date; a new user fee goal date has not been assigned. At the AADPAC meeting, six advisory committee members voted to recommend that the efficacy, safety, and overall risk-benefit profile of POSIMIR support approval, while six did not support approval based on the information presented. Although the FDA considers the recommendations of the AADPAC, the recommendations by the panel are non-binding. The final decision regarding pending regulatory actions for a product is made by the FDA. There can be no assurance that the FDA will complete their review in a timely manner, or will assign a new user fee goal date, or will agree with our response to the CRL, or will approve POSIMIR for marketing, or will provide a commercially favorable label if they do approve the product. The FDA may require additional studies or additional information regarding POSIMIR. We would need to review any such requests to determine whether we believe that a viable path for regulatory approval of POSIMIR exists and a reasonable commercial opportunity remains available.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, our product development expenses may increase, clinical trial data could be delayed and receipt of necessary regulatory approvals could be delayed or prevented

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects and/or patients. Enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, our ability to recruit clinical sites and the ability of clinical sites to successfully recruit subjects to participate in clinical trials. Initiation of and enrollment in many clinical trials is being adversely affected by COVID-19, which has caused many institutions to stop enrolling patients, has created a large number of clinical trial proposals for potential clinical trial sites to review and consider and has caused many individuals to avoid contact with hospitals or other healthcare providers. Additionally, some of the patients in our clinical trials, including AH patients and patients with COVID-19, are hospitalized and concerns about exposure to COVID-19 limit clinical trial staff's access to patients, the frequency of interactions between patients and staff, the ability to obtain blood draws and other biological sample collection, and may limit the ability to ship samples to outside laboratories for analysis. In areas heavily impacted by COVID-19, there may be limited hospital staff available for clinical trial activities due to staff becoming infected or due to deprioritization of non-urgent activities. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for DUR-928 if we are unable to sign sufficient clinical sites, locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States or if we are unable to collect and analyze biological samples required for trial endpoints. It is possible that the inclusion and exclusion criteria for patients to be included in these trials or COVID-19-related issues may make the trials more difficult to conduct or may significantly extend the time required for enrollment and the cost of these trials.

We cannot predict how successful we will be at enrolling patients in our clinical trials. Enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the prevalence and incidence of the conditions being studied in the clinical trials;
- COVID-19-related challenges with patient access, hospital prioritization, clinical trial staff availability, ability to collect, ship and analyze patients' biological samples;
- the perceived risks and benefits of our product candidates;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical trials;
- competition for clinical sites and patients from other clinical trials;
- the willingness of potential clinical trial patients to provide informed consent to participate in the trial;
- the patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to sign up sufficient clinical trial sites and/or enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our drug candidates or delays in regulatory filings and progression, which would cause the value of our company to decline and limit our ability to obtain additional financing.

The FDA may require more information or clinical studies for all of our product candidates, and our product candidates may never be approved

The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development to the satisfaction of FDA and other regulatory agencies will result in delays to the regulatory approval or non-approvability of our product candidates, and could materially harm our business. Clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our product candidates, or may require such significant numbers of patients or additional costs to make it impractical to satisfy the FDA's requirements, and thus our product candidates may not be approved for marketing. For example, the Phase 3 PERSIST trial for POSIMIR did not meet its primary efficacy endpoint. In addition, during the review process, the FDA may request more information regarding the safety of our product candidates, as they have in their Complete Response Letter for POSIMIR, 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 lead the company to abandon the development of that product candidate. During the review process, the FDA may also request more information regarding the chemistry, manufacturing or controls related to our product candidates, 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 the product candidate. Additionally, even if our product candidates receive FDA approval, the FDA may require that we conduct additional clinical studies after such approval, place limitations on our products in applicable labels, require marketing under a REMS program, include commercially unattractive language in the approved product label, delay approval to market our products or limit the use of our products, which may harm our business and results of operations.

We currently have a significant amount of debt. Compliance with repayment obligations and other covenants may be difficult, and failure by us to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate

In July 2016, we entered into a Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC (Oxford Finance), pursuant to which Oxford Finance provided a $20 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 three amendments, we make interest only payments under the amended Loan Agreement until December 1, 2021 and the final maturity date of the loan is May 1, 2024. The Loan Agreement provides for a floating interest rate (7.95% initially and 7.47% as of June 30, 2020) 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 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 Loan Agreement contains customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of 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, the failure to deliver an unqualified audit report and board approved financial projections within time periods set forth in the Loan Agreement, 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, which could harm our business, operations and financial condition.

In addition, the term loan is secured by substantially all of our assets, except that the collateral does not include any equity interests in the Company, any intellectual property (including all 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 of our 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; make payments on any subordinated debt; and enter into transactions with any of our affiliates outside of the ordinary course of business or permit our subsidiaries to do the same. Complying with these covenants may make it more difficult for us to successfully execute our business strategy.

We will require and may have difficulty raising needed capital in the future

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 complete the research, development and clinical testing of our product candidates. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities, and to provide for the marketing and distribution of our product candidates. 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. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.

We believe that our cash, cash equivalents and investments and anticipated revenues will be adequate to satisfy our capital needs for at least the next 12 months from the date the financial statements are filed. However, our independent auditors may not agree with this assessment, and our actual capital requirements will depend on many factors, including:

- success in entering into collaboration agreements and achieving milestones under such agreements;
- the continuation of our collaborative agreements that provide financial funding for our activities;
- regulatory actions with respect to our and our collaborators' product candidates;
- 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 clearance;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- 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;
- costs involved in establishing manufacturing capabilities for pre-clinical, non-clinical, clinical and commercial quantities of our 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;
- impacts of the COVID-19 crisis;
- 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. We may seek to raise additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which 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 or pharmaceutical product candidates that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in delays in generating future product revenue.

We do not control the commercialization of PERSERIS or Methydur Sustained Release Capsules

We rely on Indivior for the commercialization of PERSERIS. Indivior has stated that it launched PERSERIS in February 2019 in the U.S. with a sales force consisting of approximately 50 representatives. There can be no assurance that Indivior will obtain market acceptance and meaningful sales. If Indivior does not successfully commercialize PERSERIS, the earn-out payments we receive under our agreement with them may be limited. We rely on Orient Pharma for the commercialization of Methydur Sustained Release Capsules in the territories licensed to Orient Pharma. If Orient Pharma does not successfully commercialize Methydur Sustained Release Capsules throughout their territory, the royalty payments we receive under our agreement with them may be limited. The sales of both of these products may be negatively impacted by the COVID-19 pandemic.

Development of our pharmaceutical product candidates is not complete, and we cannot be certain that our product candidates will be able to be commercialized

To be profitable, we or our third-party collaborators must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our pharmaceutical product candidates under development. For each product candidate that we or our third-party collaborators intend to commercialize, we must successfully meet a number of critical developmental milestones for each disease or medical condition targeted, including:

- with respect to each product candidate based on a new chemical entity, determining appropriate indication(s);
- with respect to our Proprietary Pharmaceutical Programs based on our drug delivery technologies, selecting and developing a drug delivery technology to deliver the proper dose of drug over the desired period of time;
- determining the appropriate route of administration and drug dosage for each product candidate in each indication;
- developing product candidates that will be tolerated, safe and effective and that will be compatible with the active pharmaceutical agent;
- demonstrating each product candidate will be chemically and physically stable for commercially reasonable time periods;
- demonstrating through clinical trials that each product candidate is safe and effective in patients for the intended indication at an achievable dose and that the product candidate’s benefits outweigh its risks; and
- completing the manufacturing development and scale-up to permit manufacture of the product candidate in commercial quantities and at acceptable cost.

The time frame necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any of our product candidates in development. Except for marketing authorization for PERSERIS by Indivior in the U.S. and for Orient Pharma's approval of Methydur Sustained Release Capsules in Taiwan, development is incomplete for all product candidates in our development programs, including DUR-928. We may not be able to finalize the design or formulation of any of these product candidates. Further, although we believe our design and formulation of POSIMIR to be substantially complete, there can be no assurance that additional development will not be required prior to regulatory approval of this product. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us or our collaborators to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our product candidates and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency, stability and performance. We or our collaborators may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we or our third-party collaborators are unable to complete development of DUR-928, POSIMIR, or other product candidates, we will not be able to earn revenue from them, which would materially harm our business.

We depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our product candidates which are the subject of third-party collaborative or license agreements

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

Cancellation of collaborations regarding our product candidates may adversely affect potential economic benefits

Third-party collaboration agreements typically allow the third party to terminate the agreement (or a specific program within an agreement) by providing notice. Termination can result from failure of the collaboration to achieve anticipated milestones, for changes in strategy of the other party or for other reasons. In these cases, the product rights revert to us or certain rights of the partner to use our proprietary technology are terminated. If there have been payments under such agreements that are being recognized over time, termination of such agreements (or programs) can lead to a near-term increase in our reported revenues resulting from the immediate recognition of the balance of such payments. Termination deprives us of potential future economic benefits under such agreements, and may make it more difficult or impossible to enter into agreements with other third parties for use of the assets and/or technologies that were subject to the terminated agreement. For example, termination of our agreements with Santen or Orient Pharma could have negative effects on the Company.

A significant component of our revenues resulted from collaboration agreements with other companies that have terminated, and we expect our revenues to decrease

Our revenues have been based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in these agreements. In particular, for 2019, approximately 58% of our total revenues were derived from our collaboration agreement with Gilead. In June 2020, Gilead notified us that they were terminating this collaboration. In addition, we have seen periodic declines in revenues associated with our other collaboration agreements, which reflect the current development stage of the product candidates subject to those agreements, and our collaborator's decreased needs for our services. Long-term growth of our collaboration revenues requires us to enter into new collaboration agreements, and there can be no assurance that we will do so. Even if we enter into new collaboration agreements, we may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues and/or cash flows to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to

legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new product candidates, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Orient Pharma with respect to Methydur Sustained Release Capsules and Santen with respect to an investigational ophthalmic product may be terminated by the other party at will or upon specified conditions including, for example, if we fail to satisfy specified performance milestones or if we breach the terms of the agreement. Acquisitions of our collaborators or strategic changes or re-organizations or re-prioritizations of our collaborators can lead to turnover of program staff, a review of development programs and strategies by the acquirer, and other events that can disrupt a program, resulting in program delays or discontinuations.

If we do not enter into new collaboration agreements, our anticipated revenues and/or cash flows will be reduced.

We have an ongoing dispute with Sandoz AG related to a disputed termination fee

The Company and Sandoz are in dispute with regard to Sandoz's obligation to pay a termination fee to DURECT. DURECT has initiated a formal dispute resolution process related to the termination fee. The Company's management may devote significant time and resources to this dispute resolution process, which may detract from time our management would otherwise devote to managing our operations and could have a material adverse effect on our business.

Our cash flows are likely to differ from our reported revenues

Our revenues will likely differ from our cash flows from revenue-generating activities. Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and generally recognized over the period of our performance obligations with the third-party collaborator pursuant to the applicable agreement. The period of performance obligations may also be revised on a prospective basis. As of June 30, 2020, we had $812,000 of deferred revenue which will be recognized in future periods and may cause our reported revenues to be greater than cash flows from our ongoing revenue-generating activities. Assumptions related to revenue recognition of deferred revenue are reviewed in each accounting period and changes are recorded in the current period. In certain circumstances, changes in assumptions related to the timing and amount of work required to complete a performance obligation tied to deferred revenue can result in negative revenue for an accounting period or the accelerated recognition of non-cash revenue.

Our revenues also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues

In addition to payments based on our performance of research and development activities, our revenues also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to development activities, including clinical and regulatory milestones, or sales accomplishments. While our involvement is generally necessary to the achievement of development-based milestones, the performance of our third-party collaborators is also generally required or sometimes solely required for us to achieve those milestones. Under our third-party collaborative agreements, our third-party collaborators will take the lead in commercialization activities and we do not expect to be involved in the achievement of sales-based milestones. Therefore, we are even more dependent upon the performance of our third-party collaborators in achieving sales-based milestones. To the extent we and our third-party collaborators do not achieve such development-based milestones or our third-party collaborators do not achieve sales-based milestones, we will not receive the associated revenues, which could harm our financial condition and could cause us to defer or cut-back development activities or forgo the exploitation of opportunities, any of which could have a material adverse effect on our business.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our product candidates, including, but not limited to POSIMIR, DUR-928 and others. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forgo the exploitation of certain opportunities, abandon development of certain product candidates or indications for certain product candidates, any of which could have a material adverse effect on our business.

We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical product candidates and components to support the non-clinical, clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience

We or our third-party collaborators to whom we have assigned such responsibility must manufacture our product candidates, and components (including active ingredients and excipients) in non-clinical (e.g., toxicology), clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our product candidates are complex. We and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any product candidates or components, including DUR-928 and POSIMIR. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our product candidates, we and our third-party collaborators, where relevant, will not be able to timely produce supplies for non-clinical, clinical trials and commercialization of our product candidates. We have also committed to manufacture and supply product candidates or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a product candidate or component at an acceptable quality and cost, then we and our third-party collaborators may not be able to develop or commercialize that product candidate or we may be in breach of our supply obligations to our third-party collaborators.

Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our product candidates, including DUR-928 and POSIMIR. If we experience delays or technical difficulties in developing acceptable manufacturing processes or scaling up the manufacturing of our product candidates, it could result in delays or added cost in our development programs. We have not manufactured commercial quantities of any of our product candidates at our Cupertino facility. In the future, we intend to develop additional manufacturing capabilities for our product candidates and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by potentially constructing additional manufacturing space at our facilities in California and/or Alabama. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely or cost effective manner.

If we and our third-party collaborators, where relevant, are unable to manufacture our product candidates or components in a timely manner or at an acceptable cost, quality or performance level, and are unable to attain and maintain compliance with applicable regulations, the non-clinical and clinical trials and the commercial sale of our product candidates and those of our third-party collaborators could be delayed or never occur. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the non-clinical trials, clinical trials, chemistry, manufacturing and controls (CMC) and commercial launch of our product candidates and those of our third-party collaborators.

If we or our third-party collaborators cannot manufacture our pharmaceutical product candidates or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

Failure to comply with ongoing governmental regulations for our pharmaceutical product candidates could materially harm our business in the future

Developing, manufacturing, marketing or promoting a drug is subject to very strict regulations and controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our product candidates, which in turn would materially harm our business, financial condition and results of operations:

- failure to obtain or maintain requisite governmental approvals;
- failure to meet GMP, GLP and/or other governmental requirements for drug development;
- failure to obtain approvals for clinically intended uses of our pharmaceutical product candidates under development; or
- FDA required product withdrawals or warnings arising from identification of serious adverse side effects in our product candidates.

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state and in some cases, foreign agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our product candidates. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA and/or foreign regulatory requirements. We have not been subject to a good manufacturing practice

regulation inspection by the FDA relating to our product candidates. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our product candidates we or they manufacture, the FDA or foreign equivalents may refuse or withdraw marketing clearance, put our or our partner's clinical trial on hold, withdraw or reject an investigational new drug (IND) application or require product recall, which may cause interruptions or delays in the development, manufacture and sale of our product candidates.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability

We have incurred significant operating losses since our inception in 1998 and, as of June 30, 2020, had an accumulated deficit of approximately $484.8 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed product candidates, obtain the required regulatory clearances, and manufacture and market our proposed product candidates. Development of pharmaceutical product candidates is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology and/or intellectual property rights for use in our product candidates. The license fees for these technologies or rights would increase the costs of our product candidates.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical product candidates and do not expect to do so in the near future. Our current revenues are from the ALZET product line, from the LACTEL product line, from certain excipient sales, from earn-out payments from Indivior related to sales of PERSERIS, and from payments under collaborative research and development agreements with third parties. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses in the near future. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our product candidates in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may develop our own sales force and commercial group to market future products but we have limited sales and marketing experience with respect to pharmaceuticals and may not be able to do so effectively

We have a small sales and marketing group focused on our ALZET and LACTEL product lines. We may choose to develop our own sales force and commercial group to market products that we have developed or may develop in the future, including POSIMIR and/or DUR-928, if approved. Developing a sales force and commercial group would require substantial expenditures and the hiring of qualified personnel. We have limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales and marketing personnel. If we are not able to put in place an appropriate sales force and commercial group for our products in development, we may not be able to effectively launch these products. We may not be able to effectively sell our product candidates, if approved, and our failure to do so could limit or materially harm our business.

We and our third-party collaborators may not sell our product candidates effectively

We and our third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborators may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these collaborators and distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our product candidates;
- cease operations with little or no notice to us;
- offer, design, manufacture or promote competing product lines;
- fail to maintain adequate inventory and thereby restrict use of our product candidates; or
- build up inventory in excess of demand thereby limiting future purchases of our product candidates resulting in significant quarter-to-quarter variability in our sales.

The failure of us or our third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our product candidates will hurt our business, prospects, financial results and may impact our access to capital.

We rely heavily on third parties to support development, clinical testing and manufacturing of our product candidates

We rely on third-party contract research organizations, consultants, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our product candidates. For example, we currently depend on third-party vendors to manage and monitor our clinical trials. We rely on third-parties to manufacture or perform manufacturing steps relating to our product candidates or components. We anticipate that we will continue to rely on these and other third-party contractors to support

development, clinical testing, and manufacturing of our product candidates. These third parties may not execute their responsibilities and tasks competently in compliance with applicable laws and regulations or in a timely fashion. Failure of these contractors to provide the required services in a competent or timely manner or on reasonable commercial terms could materially delay the development and approval of our product candidates, increase our expenses and materially harm our business, financial condition, results of operations and access to capital.

Key components of our product candidates are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs

Certain components and drug substances used in our and our collaborators' product candidates, including DUR-928, POSIMIR, Methydur Sustained Release Capsules, and PERSERIS, are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemical is the sole supplier of our requirements of sucrose acetate isobutyrate, a necessary component of POSIMIR and certain other pharmaceutical product candidates we have under development. A third party manufacturer is our sole supplier for future clinical and commercial supplies of POSIMIR. Another third party manufacturer is our sole supplier for future non-clinical, clinical and commercial supplies of DUR-928. The reliance on a sole or limited number of suppliers could result in:

- delays associated with redesigning a pharmaceutical product candidate due to a failure to obtain a single source component;
- delays associated with finding and contracting with a new supplier (if we can find one capable of replacing the old supplier and negotiate commercially reasonable terms) and then transferring the technology required to perform the services to the new supplier;
- an inability to obtain an adequate supply of required product candidate, active pharmaceutical ingredient or excipients or other components; and
- reduced control over pricing, quality and delivery time.

We have entered into a commercial manufacturing and packaging agreement with a third party manufacturer for future supply of POSIMIR. This third party is our sole source for the drug product required for development and commercialization of this drug candidate. There may be technical risks associated with establishing an alternative commercial manufacturer that could entail delays in supply, quality issues or delays in the possible regulatory approval of POSIMIR. Furthermore, we and our contract manufacturer may also need or choose to subcontract with additional third-party contractors to perform manufacturing steps of POSIMIR or supply required components for POSIMIR. Where third party contractors perform manufacturing services for us, we will be subject to the schedule, expertise and performance of third parties as well as incur significant additional costs. Failure of third parties to perform their obligations could adversely affect our operations, development timeline and financial results. If we proceed with the development of POSIMIR, we expect to put in place in the future second source supply arrangements, which may be costly and time consuming.

While we have entered into contract manufacturing agreements with multiple vendors for DUR-928, we currently have a third party sole supplier for GMP supplies of DUR-928. This third party is our sole source for the drug product required for development and commercialization of this drug candidate. There can be no assurance that we will receive sufficient quantities of DUR-928 to commence and conduct the non-clinical trials, clinical trials and CMC activities we are planning, and delays in supply could delay development of DUR-928. In addition, certain of our third party manufacturers and suppliers may be experiencing delays as a result of the COVID-19 coronavirus pandemic or have otherwise encountered delays in providing their services. As a result, we may not be able to manufacture our product candidates for our clinical trials and conduct other research and development operations and maintain current clinical and pre-clinical timelines. In addition, if additional third parties in our supply chain are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted in other ways, further limiting our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations.

We have supply agreements in place for certain components of our pharmaceutical product candidates, but do not have in place long term supply agreements with respect to all of the components of any of our product candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components (including active pharmaceutical ingredients or excipients) or product candidates, could cause us to seek alternative sources of supply or manufacture these items internally if feasible. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our product candidates is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete development and obtain approval for commercialization and marketing of our product candidates, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation and make access to capital more difficult, expensive or impossible.

Some of our pharmaceutical product candidates contain controlled substances, the making, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies

Some of our product candidates currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. ORADUR-Methylphenidate ER and certain other product candidates we may develop contain active ingredients which are classified as controlled substances under the regulations of the U.S. Drug Enforcement Agency. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our product candidates containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Write-offs related to the impairment of our goodwill, long-lived assets, inventories and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill. We are required to perform periodic impairment reviews of our goodwill at least annually. The carrying value of goodwill on our balance sheet was $6.4 million at June 30, 2020. To the extent these reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the cost of our long-lived assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values. We completed our last review during the fourth quarter of 2019 and determined that goodwill was not impaired as of December 31, 2019. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

Inventories, in part, include certain excipients that are sold to customers and included in product candidates in development. These inventories are capitalized based on management’s judgment of probable sale prior to their expiration date which in turn is primarily based on management’s internal estimates. The valuation of inventory requires us to estimate the value of inventory that may become expired prior to use. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval of a product by the necessary regulatory bodies, changes in product development timelines, or other information that suggests that the inventory will not be saleable. In addition, these circumstances may cause us to record a liability related to minimum purchase agreements that we have in place for raw materials. For example, during the year ended December 31, 2017, we recorded charges to cost of goods sold of approximately $2.0 million, of which approximately $503,000 related to the write-down of the cost basis of inventory on hand, $500,000 related to the prepaid inventory for the minimum purchase commitment for the excipient, and $1.0 million related to the recognition of our remaining minimum purchase commitment at that time for the same excipient after we announced that PERSIST, the Phase 3 clinical trial for POSIMIR, did not meet its primary efficacy endpoint.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with original maturities of greater than 90 days from the date of purchase but remaining maturities of less than one year from the balance sheet date. Our long-term investments consist primarily of readily marketable debt securities with maturities in one year or beyond from the balance sheet date. While, as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since June 30, 2020, no assurance can be given that deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents, short-term investments or long-term investments or our ability to meet our financing objectives.

We depend upon key personnel who may terminate their employment with us at any time, and we may need to hire additional qualified personnel

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, particularly as we develop and expand our Epigenetic Regulator Program. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key

personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources as well as difficulties or inability to raise sufficient capital to fund the Company's operations.

We may not successfully manage our company through varying business cycles

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. For example, in connection with the coronavirus pandemic, we asked most of our personnel, including all of our administrative employees, to work remotely, restricted on-site staff to only those personnel who must perform activities that must be completed on-site, implemented social distancing on-site, and closed certain of our offices temporarily. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with the FDA, manufacturing sites, research or clinical trial sites. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

Our business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials and product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations

We utilize information technology, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, and may cause a disruption in our operations, harm our reputation, cause us to pay to retrieve our data if it becomes infected or otherwise subject to ransomware and increase our stock trading risk. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our third-party collaborators, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Our corporate headquarters, certain manufacturing facilities and personnel are located in a geographical area that is seismically active and near wildfire zones

Our corporate headquarters, certain manufacturing facilities and personnel are located in a geographical area that is known to be seismically active and prone to earthquakes, as well as wildfires and related power outages or power shortages. Should such a natural disaster occur or power outage or power shortage, our ability to conduct our business could be severely restricted, and our business and assets, including the results of our research, development and manufacturing efforts, could be harmed or destroyed.

As a non-accelerated filer, we are not required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act and, consequently, some investors may find our common stock less attractive

We are a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, and as such, are not required to provide an auditor attestation of management's assessment of internal control over financial reporting, which is generally required for SEC reporting companies under Section 404(b) of the Sarbanes-Oxley Act. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. Because we are not required to have our auditors provide an attestation of our management's assessment of internal control over financial reporting, a material weakness in internal control may remain undetected for a longer period. In addition, we cannot predict if investors will find our common stock less attractive because we are not required to comply with the auditor attestation requirements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the trading price for our common stock may be negatively affected.

Risks Related to Our Intellectual Property

If we are unable to adequately protect, maintain or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us

Our ability to commercially exploit our products will depend significantly on our ability to obtain and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others.

As of July 31, 2020, we owned or exclusively in-licensed over 35 unexpired issued U.S. patents and over 175 unexpired issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have over 45 pending U.S. patent applications and over 140 foreign applications pending in Europe, Australia, Japan, Canada and other countries.

The patent status of our most advanced drug candidates is as follows:

Our Epigenetic Regulator Program includes nine in-licensed patent families and four patent families solely owned by us. Three patent families each include at least one granted patent providing protection until at least 2026, 2032, and 2034, respectively. The other patent families include pending patent applications, which if granted, could result in patents expiring in 2033, 2035, 2037, 2037, 2037, 2040, 2040, 2041, 2041 and 2041, respectively, plus any eligible patent term adjustments and extensions. Of the thirteen patent families covering DUR-928 and/or other molecules in the Epigenetic Regulator Program, two were only filed in the United States, and the other eleven have been filed or likely will be filed both in the U.S. and internationally. Since DUR-928 is an endogenous molecule, patent claims directed to DUR-928 compositions of matter may be more difficult to maintain or enforce in the United States under Myriad Genetics and other recent court decisions. One of the U.S. patents issued before Myriad Genetics, and five of the DUR-928 U.S. patents issued after Myriad Genetics. The granted claims in the U.S. include both composition of matter and method of treatment claims. There can be no assurance that the pending patent applications will be granted. Further, there can be no assurance that VCU will not attempt to terminate their license to us, which termination could result in the loss of our rights to these patent families.

In the United States, POSIMIR is covered by three patent families. One patent family includes granted patents expiring in at least 2025. The other two patent families include pending patent applications, which if granted, could result in a patent expiring in 2026 and 2041, respectively, plus any eligible patent term adjustments and extensions. In Europe, POSIMIR is covered by four granted patents with two expiring in 2025 and two expiring in 2026, plus any eligible patent term extensions. The family providing protection until at least 2041 will likely be filed in Europe.

In the United States, our ORADUR-Methylphenidate ER patent portfolio includes five patent families. Two patent families include granted patents providing protection until at least 2023 and 2029, respectively. The other patent families include pending patent applications, which if granted, could result in patents expiring in 2026, 2028, and 2037, respectively, plus any eligible patent term adjustments and extensions. There can be no assurance that the pending patent applications will be granted.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us

will be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation or arbitration to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may be unsuccessful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

Our collaboration agreements may depend on our intellectual property

We are party to collaborative agreements with Orient Pharma and Santen among others. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business.

We may be sued by third parties claiming that our product candidates infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We or our collaborators may be exposed to future litigation by third parties based on claims that our product candidates or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology, pharmaceutical and biotechnology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

- cease selling, incorporating or using any of our product candidates that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our product candidates, which would be costly and time-consuming.

Risks Related To Our Industry

The markets for our pharmaceutical product candidates and for our ALZET and LACTEL product lines are rapidly changing and competitive, and new products or technologies developed by others could impair our ability to maintain or grow our business and remain competitive

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our product candidates under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, biotechnology, medical devices and drug delivery. Competition for DUR-928, if approved, will depend on the specific indications for which DUR-928 is approved. Intercept, Gilead, Shire, Conatus Pharmaceuticals, Galectin Therapeutics, Genfit, Pfizer, Roche, Bristol Myers Squibb, Novartis, Terns Pharmaceuticals, Galmed Pharmaceuticals, Enanta Pharmaceuticals, Novo Nordisk, Takeda, Vital Therapies, Allergan, Akarna Therapeutics, Inventiva Pharma, Genkyotex, VBL Therapeutics, NGM Biopharmaceuticals, Gemphire Therapeutics, Albireo Pharma, CymaBay Therapeutics, Madrigal Pharmaceuticals, Viking Therapeutics, CohBar, FALK Pharma, Acorda, Akero, Generon, and others have development plans for products to treat NAFLD/NASH, AH or other liver diseases. AbbVie, Ischemix, Thrasos Therapeutics, AM-Pharma, Complexa, Quark Pharmaceuticals and others have development plans for products to treat acute kidney injury. There are press reports of more than 60 candidates being evaluated for the treatment of patients afflicted with COVID-19.

POSIMIR, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Pacira, Purdue Pharma, AbbVie, Janssen, Actavis, Medtronic, Endo, AstraZeneca, Pernix Therapeutics, Tricumed, Halyard Health, Cumberland Pharmaceuticals, Acorda Therapeutics, Mallinckrodt, Inspirion Delivery Technologies, Mylan, Shire, Johnson & Johnson, Eli Lilly, Pfizer, Novartis, Zyla Life Sciences, Teva Pharmaceuticals, Collegium Pharmaceutical and others. Additional competition for POSIMIR may come from Heron Therapeutics if their product candidate, HTX-011, is approved or from Innocoll if their product candidate, XARACOLL®, is approved. PERSERIS competes with currently marketed or approved products by Johnson & Johnson, Eli Lilly, Otsuka, Alkermes, Merck, Allergan, Novartis, and others. Our ORADUR-ADHD product candidates, if approved, will compete with currently marketed or approved products by Shire, Johnson & Johnson, UCB, Novartis, Noven, Eli Lilly, Pfizer and others.

Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Pacira, Heron Therapeutics, Alkermes, Immune Pharmaceuticals, Innocoll, Nektar, Acorda Therapeutics, Flamel, Alexza, Mallinckrodt, Pfizer, Cumberland Pharmaceuticals, Zyla Life Sciences, Acura, Elite Pharmaceuticals, Phosphagenics, Intellipharmaceutics, Collegium Pharmaceutical, Charleston Laboratories, Daiichi Sankyo and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

Competition for our ALZET product line primarily consists of customers choosing to utilize delivery methods for their research projects other than an osmotic pump. Competition for our LACTEL product line comes from companies including Evonik, Corbion, FUJIFILM Wako Pure Chemical Corporation, PCAS and others. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. We may also face competition for our ALZET and LACTEL product lines from other companies including low cost foreign competitors.

We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our product candidates even if commercialized. Post-operative pain is currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices which will be competitive with our product candidates. Many of these treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our product candidates to receive widespread acceptance if commercialized.

Our relationships with customers and third-party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. These regulations include:

- the Federal Healthcare Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, and which as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payers, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare reform measures could hinder or prevent our product candidates' commercial success

In the United States and some non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, affect our ability to profitably sell any product candidates for which we obtain marketing and otherwise affect our future revenue and profitability and the future revenue and profitability of our collaborators or potential collaborators.

For example, in March 2010, the Affordable Care Act was enacted in the United States to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law appears likely to continue the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

The current U.S. presidential administration has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". As legislative and regulatory developments are ongoing, we cannot predict the ultimate content, timing or effect of healthcare reform legislation or the impact of potential legislation on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include reductions to Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2027; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, the marketing, pricing and sale of the Company's products are subject to regulation, investigations and legal actions including under the Medicaid Drug Rebate Program under the Affordable Care Act, which has increased the statutory minimum rebates a manufacturer must pay under the program as well as a new methodology by which rebates are owed for drugs that are inhaled, infused, instilled, implanted or injected. We are also subject to federal and state false claims acts, as well as federal and state antitrust and consumer protection laws. Increased scrutiny of health care industry business practices in recent years by government agencies and state attorneys general in the U.S., and any resulting investigations and prosecutions, carry risk of significant civil and criminal penalties including, but not limited to, debarment from participation in such government healthcare programs.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in October 2017, California passed a new law, effective in January 2019, which requires transparency from biopharmaceutical companies regarding price increases for prescription drugs. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our products and product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, or be able to enter attractive collaboration agreements, which would adversely affect our business.

We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, clinical development, manufacture, marketing and sale of our product candidates involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our product candidates, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our product candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our product candidates.

Acceptance of our pharmaceutical product candidates in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues

Our future financial performance will depend upon the successful introduction and customer acceptance of our product candidates in research and development, including DUR-928 and POSIMIR, if approved, and including Indivior's PERSERIS. Even if approved for marketing, our product candidates may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

In addition, market adoption of POSIMIR and other product candidates in development may depend on what is included in the approved product label, including which clinical data, warnings and precautions is included, and there can be no assurance as to what the final product labels will contain. Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve meaningful revenues.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve meaningful revenues

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of our product candidates and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payers often limit payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably and access capital.

If we or our third-party collaborators are unable to train physicians to use our pharmaceutical product candidates to treat patients' diseases or medical conditions, we may incur delays in market acceptance of our products

Broad use of our certain of our product candidates, such as POSIMIR, will require extensive training of numerous physicians on the proper and safe use of our product candidates. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our product candidates may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our product candidates. Any delay in training would materially delay the demand for our product candidates and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

Potential new accounting pronouncements and legislative actions are likely to impact our future financial position or results of operations

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, PCAOB pronouncements and NASDAQ rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are high as a result of this uncertainty and other factors. Compliance with evolving corporate governance and public disclosure standards may result in increased general and administrative expenses and a diversion of management time and attention from value-creating activities to compliance activities.

Risks related to actions on trade by the U.S. and foreign governments could adversely affect the Company's results of operations and financial condition

The U.S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multilateral trade agreements. It has also initiated or is considering the imposition of tariffs on certain foreign products. Changes in U.S. trade policy have resulted in, and could continue to result in, one or more U.S. trading partners adopting responsive trade policy making it more difficult or costly for us to export our products to those countries. These measures could also result in increased costs for goods imported into the United States. This in turn could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, result in lowering our margin on products sold.

There is also a concern that the imposition of additional tariffs by the United States could result in the adoption of tariffs by other countries. A potential resulting trade war could have a significant adverse effect on world trade and the world economy. We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U.S. economy, which in turn could adversely impact our business, financial condition and results of operations.

Risks Related To Our Common Stock

Our operating history makes evaluating our stock difficult

Our quarterly and annual results of operations have historically fluctuated and we expect will continue to fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and commercialize our product candidates, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our product candidates and to fund operating losses to be incurred in the next several years.

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 August 2018, we filed a shelf registration statement on Form S-3 with the SEC that allows us to offer up to $175 million of securities from time to time in one or more public offerings, inclusive of up to $75.0 million of additional shares of common stock which the Company may sell, subject to certain limitations, under the 2015 Sales Agreement through Cantor Fitzgerald, acting as agent. In 2019, we raised net proceeds (net of commissions) of approximately $3.5 million from the sale of 2,349,820 shares of the Company’s common stock in the open market at a weighted average price of $1.55 per share pursuant to the August 2018 registration statement. On June 20, 2019, we entered into a privately negotiated transaction to sell 29,000,000 shares of our common stock to certain investors in a registered offering at a price of $0.52 per share, raising total gross proceeds to DURECT of approximately $15.1 million. This transaction closed on June 24, 2019. Total stock issuance costs related to this financing were approximately $124,000. In the six months ended June 30, 2020, we raised net proceeds (net of commissions) of approximately $6.2 million from the sale of 2,610,375 shares of the Company’s common stock in the open market at a weighted average price of $2.45 per share pursuant to the August 2018 registration statement. In July 2020, we raised net proceeds (net of commissions) of approximately $2.2 million from the sale of 1,007,392 shares of the Company’s common stock in the open market at a weighted average price of $2.30 per share, pursuant to the 2015 Sales Agreement. Any additional sales in the public market of our common stock, under our 2015 Sales Agreement with Cantor Fitzgerald, in other offerings under the shelf registration statement or otherwise, could adversely affect prevailing market prices for our common stock. In addition, as of June 30, 2020, 28,515,309 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 $1.44 per share, 7,575,815 additional shares of common stock were reserved for potential future issuance under our stock option plan, and an aggregate of 551,902 shares of common stock were reserved for potential future issuance under our 2000 Employee Stock Purchase Plan. Investors will incur dilution from the sale of any additional shares or upon the issuance of any shares pursuant to such plans, or upon exercise of any outstanding options.

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 December 2018, we received written notification from Nasdaq informing us that because the closing bid price of our common stock was below $1.00 for 30 consecutive trading days, 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. One strategy to regain compliance in such circumstances would be to implement a reverse stock split. The Company may appeal Nasdaq's determination to delist its 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 maintain 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 the 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 financing 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.

Our ability to use net operating losses and certain other tax attributes is uncertain and may be limited

Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. In addition, utilization of net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Internal Revenue Code) and similar state provisions, which may result in the expiration of net operating losses before future utilization. In general, under the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. If an ownership change limitation were to apply, utilization of our domestic net operating losses and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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 could result from general market and economic conditions and a variety of other factors, including:

- adverse results (including adverse events or failure to demonstrate safety or efficacy) or delays in our clinical and non-clinical trials of DUR-928 or other product candidates;
- announcements of FDA non-approval of our product candidates, 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 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 or new products by our competitors;
- failure of third-party collaborators to continue development of the respective product candidates they are developing;
- regulatory, judicial and patent developments in the United States and foreign countries;
- any lawsuit or arbitration involving us or our 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 acquisitions or termination of such alliances;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- negative press coverage or online 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 recently experienced extreme price and volume fluctuations. For example, the recent outbreak of the COVID-19 coronavirus, 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 and divert management's attention and our company's resources.

We have broad discretion over the use of our cash and investments, and their investment may not always yield a favorable return

Our management has broad discretion over how our cash and investments are used and may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

Executive officers, directors and principal stockholders have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders

Our directors, executive officers and principal stockholders, together with their affiliates, have substantial control over us. The interests of these stockholders may differ from the interests of other stockholders. As a result, these stockholders, if acting together, could have the ability to exercise control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

- the election of directors;
- the amendment of charter documents;
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets; or
- the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us

Provisions of Delaware law, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company, any action asserting a claim arising pursuant to any provision of the General Corporation Law of Delaware or our Certificate of Incorporation or bylaws or any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

None

Item 6. Exhibits

Exhibit Number	Exhibit Name
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.INS*	INLINE XBRL Instance Document
101.SCH*	INLINE XBRL Taxonomy Extension Schema Document
101.CAL*	INLINE XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	INLINE XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	INLINE XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	INLINE XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 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: August 4, 2020

By: /S/ MICHAEL H. ARENBERG

Michael H. Arenberg
Chief Financial Officer and Principal Accounting Officer

Date: August 4, 2020

Exhibit 31.1

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

I, James E. Brown, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DURECT Corporation for the quarter ended June 30, 2020;

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

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

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

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

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

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

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

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

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

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

August 4, 2020

/S/ JAMES E. BROWN

James E. Brown
Chief Executive Officer

Exhibit 31.2

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

I, Michael H. Arenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DURECT Corporation for the quarter ended June 30, 2020;

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

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

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

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

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

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

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

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

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

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

August 4, 2020

/S/ MICHAEL H. ARENBERG

Michael H. Arenberg
Chief Financial Officer and
Principal Accounting Officer

Exhibit 32.1

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

In connection with the Quarterly Report of DURECT Corporation (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James E. Brown, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 4, 2020

/S/ JAMES E. BROWN

James E. Brown
Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of DURECT Corporation (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael H. Arenberg, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 4, 2020

/S/ MICHAEL H. ARENBERG

Michael H. Arenberg
Chief Financial Officer and
Principal Accounting Officer