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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from to

Commission file number: 000-31615

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

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

10240 Bubb Road
Cupertino, CA 95014
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: (408) 777-1417

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock $0.0001 par value per share	**DRRX**	**The NASDAQ Stock Market LLC (The Nasdaq Capital Market)**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $39,696,286 as of June 30, 2024 based upon the closing sale price on The Nasdaq Capital Market reported for such date. Shares of Common Stock held by each officer and director and by each person who may be deemed to be an affiliate have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 31,041,981 shares of the registrant's Common Stock issued and outstanding as of March 25, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

None.

DURECT CORPORATION

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

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Part I

Item 1. Business.

Overview

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

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

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

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

Epigenetic Regulator Program and New Chemical Entities

Epigenetic regulation influences the expression of genes through the silencing or initiation of gene activity without modifying the DNA sequence. For instance, methylation (the chemical binding of a methyl group) of cytosine nucleotides in promoter regions of DNA, facilitated by DNA methyltransferases ("DNMTs"), will generally result in downregulation of gene expression, while demethylation (removal of a methyl group) generally results in upregulation. DNA methylation/demethylation can thus regulate the expression of relevant genes, especially clusters of master genes that further modulate crucial cellular activities.

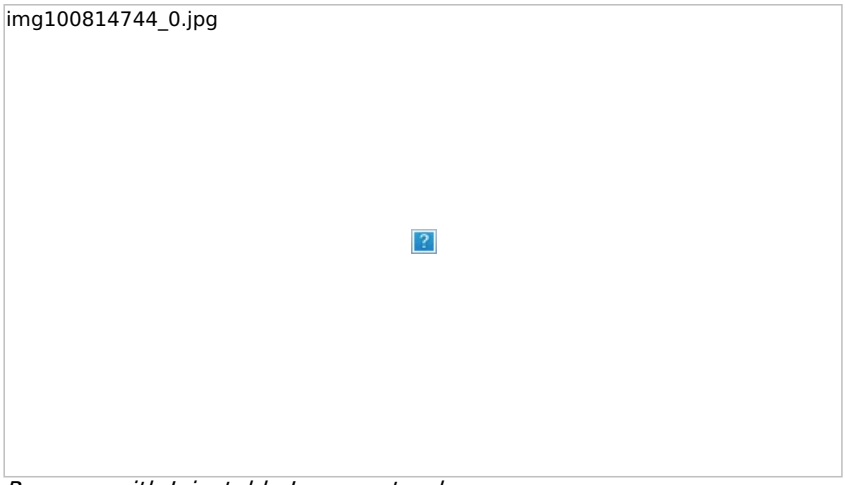
Our Epigenetic Regulator Program involved a multi-year collaborative effort with the Department of Internal Medicine at Virginia Commonwealth University ("VCU"), the VCU Medical Center and the McGuire VA Medical Center. The knowledge base supporting this program is a result of more than 30 years of lipid research by Shunlin Ren, M.D., Ph.D., Professor of Internal Medicine at the VCU Medical Center. The lead compound from this program, larsucosterol, is an endogenous sulfated oxysterol, which acts as an epigenetic regulator. Under a license with VCU, we hold the exclusive royalty-bearing worldwide right to develop and commercialize larsucosterol and related molecules discovered in the program.

In March 2021, a peer-reviewed research paper regarding the proposed mechanism of action of larsucosterol was published in The Journal of Lipid Research. The research showed that larsucosterol (referred to in the paper as "25HC3S") bound to and inhibited the activities of DNMTs 1, 3a and 3b, enzymes that add methyl groups to DNA (a process called "DNA methylation"), as well as reduced DNA hypermethylation. DNMTs 1 and 3a have been shown to be over-expressed in the livers of patients with severe AH. As such, by inhibiting DNMTs 1 and 3a activity, larsucosterol may inhibit DNA

hypermethylation, thereby modulating the expression of genes and pathways that are involved in crucial cellular activities, including those associated with cell death, stress response, and lipid biosynthesis. These modulations may lead to improved cell survival, reduced lipid accumulation or lipotoxicity, minimized inflammation, and enhanced liver regeneration, as has been observed in various *in vivo* animal models and in results from our completed clinical trials in AH and MASH patients.

The biological activity of larsucosterol 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., LPS-induced endotoxin shock, drug-induced acute oxidative stress injury, ischemic-reperfusion-induced kidney and brain injury), and some represent chronic metabolic disorders (e.g., MASH).

Our major product research and development efforts for larsucosterol are described in the following table:



Alcohol-Associated Hepatitis Program with Injectable Larsucosterol

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

Market Opportunity. AH, an acute form of alcohol-associated liver disease, is 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. A Model of End-Stage Liver Disease ("MELD") score is a commonly used scoring system to assess the severity and prognosis of AH patients. AH was associated with approximately 164,000 U.S. hospitalizations in 2021 according to the available data published for that year. A retrospective 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, 29% at 90 days and 44% at 180 days. A subsequent global study published in December 2021, which included 85 tertiary centers in 11 countries across 3 continents, prospectively enrolled 2,581 AH patients with a median MELD score of 23.5, reported mortality at 28 and 90 days of approximately 20% and 31%, respectively.

There are no FDA approved therapies for AH and stopping alcohol consumption is necessary, but frequently not sufficient for recovery in many moderate and severe patients. Corticosteroids do not improve survival at 90 days or one year, and have demonstrated an increased risk of infection. In addition, fewer than 50% of AH patients are eligible for corticosteroids. According to a recent study, the healthcare costs associated with treating hospitalized AH patients and their length of hospital stay are significant.

Each hospitalization episode with AH diagnosis for patients who:	**Average length of stay**	**Average total charges during hospital stay**
Died during the hospitalization	9 days	$147,000
Were discharged	6 days	$53,000
Marlowe, N., Lam, D., Krebs, W., Lin, W. & Liangpunsakul, S. (2022) Prevalence, co-morbidities, and in-hospital mortality of patients hospitalized with alcohol-associated hepatitis in the United States from 2015 to 2019. *Alcoholism: Clinical and Experimental Research.*		

The rate of AH patients undergoing liver transplantation has increased in recent years, although the total number of such transplants is still relatively small and limited by organ availability. Average charges for a liver transplant exceed $875,000, and patients require lifelong immunosuppressive therapy to prevent organ rejection.

Clinical Program.

Phase 2b AHFIRM Study

In January 2021, we announced the dosing of the first patient in our Phase 2b AHFIRM study of patients with severe AH. AHFIRM was a randomized, double-blind, placebo-controlled, international, multi-center Phase 2b study to evaluate the safety and efficacy of larsucosterol in 307 patients with severe AH. The study was comprised of three arms targeting approximately 100 patients each: (1) placebo; (2) larsucosterol (30 mg); and (3) larsucosterol (90 mg). All patients received supportive care at the investigators' discretion, which for placebo patients may include 32 mg methylprednisolone if prescribed. In order to maintain blinding, patients in the two active arms received matching placebo capsules if the investigator prescribed steroids. Patients received an IV dose of larsucosterol or placebo (sterile water) on Day 1 and a second identical IV dose on Day 4 if they were still hospitalized. The primary outcome measure was the 90-Day incidence of mortality or liver transplantation for patients treated with larsucosterol compared to those treated with placebo. Secondary endpoints included the difference in 90-Day mortality between patients treated with larsucosterol compared to those treated with placebo, the difference in 28-Day mortality or liver transplantation for patients treated with larsucosterol compared to those treated with placebo, and the difference in mortality between patients treated with larsucosterol compared to those treated with placebo. In November 2023, we announced topline results from the AHFIRM trial, comprising 307 patients with severe AH.

Key AHFIRM Trial Topline Data Results:

- Both the 30 mg and 90 mg larsucosterol doses demonstrated clinically meaningful trends in reduction of mortality at 90 days, the key secondary endpoint, with mortality reductions of 41% (p=0.068) in the 30 mg arm and 35% (p=0.124) in the 90 mg arm compared with placebo.
- The numerical improvement in the primary endpoint of mortality or liver transplant at 90 days did not achieve statistical significance for either dose of larsucosterol.

- Both doses of larsucosterol showed a more pronounced reduction in mortality in patients enrolled in the U.S., representing 76% of patients enrolled in the trial. The reductions in mortality at 90 days were 57% (p=0.014) for the 30 mg arm and 58% (p=0.008) for the 90 mg arm compared with placebo in the U.S.
- Larsucosterol was safe and well tolerated. There were fewer TEAEs in the larsucosterol arms compared with placebo.

Mortality or Liver Transplantation at 90 Days

The primary endpoint for the AHFIRM trial was the reduction in mortality or liver transplantation at 90 days. The endpoint was analyzed using a hierarchical assessment of patient outcomes to calculate a win probability for each of the 30 mg and 90 mg dose of larsucosterol compared with placebo. The results for the primary endpoint were not statistically significant for either the 30 mg or 90 mg doses compared with placebo, though a numerical improvement was observed.

Patient Outcomes

	Placebo*	Larsucosterol 30 mg	Larsucosterol 90 mg
Number of patients randomized	103	102	102
Number of patients with 90-day outcome data	102	99	101
Deaths (%)	25 (24.5%)	15 (15.2%)	17 (16.8%)
Transplants (%)	4 (3.9%)	6 (6.1%)	9 (8.9%)
Alive & Transplant-free (%)	73 (71.6%)	78 (78.8%)	75 (74.3%)

* One subject in the placebo group was confirmed alive at Day 90 but transplant status unknown. One patient received a liver transplant and subsequently died.

Win Probability Analysis

	Larsucosterol 30 mg vs. Placebo		Larsucosterol 90 mg vs. Placebo	
	Placebo	30 mg	Placebo	90 mg
Win Probability % at 90 days[1]	15.8%	23.6%	19.2%	23.1%
p-value		0.196		0.533

[1] Win probability was calculated based on the hierarchy of alive and transplant-free being superior to transplant and death and transplant being superior to death. Comparisons of the same outcome were included in the denominator as ties.

Mortality at 90 Days

Mortality at 90 days was a key secondary endpoint for the AHFIRM trial. In this analysis, the 30 mg and 90 mg doses of larsucosterol showed numerical trends toward a clinically meaningful survival benefit with 90-day mortality reductions of approximately 41% and 35%, respectively, when compared to placebo, although these results were not statistically significant.

Group	Mortality at 90 Days	% Reduction vs. Placebo	Difference vs. Placebo	p-value
Larsucosterol 30 mg (n=102)	15.3%	-40.7%	-10.5%	0.068
Placebo (n=103)	25.8%			
Larsucosterol 90 mg (n=102)	16.2%	-34.9%	-8.7%	0.124
Placebo (n=103)	24.9%			

Mortality at 90 Days (U.S. patients)

When further analyzed by geography, both the 30 mg and 90 mg doses showed an enhanced survival benefit at 90 days with reductions in 90-day mortality of 57% and 58%, respectively, in patients enrolled in the U.S., which represented 76% of the total patients enrolled.

Group	Mortality at 90 Days	% Reduction vs. Placebo	Difference vs. Placebo	p-value
Larsucosterol 30 mg (n=76)	12.3%	-56.8%	-16.1%	0.014
Placebo (n=78)	28.5%			
Larsucosterol 90 mg (n=78)	11.7%	-58.1%	-16.2%	0.008
Placebo (n=78)	27.9%			

Safety and Tolerability

Both the 30 mg and 90 mg doses of larsucosterol were well tolerated. There were fewer TEAEs in the larsucosterol arms compared with placebo.

	Placebo	Larsucosterol 30 mg	Larsucosterol 90 mg
Number of TEAEs	721	545	567

Phase 2a clinical trial

In 2019, we completed a Phase 2a clinical trial evaluating safety and PK of intravenously ("IV") infused larsucosterol in patients with moderate and severe AH. Severity of AH was determined by MELD scores with moderate defined as MELD 11-20 and severe as MELD 21-30. This was an open label, dose escalation (30 mg, 90 mg and 150 mg), multi-center U.S. study, designed to be conducted in two sequential parts. Part A included patients with moderate AH and Part B included patients with severe AH.

In this Phase 2a trial, dose escalation was permitted following review of safety and PK results of the prior dose level by a Dose Escalation Committee. The target number of patients for the study was 4 per dose group. Final enrollment included 19 patients with moderate (7 of 19) and severe AH (12 of 19), who received IV larsucosterol at 30 mg, 90 mg, or 150 mg doses. Eight patients (four moderate and four severe) were dosed at 30 mg, seven patients (three moderate and four severe) were dosed at 90 mg and four patients (all severe) were dosed at 150 mg. After being discharged on Day 2, one patient did not return for the scheduled Day 7 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 signals, including liver biochemistry, biomarkers and prognostic scores, including the Lille score, following larsucosterol treatment.

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

All 19 patients treated with larsucosterol in this trial survived the 28-day follow-up period and there were no drug-related serious adverse events. Using an alternative measure of AH severity to MELD, Maddrey's Discrimination Function ("DF"), 15 of the 19 patients had DF scores of 32 or greater, indicating that they had severe AH. Patients treated with larsucosterol had a statistically significant reduction from baseline in bilirubin at Day 7 and Day 28, and MELD at Day 28. Lille scores, which are used in clinical practice to help determine the prognosis and response of AH patients after 7 days of treatment, were also statistically significantly lower than those from a well-matched group of patients in a contemporary trial as well as several published historical controls. 74% of all larsucosterol treated patients and 67% of those with severe AH were discharged from the hospital within 4 days after receiving a single dose of larsucosterol.

In the Phase 2a study of larsucosterol in AH, larsucosterol was well tolerated at all doses tested. There were no drug-related serious adverse events and only three adverse events designated as possibly or probably related to larsucosterol: one occurrence of moderate generalized pruritus, one mild rash and one grade two alkaline phosphatase elevation. There were no discontinuations, early withdrawals or termination of study drug or study participation due to adverse events. All patients treated with larsucosterol survived through the 28-Day follow-up period. Drug exposures were dose proportional and were not affected by the severity of the disease.

Fast Track Designation and Breakthrough Therapy Designation

In December 2020, we announced that the FDA had granted larsucosterol Fast Track Designation for the treatment of AH. The FDA grants Fast Track Designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track Designation may benefit from early and frequent communication with the agency in addition to a rolling submission of the marketing application, with the objective of getting important new therapies to patients more quickly. In May 2024, we announced that the FDA granted BTD to larsucosterol for the treatment of AH.

Phase 3 clinical trial design

In July 2024, we held a Type B meeting with the FDA to discuss the design of our planned Phase 3 clinical trial of larsucosterol in AH that, if successful, could support a potential New Drug Application filing. In September 2024, we provided details on the design of our upcoming registrational Phase 3 trial which will evaluate larsucosterol for the treatment of patients with severe AH. The proposed Phase 3 trial design incorporates feedback from the Type B meeting held with the FDA under the BTD. It is designed as a randomized, double-blind, placebo-controlled, multi-center study conducted in the U.S., which will evaluate the safety and efficacy of larsucosterol for the treatment of patients with severe AH. The primary outcome measure will be a 90-day survival endpoint. The Phase 3 trial is planned to enroll approximately 200 patients randomized in a 1:1 ratio across two arms: (1) larsucosterol (30 mg) or (2) placebo, which will be added to the current standard of care, with or without methylprednisolone capsules in the placebo patients at the investigators' discretion. Patients enrolled in the trial will be monitored for an additional 90 days to collect additional safety and outcomes data. Our plan is to initiate a Phase 3 clinical trial of larsucosterol in AH, subject to obtaining sufficient funding, and present topline results within two years of initiation.

Chronic Liver Disease Program with Orally Administered Larsucosterol

Market Opportunity. Metabolic dysfunction-associated steatotic liver disease ("MASLD") is the most common form of chronic liver disease in both children and adults. It is estimated that MASLD, also known as nonalcoholic fatty liver disease (NAFLD), affects approximately 35% to 50% of adults and 5-10% of children in North America. Metabolic dysfunction-associated steatohepatitis ("MASH"), also known as nonalcoholic steatohepatitis or NASH, a more severe and progressive form of MASLD, is one of the most common chronic liver diseases worldwide, with an estimated prevalence of 3-5% globally. In addition to these liver diseases, there are a number of orphan liver diseases for which we may seek to develop larsucosterol.

Clinical Program. In 2020, we completed a Phase 1b randomized, multi-center, and open-label clinical study in the United States to evaluate safety, PK and signals of biological activity of larsucosterol in MASH patients with stage 1-3 fibrosis. Larsucosterol (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. Key endpoints included safety and PK, and clinical chemistry/efficacy signals, such as liver enzymes (e.g., ALT, AST and GGT (each as defined below)), serum lipids (e.g., triglycerides), biomarkers (e.g., CK-18s, inflammatory cytokines), and insulin resistance (i.e., HOMA-IR), as well as liver fat content and liver stiffness by imaging (e.g., MRI-PDFF (as defined below) and FibroScan®).

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 150 mg 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% ($p < 0.01$). Furthermore, patients in the 50 mg and 150 mg groups had 22% and 18%, respectively, median reductions (not statistically significant) of HOMA-IR from baseline respectively after 4 weeks of daily oral dosing of larsucosterol. The 600 mg group did not show a change in HOMA-IR.

At Day 28, 43% of patients in all three dose groups showed greater than or equal to 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), as well as both CK-18, M30 and M65 (each as defined below) in the 50 mg and 600 mg groups.

Larsucosterol was well tolerated at all three doses evaluated. There were no serious adverse events reported during the study, and no discontinuations, early withdrawals or termination of study drug or study participation due to adverse events. PK parameters after repeat dosing were comparable to those after a single dose (from a prior study), indicating no accumulation of the drug after repeat dosing.

We have completed multiple Phase 1 trials in healthy subjects with orally administered larsucosterol. These include single-ascending-dose and multiple-ascending-dose studies as well as a food effect study. In all these studies larsucosterol 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.

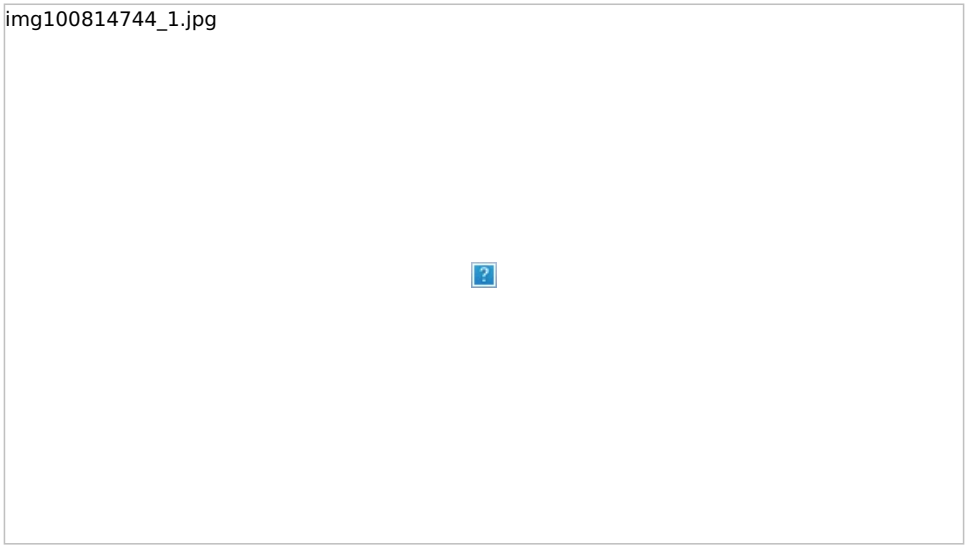
We also conducted a Phase 1b trial in cirrhotic and non-cirrhotic MASH patients and matched control subjects (“MCS”) (matched by age, body mass index and gender with normal liver function) utilizing orally administered larsucosterol. This was an open-label, single-ascending-dose safety and PK study conducted 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 MASH patients and 6 MCS. Data from this study were presented at the International Liver Congress™ 2017 organized by the European Association for the Study of the Liver (EASL) in Amsterdam in April 2017. All patients and MCS in this study tolerated larsucosterol well. One patient (with a prior history of arrhythmia and an ongoing viral infection) in the high dose cohort experienced a serious adverse event (i.e., 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 MASH patients and the MCS. In addition, the systemic exposure following the low and high doses of larsucosterol was dose dependent.

While this study was not designed to assess efficacy, we observed statistically significant reductions from baseline levels of several biomarkers after both doses of larsucosterol. A single oral dose of larsucosterol significantly reduced the levels of both full-length (“M65”) and cleaved (“M30”) cytokeratin-18 (“CK-18”), bilirubin, hsCRP, and IL-18 in these subjects. The mean reduction 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 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.

We also conducted a Phase 1b open-label, multi-center U.S. study to evaluate the safety, tolerability, and PK of larsucosterol in subjects with moderate (Child-Pugh B scores, n=10) and severe (Child-Pugh C scores, n=7) hepatic function impairment ("HI"), and MCS (n=10) with normal hepatic function. Each subject received a single oral dose of 200 mg larsucosterol. Results from this study were presented at the International Liver Conference 2021 (EASL). Larsucosterol was safe and well-tolerated by all moderate and severe HI subjects with no adverse events and no dose-limiting toxicity reported throughout the study. As expected, clearance of larsucosterol was decreased in HI subjects compared to MCS with normal hepatic function, resulting in a 4-10-fold higher drug exposure (Cmax and AUC) in HI subjects. Additionally, a single oral dose of 200 mg of larsucosterol in subjects with HI resulted in statistically significant median reductions from baseline of the apoptosis biomarker M30 (cCK-18) at 12 hours post-dose.

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

Approved and Commercial Pharmaceutical Products



POSIMIR® (bupivacaine solution)

POSIMIR (bupivacaine solution) for infiltration use is a novel and proprietary product that combines the strength of 660 mg of bupivacaine base with the innovative SABER platform technology, enabling continuous sustained delivery of a non-opioid local analgesic over three days in adults, which we believe coincides with the time period of the greatest need for post-surgical pain control in most patients. POSIMIR contains more bupivacaine than any other approved single-dose sustained-release bupivacaine product. At the end of surgery, POSIMIR is administered into the subacromial space under direct arthroscopic visualization, where it continuously releases bupivacaine for 72 hours or more.

In February 2021, the FDA approved POSIMIR for infiltration use in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

In December 2021, we entered into the Innocoll Agreement, pursuant to which we granted to Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize POSIMIR in the U.S. with respect to all uses and applications in humans. On November 8, 2024, we received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to us, and we are evaluating next steps with respect to the commercialization of POSIMIR. We do not expect that this termination will have a material impact on our financial statements.

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. Under the terms of the agreement with Indivior, we receive 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. In July 2024, Indivior announced discontinuation of sales and marketing for PERSERIS due to the highly competitive market and impending changes that are expected to intensify payor management in the treatment category in which PERSERIS participates.

ORADUR™-ADHD Program

We developed a proprietary drug product for the treatment of ADHD called Methydur in collaboration with Orient Pharma, a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan. We have licensed worldwide Methydur rights to Orient Pharma and they launched Methydur commercially in Taiwan in September 2020. Orient Pharma may seek commercialization partners in other countries throughout the world, including China and the U.S. We receive a single-digit royalty on sales of Methydur by Orient Pharma or its commercialization partners as well as potential milestones and sub-license fees.

Our Strategy

Our objective is to develop multiple pharmaceutical products that address significant unmet medical needs and improve patients' quality of life. To achieve this objective, our strategy includes the following key elements:

Complete Clinical Development and Seek Regulatory Approval of Larsucosterol for the Treatment of AH. In the fourth quarter of 2023, we completed our Phase 2b clinical trial (AHFIRM), as described above. In September 2024, we provided details on the design of our upcoming registrational Phase 3 trial which will evaluate larsucosterol for the treatment of patients with severe AH. Our plan is to initiate a Phase 3 clinical trial of larsucosterol in AH, subject to obtaining sufficient funding, and present topline results within two years of initiation.

Maximize the Commercial Potential of Larsucosterol in AH. We are exploring the best approach to maximize the commercial potential of larsucosterol, either by licensing to a commercial entity or continuing to develop and commercialize larsucosterol ourselves. We believe that, if approved in the United States, a highly specialized commercial organization could support the commercialization of larsucosterol in the United States. We believe this market can be effectively addressed with a modest-sized commercial organization, including a hospital-focused sales force focused on hospitals. We may also seek strategic collaborations to commercialize larsucosterol outside the United States.

Enable Product Development Through Strategic Agreements. We believe that entering into selective strategic collaborations and other arrangements with respect to our product development programs and technology can enhance the success of our product development and commercialization, leverage and exploit the value of our intellectual property portfolio, mitigate our risk and enable us to better manage our operating costs. Additionally, such collaborations and arrangements enable us to leverage investment by third parties and reduce our net cash burn, while retaining significant economic rights.

Strategic Agreements

We have entered into the following strategic collaboration and other key agreements:

Innocoll Pharmaceuticals Limited. In December 2021, we entered into the Innocoll Agreement, pursuant to which, we granted to Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize POSIMIR in the U.S. with respect to all uses and applications in humans. On November 8, 2024, we received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to us, and we are evaluating next steps with respect to the commercialization of POSIMIR. We do not expect that this termination will have a material impact on our financial statements.

Virginia Commonwealth University Intellectual Property Foundation. In December 2012, we entered into an exclusive in-license and research and development agreement with the Virginia Commonwealth University Intellectual Property Foundation regarding certain new chemical entities under development through our Epigenetic Regulator Program, including larsucosterol. Under this licensing arrangement, we agreed to undertake certain efforts to bring licensed products to market, pay for prosecution of related patents and report on progress to VCU. In addition, we are obligated to pay low

single-digit percentage patent royalties on net sales of licensed products, subject to annual minimum payments and additional milestone payments. This license includes rights to ten patent families. We may terminate this agreement at any time by written notice, and VCU may terminate this agreement by written notice if there is an uncured material breach.

Indivior UK Ltd. 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. Under the terms of the agreement with Indivior, we receive 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. The agreement contains customary representations, warranties and indemnities of the parties. In July 2024, Indivior announced discontinuation of sales and marketing for PERSERIS due to the highly competitive market and impending changes that are expected to intensify payor management in the treatment category in which PERSERIS participates. We do not expect that this discontinuation will have a material impact on our financial statements.

ALZET Commercial Product Line

The ALZET product line consisted of miniature, implantable osmotic pumps and accessories used for research in mice, rats and other laboratory animals. On November 22, 2024, we sold the ALZET product line to Lafayette Instrument Co. ("LIC"), a portfolio company of Branford Castle Partners II, L.P., a North-American focused private equity firm. Under the terms of the asset purchase agreement, LIC paid DURECT $17.5 million in exchange for certain assets and liabilities associated with the ALZET product line.

Suppliers

We purchase the larsucosterol drug substance from a third-party manufacturer and larsucosterol clinical trial materials from another third-party manufacturer. As needed, we purchase sucrose acetate isobutyrate, a raw material for our SABER-based pharmaceutical systems, including Methydur and POSIMIR. We expect that we will continue to be able to obtain sufficient supply of these raw materials to meet our needs for the foreseeable future. We do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical product candidates, however, and are subject to the risk that we may not be able to procure all required components in adequate quantities with acceptable quality, within acceptable time frames or at reasonable cost.

Customers

Our product revenues principally are derived from the sale of certain key excipients that are included in POSIMIR, Methydur Sustained Release Capsules, and other products. Until such time that we are able to bring our pharmaceutical product candidates to market, if at all, we expect these to be our principal sources of product revenue. We also receive revenue from collaborative research and development arrangements with third-party collaborators and earn-out revenue from our patent purchase agreement. In 2024, Indivior accounted for 78% of our total revenue.

Manufacturing

The process for manufacturing our pharmaceutical product candidates is technically complex, requires special skills, and must be performed in qualified facilities. We have in the past entered into development and commercial manufacturing agreements with third parties for the manufacture of larsucosterol and POSIMIR (currently assigned to Innocoll, with such assignment ending effective May 6, 2025). In addition, we have a small multi-discipline manufacturing facility in California that we have used to manufacture research and clinical supplies of several of our pharmaceutical product candidates under good manufacturing practice ("GMP"), including larsucosterol dosage forms. In the future, we may develop additional manufacturing capabilities for our pharmaceutical product candidates and components to meet our demands and those of our third-party collaborators by contracting with third party manufacturers. We manufacture certain key components for POSIMIR and Methydur at our current California facility**.**

Patents and Proprietary Rights

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary molecules and technology, inventions and improvements that are important to the development of our business. As of March 25, 2025, we owned or exclusively in-licensed over 15 unexpired issued U.S. patents and over 145 unexpired issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have over 15 pending U.S. patent applications and over 95 foreign applications pending in Europe, Australia, Japan, Canada and other countries.

The patent status of our most advanced programs is as follows:

Our Epigenetic Regulator Program includes seven in-licensed patent families and seven patent families solely owned by us. Five patent families each include at least one granted patent that could provide protection until at least 2026, 2032, 2034, 2035, and 2037, respectively. The other patent families include pending patent applications, which if granted, could result in patents providing protection until at least 2040 to 2044. Patent terms are potentially subject to terminal disclaimers as well as patent term adjustments and extensions. Of the fourteen patent families covering larsucosterol and/or other molecules in the Epigenetic Regulator Program, two were only filed in the United States, and the other twelve have been filed or likely will be filed both in the U.S. and internationally. Since larsucosterol is an endogenous molecule, patent claims directed to larsucosterol 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 nine of the larsucosterol 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 four patent families. Three patent families include granted patents that could provide protection until 2025, 2026 and 2041, respectively. The other patent family includes a pending patent application, which if granted, could result in a patent expiring in 2042. In Europe, POSIMIR is covered by a pending application in the patent family that could provide protection until at least 2041.

Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. Patents owned by or licensed to us may not afford protection against competitors, and our pending patent applications now or hereafter filed by or licensed to us may not result in patents being issued. In addition, the laws of certain foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S.

The patent positions of biopharmaceutical companies involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with certainty. Our patents or patent applications, or those licensed to us, if issued, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide proprietary protection or competitive advantages to us against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

Because patent applications in the U.S. are typically maintained in secrecy for at least 18 months after filing and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first to make inventions or file for protection of inventions set forth in our patents or patent applications.

Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case we may need to obtain a license to continue developing or marketing these products. Any required licenses may not be available to us on acceptable terms, if at all. If we do not obtain any required licenses, we could encounter delays in product introductions while we attempt to design around these patents, or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. Litigation may be necessary to defend against or assert such claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Litigation or similar proceedings could result in substantial costs to and diversion of effort by us and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees and certain contractors. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and, among other things, the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products. We believe that our products in development will be regulated as drugs by the FDA rather than as biologics or devices.

U.S. Drug Development Process

The standard process required by the FDA under the new drug provisions of the Federal Food, Drug and Cosmetics Act (the "FDCA") before our products in development may be marketed in the U.S. generally involves the following:

- preclinical laboratory and animal tests performed under current good laboratory practices;
- submission to the FDA of an Investigational New Drug ("IND") application which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") or ethics committee before each human clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with IND regulations, code of good clinical practice ("GCP"), requirements and other clinical trial-related regulations to establish the safety and efficacy of the proposed pharmaceutical product candidates in their intended uses;

- submission of an NDA to the FDA for approval of commercial marketing and sale, or of an NDA supplement for approval of a new indication if the proposed pharmaceutical product candidate is already approved for another indication;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with current good manufacturing practice and current GCPs;
- if the FDA convenes an advisory committee, satisfactory completion of the advisory committee review;
- FDA approval of an NDA; and
- compliance with any post-approval requirements, including the potential requirement to conduct post-approval studies.

Section 505 of the FDCA describes three types of NDAs: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed pharmaceutical product candidate is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use, among other things, to a previously approved product (section 505(j)). We expect that our drug candidates deriving from our Epigenetic Regulator Program will be evaluated for approval after submission of an NDA under section 505(b)(1).

The testing and approval process require substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all. Preclinical development of a drug candidate can take several years to complete, with no guarantee that an IND based on those studies will become effective to even permit clinical testing to begin. Even though several of our pharmaceutical product candidates utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and effectiveness of those active ingredients in the formulation and dosage forms that we are developing.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the pharmaceutical product candidate. We then submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. Each subsequent new clinical protocol must also be submitted to the FDA under the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-Day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Further, an independent IRB at each medical center proposing to conduct the clinical trials must review and approve any clinical study as well as the related informed consent forms and authorization forms that permit us to use individually identifiable health information of study participants.

Human clinical trials are typically conducted in three sequential phases, which may overlap:

- Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- Phase 2: The drug is administered to a limited patient population with the target disease or condition in clinical trials to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: When Phase 2 clinical trials demonstrate that a dosage range of the product candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken and the drug is administered to an expanded patient population to further evaluate dosage, clinical efficacy and to further test for safety in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, to establish the overall risk-benefit profile of the product candidate, and to provide adequate information for the labeling of the product.

In the case of product candidates for severe diseases, such as chronic pain, or life-threatening diseases such as cancer, the initial human testing is often conducted in patients with the target diseases or conditions rather than in healthy volunteers. Since these patients already have the target disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 trials, and thus these trials are frequently referred to as Phase 1/2 clinical trials or Phase 1b trials. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 clinical trials of our pharmaceutical product candidates in development within any specific time period, if at all. Furthermore, the FDA or the IRB or the sponsor may suspend clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. During the clinical development of product candidates, sponsors frequently meet and consult with the FDA to ensure that the design of their studies will likely provide data both sufficient and relevant for later regulatory review; however, no assurance of approvability can be given by the FDA.

NDA Review and Approval Processes

Assuming successful completion of all testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. Submission of an NDA may require the payment of a substantial user fee to the FDA, and although the agency has defined user fee goals for the time in which to respond to sponsor applications, there can be no assurance that the FDA will act in any particular timeframe. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical trials be conducted. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. An NDA may be approved with significant restrictions on its labeling, marketing and distribution under a Risk Evaluation and Mitigation Strategy or otherwise that could restrict the commercial applications of a product or impose costly procedures in connection with the commercialization or use of the product. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not maintained or if safety problems occur after the product reaches the market. Requirements for additional Phase 4 studies (post approval marketing studies) to confirm safety and effectiveness in a broader commercial use population may be imposed as a condition of marketing approval. In addition, the FDA may require testing and surveillance programs to monitor the effects of approved products which have been commercialized, and the FDA has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs. Any comparative claims comparing a product to other dosage forms or competitive products typically need to be supported by two adequate and well-controlled head-to-head clinical trials.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product and of the disease or condition. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory

agency will grant approval for any of our pharmaceutical products under development on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later stage clinical trials. Targets and pathways identified *in vitro* may be determined to be less relevant in clinical studies and results in animal model studies may not be predictive of human clinical results. Furthermore, data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Evolving safety concerns can result in the imposition of new requirements for expensive and time-consuming tests, such as for QT interval cardiotoxicity testing. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, any problems associated with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Any pharmaceutical products that we may develop and obtain approval for would also be subject to adverse findings of the active drug ingredients being marketed in different dosage forms and formulations. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our pharmaceutical products abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Expedited Development and Review Programs

There are several FDA programs intended to help facilitate the development of new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product. Under a Fast Track designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a product candidate that is being studied for safety and effectiveness in treating serious or life-threatening illnesses and provides meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that it may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials with due diligence and, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, for products being considered for accelerated approval, unless otherwise informed by the FDA, the FDA generally requires that all advertising and promotional materials intended for dissemination or publication within 120 days following marketing approval be

submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

A product may also be eligible for receipt of a Breakthrough Therapy designation under the provisions of the Food and Drug Administration Safety and Innovation Act ("FDASIA"). The Breakthrough Therapy designation is intended to expedite the FDA's review of a potential new drug for serious or life-threatening diseases where "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast Track program, as well as intensive FDA guidance on the product's development program. If a drug is designated as a breakthrough therapy, the FDA will provide more intensive guidance on the drug development program and expedite its review. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but they may expedite the development or approval process.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in limited circumstances, for seven years. These circumstances are an inability to supply the drug in sufficient quantities or a situation in which a new formulation of the orphan drug has shown superior safety or efficacy or a major contribution to patient care. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity could also block the approval of one of our products for seven years if a competitor obtains earlier approval of the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union ("EU") has similar, but not identical, requirements and benefits.

Post-Approval Regulation

Any pharmaceutical products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the product or the active pharmaceutical ingredient or other components of the product. The FDA may also require post-approval clinical or non-clinical trials. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for

compliance with good manufacturing practices, which impose procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP regulations and other FDA regulatory requirements.

The FDCA strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses, and federal and state authorities are also actively litigating against sponsors who promote their drugs for unapproved uses under various fraud and abuse and false claims act statutes. We and our products are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The Drug Enforcement Administration ("DEA") regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients in ORADUR-Methylphenidate are listed by the DEA as Schedule II under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA 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, which could negatively impact us and our collaborators.

Other Healthcare Laws

In addition to FDA and DEA restrictions on the marketing of pharmaceutical products, other foreign, federal and state healthcare regulatory laws restrict business practices in the pharmaceutical industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, data privacy and security, and physician payment and drug pricing transparency laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to

scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMMS"), information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMMS ownership and investment interests held by physicians and their immediate family members.

There are federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, and such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts, compensation and other remuneration and items of value provided to physicians, other healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives. Finally, the Physician Self-Referral ("Stark") Law 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.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately, which can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price (“AMP”), and Best Price, Medicare Average Sales Price, the 340B Ceiling Price and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers’ products by Medicaid beneficiaries. Compliance with such laws and regulations require significant resources and any findings of non-compliance may have a material adverse effect on our revenues.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In the United States, by way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act (collectively, the “Affordable Care Act”), was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act: established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents; expanded eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a Medicare Part D coverage gap discount program; established a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 included a provision that repealed, 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." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. However, it is possible that the Affordable Care Act will be subject to additional judicial or Congressional challenges in the future.

Further, the Affordable Care Act has been subject to various health reform measures. For example, prior to the U.S. Supreme Court ruling, on January 28, 2021, the Biden administration issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025 and includes several measures intended to lower the cost of prescription drugs and related healthcare reforms. It is unclear how such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act. Specifically, the IRA authorizes and directs the U.S. Department of Health and Human Services ("HHS") to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs to be selected by September 1, 2023, and the first year of maximum price applicability to begin in 2026. The IRA further authorizes the HHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. On June 30, 2023, the Centers for Medicare and Medicaid Services ("CMS"), issued new guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program . In addition, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology ("NIST") published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The implementation of government-imposed cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. It is currently unclear how any such challenges and other litigation, and the healthcare reform measures of the current U.S. presidential administration will impact the Affordable Care Act and our business as well as how the IRA will be effectuated.

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 2031 unless additional Congressional action is taken, except for a temporary suspension from May 1, 2020 through March 31, 2022 and limited reductions to 1% from April 1, 2022 through June 30, 2022 due to the COVID-19 pandemic with the 2% payment reduction having resumed on July 1, 2022. Following the resumption of the sequester, under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of

this sequester. Further, 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. Additionally, on March 11, 2021, American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation 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, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

These initiatives, as well as other healthcare reform measures that have been adopted and 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 and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, 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 or our partners are slow or unable to adapt to new requirements or policies, or if we or our partners are not able to maintain regulatory compliance, our products and product candidates may lose any regulatory approval that may have been obtained, which would reduce the likelihood that we may achieve or sustain profitability, or be able to enter attractive collaboration agreements, which would adversely affect our business.

Foreign Regulation

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the EU regional registration procedures are available to companies wishing to market a product in more than one EU member state. If the competent regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application ("CTA") much like an IND prior to the commencement of human clinical trials. In the EU, a CTA must be submitted for each trial to the competent health authority and to independent ethics committees by national procedure for a single country trial or by EMA submission portal Clinical Trials Information System for a multinational study. Once the CTA is approved in accordance with the requirements in the concerned countries, clinical trial development may proceed in those countries and are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application ("MAA"). This application is similar to the NDA in the United States, with the exception of, among other things, regional and/or country-specific document requirements. Drugs can be authorized in the EU by using the centralized, mutual recognition, decentralized or national authorization procedures described below.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days (excluding clock stoppages for requests by the Committee for Medicinal Products for Human Use ("CHMP") for additional written or oral information to be provided by the applicant). A positive opinion on the MAA by the CHMP then needs to be endorsed by the European Commission within approximately 67 days. Accelerated assessment might be granted by the CHMP in exceptional cases, in which case the EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days (excluding clock stops) and the opinion issued thereafter.

The mutual recognition procedure ("MRP") for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU. The MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is based on the principle of the mutual recognition by EU member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any member state refuse to recognize the marketing authorization by the reference member state, the member states shall make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision making process. As in the centralized

procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

For other countries outside of the EU, such as non-EU countries in Eastern Europe, Middle-East, Latin America, Japan or other countries in Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Competition

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery.

Competition for larsucosterol, if approved, will depend on the specific indication(s) for which larsucosterol is approved. Alfasigma S.p.A., Nterica Bio, Inc., Aldeyra Therapeutics, Inc., Surrozen, Inc. and several academic institutes, including Yale University, and others have development plans for products or evaluating marketed products to treat AH. 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.

Any pharmaceutical products we develop will compete in highly competitive markets. Many of our potential competitors in these markets have greater development, financial, manufacturing, marketing, and sales resources than we do and we cannot be certain that they will not succeed in developing products or technologies which will render our technologies and products obsolete or noncompetitive. In addition, many of those potential competitors have significantly greater experience than we do in their respective fields.

Corporate History, Headquarters and Website Information

We were incorporated in Delaware in February 1998. Our principal executive offices are located at 10240 Bubb Road, Cupertino, California 95014. Our telephone number is (408) 777-1417, and our website address is www.durect.com. Information contained on our website is not a part of this Annual Report on Form 10-K and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to these reports or other information filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act available free of charge on our website as soon as reasonably practicable after we file these reports with the Securities and Exchange Commission ("SEC"). The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The SEC's website to access all of this information is www.sec.gov. Our Code of Ethics can be found on our website.

We also use our website, including the investor relations section of our website, to announce important information about us and other matters in order to achieve broad, non-exclusionary distribution of information to the public and to comply with our disclosure obligations under Regulation Fair Disclosure. We encourage investors and others to review the information we make public in these locations, as such information could be deemed to be material information. Information contained on or accessible through our website is not a part of this report, and all website addresses in this report are intended to be inactive textual references only.

Human Capital

Our approach to human capital resource management starts with our mission to advance novel and potentially lifesaving investigational therapies derived from our Epigenetic Regulator Program. Our industry exists in a complex regulatory environment. The unique demands of our industry, together with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, require talent that is highly educated and/or has significant industry experience. Additionally, for certain key functions, we require specific scientific expertise to oversee and conduct R&D activities and the complex manufacturing requirements for biopharmaceutical products.

The biopharmaceutical industry is highly competitive and recruiting and retaining employees is critical to the continued success of our business. We are an equal opportunity employer and we are fundamentally committed to creating and maintaining a work environment in which employees are treated with respect and dignity. All human resources policies, practices and actions related to hiring, promotion, compensation, benefits and termination are administered in accordance with the principal of equal employment opportunity, meaning that they are made on the basis of individual skills, knowledge, abilities, job performance and other legitimate criteria and without regard to race, color, religion, sex, sexual orientation, gender expression or identity, ethnicity, national origin, ancestry, age, mental or physical disability, genetic information, any veteran status, any military status or application for military service, or membership in any other category protected under applicable law. By focusing on employee retention and engagement, we also improve our ability to support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our stockholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees.

Our base pay program aims to compensate management and staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our management team and staff members in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company. Our management team and staff members are eligible for the grant of equity awards under our long-term incentive program that are designed to align the experience of these staff with that of our stockholders. All management team and staff members also participate in a regular performance measurement process that aligns pay to performance and through which they receive performance and development feedback.

Our benefit programs are also generally broad-based, promote health and overall well-being and emphasize saving for retirement. All management team and regular staff members are eligible to participate in the same core health and welfare and retirement savings plans. Other employee benefits include employee stock purchase plan, medical plans, dental plans, vacation and sick-pay plans, employee assistance programs, flexible spending accounts, life and accident insurance and short and long-term disability benefits.

Our Compensation Committee provides oversight of our compensation plans, policies and programs.

As of March 25, 2025, we had 21 employees, including 9 in research and development and 12 in selling, general and administrative. At least 13 of our employees have advanced degrees of some sort (e.g., MD, PhD, DVM, JD, MBA). The Company strives for gender diversity and diversity beyond gender throughout the organization. Of our employees, 43% are male and 57% are female. From time to time, we also employ independent contractors to support our research, development and administrative organizations. None of our employees are represented by a collective bargaining unit, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

Executive Officers of the Registrant

Our executive officers and their ages as of March 25, 2025 are as follows:

Name	Age	Position
James E. Brown, D.V.M.	68	President, Chief Executive Officer and Director
Timothy M. Papp, M.B.A.	49	Chief Financial Officer
Norman L. Sussman, M.D.	72	Chief Medical Officer

James E. Brown, D.V.M., co-founded DURECT in February 1998 and has served as our President, Chief Executive Officer and on our Board of Directors since June 1998. He previously worked at ALZA Corporation as Vice President of Biopharmaceutical and Implant Research and Development from June 1995 to June 1998. Prior to that, Dr. Brown held various positions at Syntex Corporation, a pharmaceutical company, including Director of Business Development from May 1994 to May 1995, Director of Joint Ventures for Discovery Research from April 1992 to May 1995, and held a number of positions including Program Director for Syntex Research and Development from October 1985 to March 1992. Dr. Brown holds a B.A. from San Jose State University and a D.V.M. (Doctor of Veterinary Medicine) from the University of California, Davis where he also conducted post-graduate work in pharmacology and toxicology.

Timothy M. Papp, MBA, joined DURECT in July 2022 as Chief Financial Officer and brings over 25 years of corporate finance experience to DURECT, including 15 years in the Biopharma sector. Prior to joining DURECT, he was a Managing Director of Healthcare Investment Banking at RBC Capital Markets, LLC from 2020 to 2021. Previously he was a Managing Director of Healthcare Investment Banking at Stifel, Nicolaus & Company, Inc. (“Stifel”), where he worked from 2010 to 2020. Prior to Stifel, he was a Vice President of Healthcare Investment Banking at Cowen and Company, LLC (“Cowen”), where he worked from 2007 to 2010. Mr. Papp also held positions at KeyBanc Capital Markets Inc. and Rodman & Renshaw LLC prior to joining Cowen. Mr. Papp graduated from Duke University with a Bachelor of Science in economics and earned a Master of Business Administration from The Wharton School with a concentration in finance.

Norman L. Sussman, M.D., FAASLD, joined DURECT as Chief Medical Officer in November 2020. He has extensive clinical experience and expertise in the field of liver disease and brings over 30 years of clinical research and development experience in academia and industry. Prior to joining DURECT he was an Associate Professor of Medicine and Surgery at Baylor College of Medicine and a faculty member of Baylor College of Medicine intermittently since 1985. During that time, he served as a Principal Investigator for research focused on the assessment and management of acute liver failure and artificial liver support. Dr. Sussman gained leadership experience in industry as the founder and Vice President of both Amphioxus Cell Technologies from 1995 to 2003 and Hepatix, Inc from 1993 to 1995. Most recently, he has also served in senior leadership roles as a member of the Baylor Faculty Senate and as Director of the telehealth program, Project ECHO®, at Baylor St. Luke’s Medical Center. Dr. Sussman received his MBBCh from the University of the Witwatersrand in Johannesburg, South Africa. He then completed his residency at St. Louis University Hospital and his post-doctoral fellowship at Washington University. He is Board Certified in Internal Medicine, Gastroenterology, and Transplant Hepatology. Dr. Sussman is also a Fellow of the American Association of the Study of Liver Disease, which is a designation that recognizes his superior level of professional achievement in the field of hepatology.

Item 1A. Risk Factors.

In addition to the other information in this Annual Report on Form 10-K, 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.

Summary

- We will require and may have difficulty or be unsuccessful in raising needed capital in the future to continue to operate as a going concern
- We are dependent on the success of larsucosterol and the path to regulatory approval is uncertain; we cannot be certain that it will receive regulatory approval or be commercialized
- The FDA or other regulatory agencies may require more information or clinical studies for our product candidates, and our product candidates may never be approved
- We contract with third parties for the manufacture of larsucosterol and expect to continue to do so for any required additional clinical trials as well as the commercialization of larsucosterol. Our reliance on third parties increases the risk that submissions for regulatory approval of larsucosterol may be delayed or that we will not have sufficient quantities of larsucosterol available at an acceptable cost, which could delay, prevent or impair our development and commercialization efforts of larsucosterol
- Safety data and indications of activity from completed Phase 1 and 2 clinical trials of larsucosterol may not predict safety, activity or therapeutic efficacy in future trials
- Future clinical trials for larsucosterol may be delayed and may not demonstrate efficacy or safety
- The FDA’s Fast Track Designation and Breakthrough Therapy Designation of larsucosterol may not lead to a faster development or regulatory review or approval
- Open-label trials of larsucosterol in AH and MASH have inherent limitations
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates
- Key components of larsucosterol are provided by a limited number of suppliers, and supply shortages or loss of these suppliers could result in delays or interruptions in supply or increased costs
- Macroeconomic uncertainties have in the past impacted and may continue to adversely impact our business, including posing challenges to conducting clinical trials
- We do not control the commercialization of PERSERIS or Methydur
- Our ability to obtain revenues from the commercialization of POSIMIR and PERSERIS is uncertain
- For certain of our product candidates, we depend to a large extent on third-party collaborators, and we have limited or no control over their development, sales, distribution, disclosure, regulatory strategy or potential commercialization
- Our business strategy includes relying on third parties to support development, clinical trials, manufacturing and commercialization of product candidates
- Cancellation of third-party collaborations may adversely affect potential economic benefits

- Our cash flows are likely to differ from our reported revenues and earnings
- Failure to comply with governmental regulations could materially harm our business
- We have a history of operating losses, expect to continue to have losses and may never achieve or maintain profitability and we may not successfully manage our Company through varying business cycles
- We depend upon key personnel who may terminate their employment with us at any time, and we may not be able to attract and retain sufficient qualified personnel on a timely basis, if at all
- 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
- Our business involves environmental risks and risks related to handling regulated substances
- If we are unable to protect, maintain or enforce our intellectual property rights or secure rights to third-party intellectual property, or if our intellectual property rights are inadequate to protect our technology and product candidates, our competitive position could be harmed, we may lose valuable assets, lose market share or incur costly litigation or our third-party collaborators may choose to terminate their agreements with us
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed
- The markets for our pharmaceutical products and product candidates are rapidly changing and competitive, and new products or technologies developed by others could impair our ability to establish, maintain or grow our business and remain competitive
- Our relationships with physicians, patients and third-party payers are subject to anti-kickback, fraud and abuse, privacy 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
- We could be exposed to significant product liability claims and we are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages and reputational harm
- Healthcare reform measures could hinder or prevent our product candidates' commercial success
- Market acceptance of, and market opportunity for, our products or product candidates is uncertain, and failure to achieve market acceptance or adequate reimbursement from third-party payers will delay our ability to generate or grow revenues
- Inability to train physicians to use our products may prevent market acceptance of our products
- Our stock price does not currently meet the minimum bid price for continued listing on Nasdaq
- Our operating history makes evaluating our stock difficult and the price of our stock may be volatile
- Investors may experience substantial dilution of their investment
- Our ability to use net operating losses and other tax attributes is uncertain and may be limited
- We have broad discretion over the use of our cash and investments, which may not always yield a favorable return
- Our certificate of incorporation, bylaws and Delaware law could discourage an acquisition of us

- Having Delaware as the exclusive forum for substantially all disputes between us and our stockholders could limit our stockholders' ability to obtain a favorable judicial forum for disputes
- 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
- Because our Company is a "smaller reporting company," we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company

Risks Related To Our Business

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

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

Presently, we do not have sufficient cash resources to meet our plans for the next twelve months from the issuance of the financial statements included herein. Our recurring losses from operations, negative cash flows and need for additional capital raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2024. We will require additional financing to fund our operations or we will have to significantly curtail or discontinue our operations to conserve our capital resources. Additional funds may not be available on acceptable terms, if at all, and such availability will depend on a number of factors, some of which are outside of our control, including general capital markets conditions and investors' view of our prospects and valuation. In addition, our ability to raise capital in the public capital markets may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Annual Report on Form 10-K, we are only permitted to utilize the shelf registration statement subject to Instruction I.B.6. to Form S-3, which is referred to as the "baby shelf" rule. For so long as our public float is less than $75 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms. Further, investors' perception of our ability to continue as a going concern may make it more difficult for us to obtain financing, or necessitate that we obtain financing on terms that are more favorable to investors, and could result in the loss of confidence by investors, suppliers and employees. Our continued operations are contingent on our ability to raise additional capital or license or otherwise monetize our assets. If we do not acquire sufficient additional funding or alternative sources of capital to meet our working capital needs, we will have to substantially curtail or discontinue our operations, resulting in delays in the development of larsucosterol and in generating revenue.

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

- continued progress and cost of our research and development programs;
- progress with clinical trials, including a Phase 3 clinical trial for larsucosterol in AH;
- the time and costs involved in obtaining regulatory approvals, if any;

- costs involved in establishing manufacturing capabilities for pre-clinical, non-clinical, clinical and commercial quantities of our product candidates;
- success in entering into collaboration agreements and achieving milestones under such agreements;
- regulatory actions with respect to our products and product candidates;
- costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property rights;
- costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our products, products we have a financial interest in and, product candidates;
- competing technological and market developments;
- market acceptance of our products, products we have a financial interest in and, product candidates;
- costs for recruiting and retaining employees and consultants; and
- unexpected legal, accounting and other costs and liabilities related to our business.

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

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

Our business depends substantially on the successful development of larsucosterol, which has completed multiple clinical trials, including a Phase 2b clinical trial (AHFIRM) in patients with severe AH, topline results of which were announced in November 2023. The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant for each dose of larsucosterol versus placebo. Accordingly, future clinical trials will be required to establish clinically and statistically significant proof of efficacy, and sufficient evidence of safety to support regulatory approval. Our plan is to initiate a Phase 3 clinical trial of larsucosterol in AH, subject to obtaining sufficient funding, and present topline results within two years of initiation. There is no assurance that future clinical trials will establish efficacy of larsucosterol to treat AH or will not result in unanticipated side effects. If larsucosterol fails to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon development of larsucosterol, which would materially harm our business.

Larsucosterol may not be eligible to receive regulatory approval from the FDA or other regulatory agencies and begin commercialization for a number of years, if ever. This uncertainty may make it difficult to predict the timing or expense required to obtain regulatory approval for larsucosterol. If we are unable to reach an agreement with the FDA or other regulatory agencies regarding the development of larsucosterol, including the trial design for a Phase 3 clinical trial in AH for larsucosterol's clinical development, we may curtail, limit or discontinue our development activities for this product candidate. Even if we ultimately receive regulatory approval for larsucosterol, we or our potential future partners, if any, may be unable to commercialize it successfully for a variety of reasons. These include, for example,

the future availability of alternative, potentially superior or less expensive treatments, lack of cost-effectiveness, the lack of favorable access and/or commercial pricing, the cost or technical challenges of manufacturing the product on a commercial scale and competition with other treatments. The success of larsucosterol may also be limited by the prevalence and severity of any adverse side effects, including mortality.

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

The AHFIRM trial did not achieve the primary endpoint of a statistically significant difference in 90-day mortality or liver transplant for each dose of larsucosterol versus placebo. The failure to adequately demonstrate the safety and effectiveness of larsucosterol to the satisfaction of the FDA and other regulatory agencies will result in delays to the regulatory approval or non-approvability of larsucosterol. Future clinical trials, including the planned Phase 3 clinical trial of larsucosterol in AH, may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for larsucosterol or may require such significant numbers of patients or additional costs to make it impractical to satisfy the regulatory agency's requirements, and thus larsucosterol may not be approved for marketing. During the review process, the FDA or other regulatory agencies may request additional information regarding the efficacy or safety of larsucosterol and providing such additional information could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval or lead our Company to abandon the development of larsucosterol. Additionally, the FDA, or other regulatory agencies, may also request more information regarding the chemistry, manufacturing or controls related to larsucosterol, and answering such questions could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval or abandonment of larsucosterol. Even if larsucosterol receives FDA or other regulatory agency approval, the regulatory agency may require that we conduct additional clinical or non-clinical studies after such approval, place limitations on the use of our products in applicable labels, require marketing under a Risk Evaluation and Mitigation Strategy program, include commercially unattractive language in the approved product label, delay approval to market our products or limit the indicated use of our products, which may harm our business and results of operations.

We contract with third parties for the manufacture of larsucosterol and expect to continue to do so for any required additional clinical trials as well as the commercialization of larsucosterol. Our reliance on third parties increases the risk that submissions for regulatory approval of larsucosterol may be delayed or that we will not have sufficient quantities of larsucosterol available at an acceptable cost, which could delay, prevent or impair our development and commercialization efforts of larsucosterol

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

- our inability to identify and negotiate manufacturing and supply agreements with suitable manufacturers;
- delays in the development of manufacturing process technologies and stability testing;
- our inability to control manufacturing process development and its timing;

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

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

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is

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

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

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

- the FDA or other regulatory agencies disagreeing as to the design or implementation of our clinical trials;
- failure to agree with the FDA or other regulatory agencies regarding the trial design, including without limitation inclusion and exclusion criteria or primary and secondary endpoints;
- failure to reach, or delays in reaching, an agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to obtain institutional review board ("IRB") approval at each site;
- delays, suspension, or termination of clinical trials by the IRB responsible for overseeing the trial at a particular trial site;
- slower than expected rates of recruitment of patients or failure to recruit a sufficient number of patients;
- delays in manufacturing or delivery of drug product to clinical trial sites;
- patients dropping out of the trial after enrollment or withdrawing consent;
- clinical sites deviating from trial protocol, dropping out of a trial, or failing to comply with regulatory requirements;
- government, IRB, or other regulatory delays or “clinical holds” requiring suspension or termination of the trials;
- COVID-19, flu or other diseases having an adverse effect on patients’ willingness to participate in a trial;
- protocol amendments; and
- the availability of capital to conduct such future trials.

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

Moreover, success in future research, preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and non-clinical testing. Any future clinical trial process may fail to demonstrate that our potential drug candidates are safe for humans and effective for indicated uses.

This failure would cause us to abandon a drug candidate and may delay development of other potential drug candidates. Any delay in, or termination of, future non-clinical testing or clinical trials will delay the filing of any future investigational new drug application ("IND") and new drug application ("NDA") with the FDA or the equivalent applications with pharmaceutical regulatory authorities outside the United States and, ultimately, our ability to commercialize any potential drugs and generate product revenues.

The FDA's Fast Track Designation and Breakthrough Therapy Designation of larsucosterol may not lead to a faster development or regulatory review or approval

The FDA grants Fast Track Designation to therapies that are considered capable of addressing unmet medical needs and possess the potential to treat serious or life-threatening disease conditions in order to facilitate its development and expedite the review procedure. Additionally, the FDA grants Breakthrough Therapy Designation to expedite its review of potential new drugs for serious or life-threatening diseases where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast Track program, as well as intensive FDA guidance on the product's development program.

Even though larsucosterol has received both Fast Track Designation and Breakthrough Therapy Designation for the treatment of AH, we may not experience a faster development process, review or approval compared to conventional FDA procedures, or receive FDA approval at all, in that indication or any other. Such designations do not change the standards for approval. The FDA may also withdraw such designations if it believes that they are no longer supported by data from our clinical development program.

In addition, the statutes and regulations that define the timelines and criteria for approval of drugs and biologics are subject to change by the U.S. Congress and the responsible administrative agencies. For example, the Prescription Drug User Fee Act ("PDUFA") authorizes the FDA to collect fees and use them for the review of human drug applications and defines the review time targets for such applications. The current legislative authority for PDUFA will expire in September 2027. New legislation will then be required for the FDA to continue collecting prescription drug user fees in future fiscal years and for manufacturers to have clarity regarding the time the FDA will spend in review before granting regulatory approval. If PDUFA reauthorization is not completed in the future, the review and approval times for new drugs like larsucosterol could be significantly longer than currently expected, which could delay potential marketing approval and launch.

Open-label trials of larsucosterol in AH and MASH have inherent limitations

Certain previously completed AH and MASH trials of larsucosterol were open-label trials with no control groups. Open label trials have inherent risk of bias given that the patients and physicians know that the patients 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. Additionally, larger placebo-controlled clinical trials are required to evaluate the safety and efficacy of larsucosterol to treat any indication, including AH and MASH. There can be no assurance that ongoing or future studies will demonstrate the safety or efficacy of larsucosterol in a statistically significant or clinically meaningful manner.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates

We may experience delays in completing our preclinical studies and initiating or completing clinical trials, and we may experience numerous unfavorable events during, or as a result of, any future clinical

trials that we may conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators, institutional review boards ("IRBs"), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at one or more prospective trial sites;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites. We may be forced to accept unfavorable contract provisions in such agreements based on country, territory or local laws or requirements of institutions or IRBs where important clinical investigators practice;
- clinical trials of our product candidates have in the past and may in the future produce negative or inconclusive results, clinical trial subjects receiving placebo or placebo may experience better than expected outcomes, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- clinical trial sites or clinical investigators may not comply with the study protocol or applicable laws;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates.

We could encounter delays if a clinical trial is delayed, suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, changes in clinical trial design, safety issues or adverse side effects, failure to demonstrate a benefit from using a product, or changes in governmental regulations or administrative actions. We may also delay, suspend or terminate a clinical trial due to a lack of adequate funding to commence or continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to

the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our ongoing or future preclinical or clinical development programs may harm our business, financial condition and prospects significantly.

Key components of larsucosterol are provided by a limited number of suppliers, and supply shortages or loss of these suppliers could result in delays or interruptions in supply or increased costs

We purchase larsucosterol from a third-party supplier and we currently have a third-party sole manufacturer for GMP supplies of larsucosterol. The third-party supplier is our sole manufacturer of the larsucosterol drug substance and the third party manufacturer is our sole source for the drug product required for development and commercialization of our larsucosterol drug candidate.

The reliance on a sole or limited number of manufacturers and suppliers could result in:

- an inability to obtain an adequate supply of larsucosterol, which may be exacerbated by trade wars or other governmental action related to tariffs or trade agreements;
- delays associated with finding and contracting with a new supplier/manufacturer (if we can find one capable of replacing the old supplier and negotiate commercially reasonable terms) and then transferring the know-how and technology required to perform the services to the new supplier; and
- reduced control over pricing, quality and delivery time.

There can be no assurance that we will receive sufficient quantities of larsucosterol to commence and conduct the non-clinical trials, clinical trials and CMC activities we are planning, and delays in supply or manufacturing could delay development of larsucosterol. In addition, if additional third parties in our supply chain are adversely impacted by restrictions resulting from macroeconomic events, including staffing shortages, trade wars or other governmental action related to tariffs or trade agreements, raw material shortages, production slowdowns and/or 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 products and product candidates, but do not have in place long term supply agreements with respect to all of the components of any of our products or product candidates. Therefore, the supply of a particular component could be terminated without our consent 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 commercially reasonable quantity, quality, cost and timing. In addition, certain of our suppliers may encounter delays in providing their services. Any interruption in the supply of single source components (including active pharmaceutical ingredients, excipients, or components like vials, stoppers, filters and the like), products or product candidates, could cause us to seek alternative sources of supply or attempt to 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 products or 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 obtain commercial product supplies or 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. Supply chain disruptions have affected and may continue to affect the manufacturing and shipment of goods globally. Any delay in production or delivery of the components and drug substances used in our products or product candidates for any reason, could adversely impact our business and hinder our growth.

Macroeconomic uncertainties have in the past impacted and may continue to adversely impact our business, including posing challenges to conducting clinical trials

Global economic and business activities continue to face widespread macroeconomic uncertainties, including labor shortages and supply chain disruptions, inflation and monetary supply shifts, as well as recession risks, which may continue for an extended period, which 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 have an adverse impact on our business operations and financial condition. Further, such macroeconomic uncertainties may also adversely impact our ability to raise additional capital to provide sufficient funding to continue our product development efforts, including clinical trials, which would make it more difficult for companies such as ours to access capital.

Additionally, inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, increased manufacturing costs and clinical trial costs, weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience cost increases.

The extent to which such macroeconomic uncertainties impact our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence. As a result, there have been and may continue to be longer lead times required for acquiring components and supplies used in manufacturing of larsucosterol. We may continue to 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 or safety precautions imposed or recommended by federal, state or local 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 certain diseases;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- disruption or delays in manufacturing of clinical and commercial supplies due to issues experienced by our contract manufacturing organizations and/or shortages and delays in obtaining raw materials and supplies required in the manufacturing processes;

- interruption of or delays in receiving supplies of our products and product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages, prioritization of other activities over ours 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, clinical trials, and manufacturing activities including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; and
- material delays and complications with respect to our research and development programs.

We do not control the commercialization of PERSERIS or Methydur

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

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

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

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

Our performance for certain of our product candidates depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain regulatory approvals. We have entered into agreements with Indivior and Orient Pharma under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute certain products or product candidates, subject to payments to us in the form of product royalties, earn-out and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these product candidates, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Enforcing any of these agreements in the event of a breach by the other party could require the expenditure of significant resources and consume a significant amount of management time and attention. Our collaborators may also conduct their activities in a manner that is different from the manner we would recommend or would have chosen had we been developing such product candidates ourselves. Further, our collaborators may elect not to develop or commercialize product candidates arising out of our collaborative arrangements or

not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these product candidates. If any of these events occur, we may not recognize revenue from the commercialization of our product candidates based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our products or product candidates. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Our business strategy includes relying on third parties to support development, clinical testing, manufacturing and commercialization of our products and product candidates.

Our current business strategy includes reliance on third-party CROs, consultants, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our products and product candidates, including, but not limited to larsucosterol and others. For example, we currently depend on third-party vendors to manage and monitor most of our clinical trials. We rely on third parties to manufacture or perform manufacturing steps relating to our products, product candidates and 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 products and product candidates. Third parties may not execute their responsibilities and tasks competently in compliance with their contractual obligations to us, applicable laws and regulations or in a timely or cost-effective 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 or commercialization of our products, increase our expenses and materially harm our business, financial condition, results of operations and access to capital.

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

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

Our cash flows are likely to differ from our reported revenues and earnings

Our revenues and earnings may differ from our cash flows from revenue-generating activities. Upfront payments received upon execution of collaborative agreements may be recorded as deferred revenue, in which case they would be recognized over the period of performance for the related 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. Assumptions related to revenue recognition for performance obligations provided over time are reviewed in each accounting period and changes are recorded in the current period. In certain circumstances, changes in assumptions related to the measure of progress for a performance obligation performed over time could result in negative revenue or the acceleration of revenue for an accounting period.

Failure to comply with governmental regulations could materially harm our business

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 or surveillance. 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 value of our products or 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, good laboratory practice and/or other governmental requirements for drug development;
- failure to obtain approvals for commercially valuable intended uses of our products and product candidates; or
- FDA required product withdrawals, clinical holds or warnings arising from identification of serious adverse side effects in our products and product candidates.

Manufacturers of drugs must comply with the applicable FDA GMP 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 GMP 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 products and product candidates. We and/or our present or future suppliers and distributors may be unable to comply with the applicable GMP regulations and other FDA and/or foreign regulatory requirements. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our products or product candidates we or they manufacture, the FDA or foreign equivalents may refuse or withdraw marketing clearance or approvals, put our or our partner’s clinical trial on hold, withdraw or reject an IND application or NDA, or require product recall, which may cause interruptions or delays in the development, manufacture and sale of our products and product candidates.

We have a history of operating losses, expect to continue to have losses and may never achieve or maintain profitability and we may not successfully manage our Company through varying business cycles

We have incurred significant operating losses since our inception in 1998 and, as of December 31, 2024, had an accumulated deficit of approximately $597.3 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, manufacture and market our proposed product candidates and successfully commercialize our approved products. Development of pharmaceutical product candidates is costly and requires significant investment. In addition, we may choose to license from third parties either rights to particular drugs or other appropriate technology and/or intellectual property rights for use in our products and product candidates. The license fees as well as the operating costs of using or developing these technologies or rights would increase the costs of our products and product candidates as well as our operating costs generally.

Our revenues over the last two years are from earn-out payments from Indivior related to sales of PERSERIS, from certain excipient sales, from royalty payments from Orient Pharma related to sales of

Methydur in Taiwan, from payments under collaborative research and development agreements with third parties and from royalties from Innocoll related to POSIMIR. We do not expect that our revenues will exceed our operating expenses in the near future. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our products and product candidates in the near future, do not expect to receive additional milestone payments in the near term due to the termination of the Innocoll Agreement or meaningful royalties from POSIMIR until the product achieves meaningful sales (if ever) and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

Our success will depend in part 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 COVID-19 pandemic, from 2020 to 2022, we required most of our personnel, including all of our administrative employees, to work remotely, restricted on-site staff to only mandatory personnel, implemented social distancing on-site, and closed certain of our offices temporarily. While we have switched to a hybrid remote model, our continued reliance on personnel working remotely makes us more susceptible to reduced productivity, disruptions, delays, and other adverse impacts on our business. In addition, this model 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 mitigate similar future cycles, we may expand or contract our facilities, our operational, financial and management systems and our personnel. If we are unable to manage growth and contractions effectively, our business would be harmed.

We depend upon key personnel who may terminate their employment with us at any time, and we may not be able to attract and retain sufficient qualified personnel on a timely basis, if at all

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. The market for qualified personnel in the San Francisco Bay Area is very competitive and 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. We have reduced our headcount from 58 as of March 26, 2024 to 21 as of March 25, 2025 through targeted headcount reductions and the sale of the ALZET product line. We may need to terminate additional employees to maintain our operations. 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 our Company’s operations.

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 business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials, products 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 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. 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.

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, investors may 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 as well as our ability to raise capital may be negatively affected.

Delays or difficulties in the enrollment of subjects in clinical trials may increase our overall development expenses and delay clinical trial data and receipt of necessary regulatory approvals

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects and/or patients within a reasonable period of time. 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. 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 larsucosterol if we are unable to sign and maintain sufficient clinical sites, locate and enroll a sufficient

number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities, 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 enrolled in these trials 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 many factors including:

- the eligibility criteria for the trial in question;
- the prevalence and incidence of the conditions being studied;
- challenges with patient access, hospital prioritization, clinical trial staff availability, ability to collect, ship and analyze patients' biological samples, availability of personal protective equipment, swabs, reagents and other materials and supplies;
- 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 and maintain 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 approvals, which would cause the value of our Company to decline and limit our ability to obtain additional financing.

Changes in tax law could adversely affect our business and financial condition

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. Many such changes have been made in the past and changes are likely to continue to occur in the future. For example, on March 11, 2021, President Biden signed into law the "American Rescue Plan Act", which included extenders to the refundable employee retention credit under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act and limitations to executive compensation effective for tax years beginning after 2026. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

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

We may choose to develop our own sales force and commercial group to market larsucosterol, if approved, or other products that we may develop in the future. 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 and provide that commercial team with sufficient financial and other resources, we may not be able to effectively launch or commercialize these or any other products. We may not be able to effectively sell our products and 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 (including Indivior and Orient Pharma) 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, where applicable, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, where applicable, may be unable to engage qualified distributors. Even if engaged, these collaborators and distributors may:

- fail to adequately market our products or product candidates;
- fail to satisfy financial or contractual obligations to us;
- cease operations, terminate our collaboration or re-allocate resources away from our products or product candidates 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 products or product candidates; or
- build up inventory in excess of demand thereby limiting future purchases of our products or product candidates resulting in significant quarter-to-quarter variability in our sales.

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

Write-offs related to impairment of goodwill, long-lived assets, inventories and other non-cash charges may adversely impact profitability and cause cash flows to differ from reported earnings

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 $2.7 million at December 31, 2024 after the sale of the ALZET product line. 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 2024 and determined that goodwill was not impaired as of December 31, 2024. 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 products and 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 expire 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.

Global credit and financial market conditions could negatively impact the value of our investments

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 of one year or beyond from the balance sheet date. 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.

Our corporate headquarters and personnel are located in a seismically active area near wildfire zones

Our corporate headquarters 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 or power outage or power shortage occur, 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.

If we seek approval to commercialize our current or future drug candidates outside of the United States, a variety of risks associated with international operations could harm our business

If we seek approval of our current or future drug candidates outside of the United States, we expect that we will be subject to additional risks including:

- different regulatory requirements for approval of therapies in foreign countries;
- the potential for reduced protection for intellectual property rights;
- the potential requirement of additional clinical studies in international jurisdictions;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters and public health pandemics.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in and outside of Europe with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their own products in foreign countries to be very challenging.

Risks Related to Our Intellectual Property

If we are unable to protect, maintain or enforce our intellectual property rights or secure rights to third-party intellectual property, or if our intellectual property rights are inadequate to protect our technology and product candidates, our competitive position could be harmed, we may lose valuable assets, lose market share or incur costly litigation 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. The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There can be no assurance that the pending patent applications will be granted, and if granted, they may fail to result in issued patents with claims that cover our product candidates or technologies.

As of March 25, 2025, we owned or exclusively in-licensed over 15 unexpired issued U.S. patents and over 145 unexpired issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have over 15 pending U.S. patent applications and over 95 foreign applications pending in Europe, Australia, Japan, Canada and other countries.

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 certain of these patent families.

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. Even if patents have been issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Changes in either the patent laws or interpretation of the patent laws in the United States or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. 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 certain of these patent families. 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. Moreover, patents have a limited lifespan. In the United States and in many other countries, the natural expiration of a patent is generally 20 years after it is filed, and once any patents covering a product expire, generic competitors may enter the market. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law, if at all. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed

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 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 also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may be subject to claims challenging the inventorship of our patents and other intellectual property

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual

property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and our patent protection could be reduced or eliminated for non-compliance with these requirements

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in premature abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

We may be involved in lawsuits and other legal proceedings to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Any such adverse result or determination could have a material adverse effect on our business.

Competitors may infringe our issued patents or any patents issued as a result of our pending or future patent applications. 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. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. 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. In addition, in some circumstances our collaborators have the first right to enforce our patents against third party infringers, and such collaborators may not enforce such claims adequately or successfully or in the manner that we would do ourselves. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and, even if resolved in our favor, are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the

initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates, and there may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. We or our collaborators may be exposed to future litigation by third parties based on claims that our products, product candidates or activities infringe the intellectual property rights of others. We may also be subject to claims asserting that we, our collaborators, our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. These risks are 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 and business prospects. We also may not have sufficient funds to litigate, particularly 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 successfully 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 products or product candidates that incorporate the challenged intellectual property;
- 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 products or product candidates, which would be costly and time-consuming and may not be successful.

Our collaboration agreements may depend on our intellectual property

We are party to collaborative agreements with Orient Pharma, 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 disputes which we would otherwise spend on our business.

Risks Related To Our Industry

The markets for our pharmaceutical products and product candidates are rapidly changing and competitive, and new products or technologies developed by others could impair our ability to establish, 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 products, 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 larsucosterol, if approved, will depend on the specific indication(s) for which larsucosterol is approved. Alfasigma S.p.A., Nterica Bio, Inc., Aldeyra Therapeutics, Inc., Surrozen, Inc. and several academic institutes, including Yale University, and others have development plans for products or evaluating marketed products to treat AH.

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 products and product candidates. Our competitors may develop products that are safer, more effective or less costly than our products and product candidates and, therefore, present a serious competitive threat to our product candidates and product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products and product candidates if commercialized. 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 products and product candidates to receive widespread acceptance if and when commercialized.

Our relationships with physicians, patients and third-party payers are subject to anti-kickback, fraud and abuse, privacy 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 and our partners 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 and our partners may 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;
- 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, 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; and
- HIPPA and other state and foreign laws governing the privacy and security of health information or other personal information, such as the European Union General Data Protection Regulation ("GDPR") (EU 2016/679), which require limitations regarding access and use of certain personal and health information.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare and privacy laws and regulations do and will in the future 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 or privacy 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.

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 products and product candidates involve an inherent risk that product liability claims will be asserted against us. Our present product liability insurance may be inadequate and may not fully cover the costs of any claim(s) or any ultimate damages we might be required to pay. Product liability claims or other claims related to our products and 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 products or product candidates if and when approved. A product liability claim could also significantly harm our reputation and delay or prevent market acceptance of our products and product candidates.

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs, 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 or product candidates for which we obtain marketing approval and otherwise affect our future revenue and profitability and the future revenue and profitability of our collaborators or potential collaborators. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For examples of healthcare reform measures, see "Part I, Item 1. Business—Government Regulation—Healthcare Reform" above.

Market acceptance of, and market opportunity for, our products or product candidates 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 products or products we have licensed to others, including larsucosterol, if approved. Even if approved for marketing, this product candidate may not achieve market acceptance or the market opportunities for our current and potential future product candidates may be smaller than we predicted, which could adversely affect our future product revenues and could cause our business to suffer. The degree of market acceptance will depend upon a number of factors, including:

- the degree of unmet need in the market for the approved indication(s);
- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the approved product labeling;
- pricing, reimbursement and formulary access;
- the degree of resources applied to promotion and other commercial activities;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapies; and
- pricing, access and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of the products we have developed. If these products do not achieve widespread market acceptance, we will not achieve meaningful revenues.

If we or our third-party collaborators are unable to train physicians to use our products and product candidates to treat patients' diseases or medical conditions, we may not achieve market acceptance of our products

Broad use of certain of our products or out-licensed products will require extensive training of numerous physicians on their proper and safe use. The time required to train physicians could delay adoption of our products and adversely affect market acceptance of our products. We or third parties selling our products may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our products. Any delay in training would materially delay the demand for our products and harm our business and financial results. In addition, we or our partners 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.

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

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, access and/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 current and future products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations ("HMOs"). Third-party payers often limit access, payments and/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 access, 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.

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

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 or tariffs making it more difficult or costly for us to export our products to those countries. The imposition of additional tariffs by the United States could result in the adoption of additional tariffs by other countries. These measures could result in increased costs for goods imported into the United States. A potential resulting trade war could have a significant adverse effect on world trade and the world economy. 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.

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, access to capital and results of operations.

Risks Related To Our Common Stock

Our stock price does not currently 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

On January 9, 2025, we received a written notification from The Nasdaq Stock Market LLC ("Nasdaq") informing us that because the closing bid price of our common stock was below $1.00 for 30 consecutive trading days (the "Minimum Closing Bid Price Requirement"), our shares no longer complied with the Minimum Closing Bid Price Requirement for continued listing on Nasdaq under Nasdaq Marketplace Rule 5550(a)(2) (the "Nasdaq Marketplace Rules"). We have until July 8, 2025 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.

If we do not regain compliance during the compliance period, then Nasdaq may grant us a second 180 calendar day grace period to regain compliance, provided we (i) meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for Nasdaq, other than the Minimum Closing Bid Price Requirement, and (ii) we notify Nasdaq of our intent to cure the deficiency. One strategy to regain compliance in such circumstances would be to implement a reverse stock split. For example, we implemented such a strategy to regain compliance with the Minimum Closing Bid Price Requirement when we completed a 1-for-10 reverse stock split in December 2022. We could also appeal Nasdaq's determination to delist our securities to a Hearings Panel. During any appeal process, shares of our common stock would continue to trade on The Nasdaq Capital Market.

There can be no assurance that we will regain compliance with the requirements for listing our common stock on The Nasdaq Capital Market. Delisting could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Additionally, there can be no assurance that a reverse stock split would result in a per-share market price that will maintain compliance with the Minimum Closing Bid Price Requirement, that will attract institutional investors or investment funds or that such share price will satisfy investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock could decline. Further, if the market price of our common stock declines, the percentage decline may be greater than would have occurred in the absence of a reverse stock split.

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 a limited number of approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals 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 expect to require additional funds to complete the development of larsucosterol or our other product candidates, and to fund operating losses to be incurred in the next several years.

The price of our common stock may be volatile

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. Price declines in our common stock have in the past and could in the future result from general market and economic conditions and a variety of other factors, including:

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

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has periodically experienced extreme price and volume fluctuations. For example, trade wars and other governmental actions, pronouncements by the Federal

Reserve, inflation, outbreaks of war such as between Russia and Ukraine or Israel and Hamas, oil price volatility and other factors have caused broad stock market and industry fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

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

Investors may experience substantial dilution of their investment

In order to raise capital and for other purposes, we have in the past and 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 the past we have engaged in equity financings that have resulted in dilution to our existing stockholders. In August 2024, we filed the 2024 Registration Statement to offer up to $250.0 million of securities from time to time in one or more public offerings. As of March 25, 2025, we had up to $250.0 million of our securities available for sale under the 2024 Registration Statement. However, due to the SEC's "baby shelf" rules discussed above, only up to approximately $8.7 million of our securities are available for sale under the 2024 Registration Statement. Any sales in the public market of our common stock in offerings under our shelf registration statement or otherwise, could adversely affect prevailing market prices for our common stock. In addition, investors have in the past and could in the future experience substantial dilution of their investment as a result of subsequent exercises of outstanding warrants to purchase our common stock.

As of December 31, 2024, common warrants to purchase 3,591,027 shares of our common stock were outstanding. In addition, as of December 31, 2024, 275,000 shares of our common stock were issuable from outstanding restricted stock units under our stock option plan, 4,619,287 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 $6.59 per share, 1,844,180 additional shares of common stock were reserved for potential future issuance under our stock option plan, and an aggregate of 49,667 shares of common stock were reserved for potential future issuance under our 2000 Employee Stock Purchase Plan. At December 31, 2024, we had 350,000,000 authorized shares of common stock and, as such, we have the ability to issue significantly more shares and options in the future, which would result in substantial dilution to our stockholders, including investors in this offering.

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 any or 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 (the "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 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.

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 made and used. We may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

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 our Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our 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.

Because our Company is a "smaller reporting company," we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company

We are a "smaller reporting company" as defined in the Exchange Act. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze our Company's results of operations and financial prospectus in comparison with other public companies.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy:

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things, operational risks; intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy or security laws and other litigation and legal risk; and reputational risks.

We also maintain an incident response plan to coordinate the activities we take to protect against, detect, respond to and remediate cybersecurity incidents, as such term is defined in Item 106(a) of Regulation S-K, as well as to comply with potentially applicable legal obligations and mitigate brand and reputational damage.

We have implemented several cybersecurity processes, technologies, and controls to aid in our efforts to identify, assess, and manage material risks, as well as to test and improve our incident response plan. Our approach includes, among other things:

- We conduct regular network and endpoint monitoring, vulnerability assessments, and penetration testing to improve our information systems, as such term is defined in Item 106(a) of Regulation S-K. Disaster Recovery is tested using various methods such as recovery exercises to simulate a response to a cybersecurity incident, and we use the findings to improve our security, processes, procedures and technologies.
- Regular cybersecurity training programs are in place for employees, management and directors. In addition, we conduct annual customer data handling and use requirements training for all employees.
- We compare our processes to standards set by the NIST.
- Incident handling incorporates the NIST incident handling framework to develop our cybersecurity response procedures and to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident.
- We routinely identify and filter out potential threats through threat intelligence processes, attack signatures, and geographic IP filtering.
- We closely monitor emerging data protection laws such as GDPR and carefully implement changes to our processes when required for compliance.
- We conduct regular phishing email simulations for all employees to enhance awareness and responsiveness to such possible threats.
- Through policy, practice and contract (as applicable), we require employees, as well as third-parties who provide services on our behalf, to treat customer information and data with care.
- We maintain cybersecurity insurance coverage.

Our process for identifying and assessing material risks from cybersecurity threats incorporates a risk matrix for identifying risk levels for interconnected systems. As part of this process appropriate disclosure personnel will collaborate with subject matter specialists, as necessary, to gather insights for identifying and assessing material cybersecurity threat risks, their severity, and potential mitigations.

As part of the above approach and processes, we regularly engage with assessors, consultants and other third-parties to review various parts of our cybersecurity program to help identify areas for continued focus, improvement and/or compliance.

Our processes also address oversight and identification of cybersecurity threat risks from our use of third-party service providers, including those in our supply chain. This involves, among other things, conducting pre-engagement risk-based diligence, implementing contractual security and notification provisions, and ongoing monitoring as needed.

We describe whether and how risks from identified cybersecurity threats have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, included as part of our risk factor disclosures at Item 1A of this Annual Report on Form 10-K, which disclosures are incorporated by reference herein.

In the last two fiscal years, we have experienced no material cybersecurity incidents, and the expenses we have incurred from any cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance:

Cybersecurity is an important part of our risk management processes and an area of increasing focus for our Board of Directors (our “Board” or “Board of Directors”) and management.

The audit committee of our Board (the "Audit Committee") is responsible for the oversight of risks from cybersecurity threats. At least annually, the Audit Committee receives an overview from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, Audit Committee members generally receive materials including a cybersecurity scorecard and other materials indicating current and emerging cybersecurity threat risks, and describing our ability to mitigate those risks, and discusses such matters with our Executive Director of IT. Members of the Audit Committee and the full Board are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Materials of our cybersecurity threat risk management and strategy processes are also periodically reviewed with the full Board.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Executive Director of IT. This individual has over 25 years of prior work experience in various roles involving: managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs, and developing and implementing IT change control policies and procedures, as well as holds several relevant degrees and certifications, including a master’s degree in Computer Information Systems, Certified in Security+, and has completed extensive cybersecurity training and testing in: Certified Professional Hacker (EMC White Hat Training), ISC2 Certified Information Systems Security Professional (CISSP) Training, and NIST Framework Development and Deployment.

Our Executive Director of IT is informed about and monitors the prevention, mitigation, detection, and remediation of cybersecurity incidents through management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. If a cybersecurity incident is determined to be a material cybersecurity incident, our incident response plan and cybersecurity disclosure controls and procedures define the process to disclose such a material cybersecurity incident.

As discussed above, our Executive Director of IT reports to our CEO and informs the members of the Audit Committee and the full Board about cybersecurity threat risks, among other cybersecurity related matters. All executives attend cybersecurity training annually.

Item 2. Properties.

The following chart indicates the facilities that we lease, the location and size of each such facility and their designated use.

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

We believe that our existing facilities are adequate to meet our current and foreseeable requirements.

Item 3. Legal Proceedings.

We are not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "DRRX".

Holders

As of March 25, 2025, there were approximately 69 holders of record of shares of our common stock. This does not include the number of persons whose stock is in nominee or "street name" accounts through brokers.

Dividend Policy

We have never paid cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying any cash dividends in the foreseeable future.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. 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 as of December 31, 2024 and 2023 should be read in conjunction with our financial statements, including the Notes thereto, and "Risk Factors" section included elsewhere in this Annual Report on Form 10-K. References to the "Company," "DURECT," "we," "us" and "our" refer to DURECT Corporation.

Unless otherwise noted, this Management's Discussion and Analysis of Financial Condition and Results of Operations relates solely to our continuing operations and does not include the operations of our ALZET product line. See "ALZET Commercial Product Line" in Part I, Item 1, above and Note 11. Discontinued Operations of our financial statements in this Annual Report on Form 10-K for additional information.

Special Note Regarding Forward-Looking Statements

This Form 10-K 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 Annual Report on Form 10-K or elsewhere by management from time to time, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "could," "potentially," "possibility," and similar expressions are forward-looking statements. Such forward-looking statements contained herein are based on current expectations and beliefs. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors.

Forward-looking statements made in this report include, but are not limited to, statements about:

- potential uses and benefits of larsucosterol to treat alcohol-associated hepatitis ("AH"), metabolic dysfunction-associated steatohepatitis ("MASH"), or other conditions;
- the potential benefits of Breakthrough Therapy Designation and Fast Track Designation;
- the results and timing of clinical trials, including clinical trial plans and timelines for larsucosterol;
- the likelihood of future clinical trial results of larsucosterol being positive with statistical significance and/or similar to results from previous trials, the possible commencement of future clinical trials;
- our communications with the U.S. Food and Drug Administration ("FDA") regarding the trial design for a Phase 3 clinical trial for larsucosterol in AH and our ability to confirm the efficacy and safety of larsucosterol in AH patients to support a New Drug Application filing with the FDA;
- our plans and ability to obtain sufficient capital resources to initiate a Phase 3 clinical trial of larsucosterol in AH and present topline results within two years of initiation;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our products and product candidates, including larsucosterol;
- the potential milestone, sub-license fees and royalty payments we may receive from Orient Pharma Co., Ltd.;
- market opportunities for product candidates in our product development pipeline;
- potential regulatory filings for or approval of larsucosterol;

- the progress and results of our research and development programs and our evaluation of additional development programs;
- requirements for us to purchase pre-clinical, clinical trial and commercial supplies of product candidates and/or products, as well as raw materials or active pharmaceutical ingredients from third parties, and the ability of third parties to provide us with our requirements for such supplies and raw materials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval and timing of responses to our regulatory submissions;
- the impact of FDA, European Medicines Agency and other government regulation on our business;
- our ability to obtain, assert and protect patents and other intellectual property rights, including intellectual property licensed to our collaborators, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with our products and the product candidates we develop and/or license to third-party collaborators;
- our employees, including the number of employees and the continued services of key management, technical and scientific personnel;
- our future performance, including our anticipation that we will not derive meaningful revenues from our products and product candidates in development for at least the next twelve months, potential for future inventory write-offs and our expectations regarding our ability to achieve profitability;
- sufficiency of our cash resources, anticipated capital requirements and capital expenditures, our need or desire for additional financing, including potential sales under our shelf registration statement and our ability to continue to operate as a going concern;
- our expectations regarding research and development expenses, and selling, general and administrative expenses;
- the composition of future revenues; and
- accounting policies and estimates.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. 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 as well as the "Overview" and "Results of Operations" sections of this Management's Discussion and Analysis of Financial Condition. 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 ("SEC").

This discussion and analysis generally addresses 2024 and 2023 items and year-over-year comparisons between 2024 and 2023. Discussions of 2022 items and year-over-year comparisons between 2023 and 2022 that are not included in this Annual Report on Form 10-K can be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our

Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024, which is available free of charge on the SEC's website at www.sec.gov and the investor relations section of our website at www.durect.com/investors/sec-filings/. These website addresses are intended to be inactive, textual references only. None of the materials on, or accessible through, these websites are part of this report or are incorporated by reference herein.

Overview

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

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

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

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

Collaborative Research and Development and Other Revenue

Collaborative research and development and other revenue consists of four broad categories: (a) the recognition of upfront license payments over the period of our continuing involvement with third parties, (b) the reimbursement of qualified research expenses by third parties, (c) milestone payments in connection with our collaborative agreements and (d) royalties and earn-out payments from our agreements with third parties. During the last two years, we generated collaborative research and development revenues from collaborative agreements with Innocoll and others.

Product Revenue

We currently generate product revenue from the sale of certain key excipients used by pharmaceutical companies as raw materials in certain of their products, including Methydur and a marketed animal health product.

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

Operating Results

Since our inception in 1998, we have generally had a history of operating losses. At December 31, 2024, we had an accumulated deficit of $597.3 million. Our net losses were $8.3 million and $27.6 million for the years ended December 31, 2024 and 2023, respectively. These losses have resulted primarily from costs incurred to research and develop our product candidates and, to a lesser extent, from selling, general and administrative costs associated with our operations and product sales. We expect our

research and development expenses and our selling, general and administrative expenses to decrease in 2025 compared to 2024. We expect to incur continuing losses and negative cash flows from operations for the foreseeable future. As disclosed in the “Liquidity and Capital Resources” section, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We believe that the most significant accounting estimates and assumptions relate to revenue recognition, prepaid and accrued clinical costs, prepaid and accrued manufacturing costs, and valuation of warrant liabilities. We base our estimates on historical experience, current circumstances and various other assumptions that our management believes to be reasonable under the circumstances. In many instances, we could reasonably use different accounting estimates, and in some instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that the critical accounting estimates discussed below are critical to understanding our historical and future performance, as these estimates involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations of the registrant.

Revenue Recognition

Product Revenue, Net

We manufacture and sell certain excipients used by pharmaceutical companies as raw materials in certain of their products, including Methydur and a marketed animal health product. Prior to the sale of the ALZET product line in November 2024, we also manufactured and sold ALZET miniature osmotic pumps used in laboratory research.

Revenue from product sales is recognized when the customer obtains control of our product, which occurs at a point in time, typically upon shipment to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Trade Discounts and Allowances: We provide certain customers with discounts that are explicitly stated in our contracts and are recorded as a reduction of revenues in the period the related product revenue is recognized.

Product Returns: Consistent with industry practice, we generally offer customers a limited right of return for products that have been purchased from us. We estimate the amount of our product sales that are probable of being returned by our customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return liabilities primarily using our own historical sales information. We expect product returns to be minimal.

Collaborative Research and Development and Other Revenue

Royalties and Earn-outs: For our arrangements that include sales-based royalties or earn-outs, including milestone payments based on first commercial sale or the level of sales, and the license is deemed to be the predominant item to which the royalties relate, 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 or earn-out has been allocated has been satisfied (or partially satisfied).

Research and development services: Revenue from research and development services that are determined to represent a distinct performance obligation related to services performed under the collaborative arrangements with our third-party collaborators is recognized over time as the related research and development services are performed. We evaluate the measure of progress each reporting period and recognize revenue on a cumulative catch-up basis, as collaborative research and development revenue. We perform analytical services for counterparties and recognize revenue upon completion of these services. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreement.

We receive payments from our 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 we performs our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do 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.

Prepaid and Accrued Clinical Costs

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

Common Stock Warrants

We review the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, we may issue freestanding options and warrants.

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

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

Results of Operations

Comparison of years ended December 31, 2024 and 2023

Revenue

Collaborative research and development and other revenue

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

We expect our collaborative research and development and other revenue to fluctuate in future periods pending our efforts to enter into potential new collaborations, 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 revenue associated with our major collaborators or counterparties were $1.9 million and $2.3 million in 2024 and 2023, respectively. The collaborative research and development and other revenue included (a) amounts related to earn-out revenue from Indivior with respect to PERSERIS net sales, (b) feasibility programs and research and development activities funded by our collaborators or counterparties, (c) royalty revenue from Orient Pharma with respect to Methydur net sales and (d) royalty revenue from Innocoll with respect to POSIMIR net sales. The decrease in collaborative research and development and other revenue in 2024 compared with 2023 was primarily due to lower earn-out revenue from Indivior and lower revenue recognized from feasibility agreements with other companies.

Product revenue, net

As previously announced, in November 2024, we completed the sale of our ALZET product line to Lafayette Instruments Co. Revenue recognized from the ALZET product line, related cost of product revenues, associated selling, general and administrative expenses have been reclassified to discontinued operations for all periods presented.

A portion of our revenues is derived from product sales, which include certain excipients used by pharmaceutical companies as raw materials in certain of their products, including Methydur and a marketed animal health product. Net product revenues were $135,000 and $313,000 in 2024 and 2023, respectively.

The decrease in product revenues in 2024 was primarily attributable to lower product revenue related to the sale of excipients that are included in Methydur compared to 2023.

Operating Expenses

Cost of product revenues

Cost of product revenues includes the cost of product revenue from certain excipients that are included in Methydur and a marketed animal health product. Cost of product revenues was $78,000 and $268,000 in 2024 and 2023, respectively.

The decrease in cost of product revenues in 2024 was primarily attributable to lower cost of goods sold related to certain excipients that are included in Methydur compared with 2023.

Stock-based compensation expense recognized related to cost of product revenues was zero in both 2024 and 2023.

As of December 31, 2024, we had no manufacturing employees compared with 9 as of December 31, 2023.

Research and development

Research and development expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation costs associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development expenses were $10.4 million and $29.4 million in 2024 and 2023, respectively. Stock-based compensation expense recognized related to research and development personnel was $747,000 and $1.2 million in 2024 and 2023, respectively.

Research and development expenses decreased by approximately $18.9 million in 2024 compared to 2023. The decrease in 2024 was primarily attributable to lower research and development costs associated with larsucosterol, the depot injectable programs and other research programs compared to 2023, as more fully discussed below. We expect our research and development expenses to decrease in 2025 compared to 2024.

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

	Year Ended December 31,	
	2024	2023
Larsucosterol	$ 10,214	$ 26,246
Depot injectable programs	2	320
Other	167	2,785
Total research and development expenses	$ 10,383	$ 29,351

Larsucosterol

Our research and development expenses for larsucosterol decreased to $10.2 million in 2024 from $26.2 million in 2023, primarily due to lower clinical trial related expenses as we completed the AHFIRM trial, and experienced lower contract manufacturing expenses and lower employee-related costs for this drug candidate compared with 2023.

Depot injectable programs

Our research and development expenses for depot injectable programs decreased to $2,000 in 2024 from $320,000 in 2023 primarily due to lower employee-related costs and lower outside expenses for these programs.

Other DURECT research programs

Our research and development expenses for all other research programs decreased to $167,000 in 2024 from $2.8 million in 2023, primarily due to lower employee-related costs and lower outside expenses associated with these programs compared with 2023.

As of December 31, 2024 and 2023, we had 17 and 27 research and development employees, respectively.

Our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete are highly speculative and subjective due to numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation, uncertainties of future preclinical and clinical study results, uncertainties with our collaborators' commitment to and progress in the programs and uncertainties associated with process development and manufacturing as well as sales and marketing. In addition, with respect to our development programs subject to third-party collaborations, the timing and expenditures to complete the programs are subject to the control of our collaborators. Therefore, we cannot reasonably estimate the

timing and costs of the efforts necessary to complete the research and development programs. For additional information regarding these risks and uncertainties, see “Risk Factors” above.

Selling, general and administrative

Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other costs associated with finance, accounting, legal, business development, sales and marketing and other administrative personnel, overhead and facility costs, and other general and administrative costs. Selling, general and administrative expenses were $10.5 million and $12.7 million in 2024 and 2023, respectively. Selling, general and administrative expenses decreased by $2.2 million in 2024 compared to 2023, primarily due to lower employee expenses as well as lower consulting, patents and audit related expenses in 2024 compared with 2023. Stock-based compensation recognized related to selling, general and administrative personnel was $1.2 million and $1.4 million in 2024 and 2023, respectively. We expect our selling, general and administrative expenses to decrease in 2025 compared to 2024 due to lower audit expenses and lower employee expenses in 2025.

As of December 31, 2024 and 2023, we had 14 and 23 selling, general and administrative personnel, respectively.

Other Income (Expense)

Interest and other income

Interest and other income were $821,000 and $2.1 million in both 2024 and 2023, respectively. Interest and other income in 2024 was lower than 2023 primarily as a result of lower cash and investments balances in 2024 compared with 2023.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities was a loss of $323,000 and a gain of $13.6 million during the years ended December 31, 2024 and 2023, respectively.

The change in fair value of warrant liabilities during the year ended December 31, 2024 was comprised of a non-cash loss of $323,000 for the common warrants issued in February 2023 and July 2023.

The change in fair value of warrant liabilities during the year ended December 31, 2023 was comprised of a non-cash gain of $1.6 million for the pre-funded warrants issued in February 2023, a non-cash gain of $7.2 million for the common warrants issued in February 2023 and a non-cash gain of $4.9 million for the common warrants issued in July 2023.

Issuance cost for warrants

The issuance cost for warrants was zero and $1.6 million during the years ended December 31, 2024 and 2023, respectively. The issuance cost for warrants during the year ended December 31, 2023 was comprised of $1.2 million for the warrants issued in February 2023 and $427,000 for the common warrants issued in July 2023.

Loss on issuance of warrants

Loss on issuance of warrants was zero and $2.0 million during the years ended December 31, 2024 and 2023, respectively. The loss on issuance of warrants during the year ended December 31, 2023 was comprised of $2.0 million for the warrants issued in February 2023.

Income Taxes

As of December 31, 2024, we had net operating loss ("NOL") carryforwards for federal income tax purposes of approximately $303.9 million, of which approximately $197.0 million will expire in the years 2025 through 2037, and approximately $106.9 million will not expire under current tax laws. As of December 31, 2024, we had federal research and development tax credits of approximately $17.0 million, which expire at various dates beginning in 2025 through 2043, if not utilized. As of December 31, 2023, we had NOL carryforwards for state income tax purposes of approximately $270.4 million, which expire

in the years 2025 through 2043, and state research and development tax credits of approximately $17.8 million, which do not expire under current tax laws. Utilization of the NOLs may be subject to a substantial annual limitation due to federal and state ownership change limitations. The annual limitation may result in the expiration of NOLs and credits before utilization.

As of December 31, 2024 and 2023, we had net deferred tax assets of $116.8 million and $124.5 million, respectively. Deferred tax assets reflect the net tax effects of NOLs and credit carryforwards and the temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

Because realization of such tax benefits is uncertain, we provided a 100% valuation allowance as of December 31, 2024 and 2023. Utilization of the NOL and R&D credits carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change is 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 NOLs 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. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders’ subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. We issued $60.0 million of convertible notes in 2003 and subsequently all of these notes had been converted as of December 31, 2008 into approximately 1.9 million shares of our common stock. We also issued approximately 440,000 shares of our common stock to an institutional investor in connection with an equity financing in September 2009. In December 2012, November 2013, April 2016, June 2019 and February 2021, we completed underwritten public offerings in which we sold an aggregate of approximately 1.4 million, 820,000, 1.4 million, 2.9 million and 2.0 million shares, respectively, of our common stock pursuant to effective registration statements. In 2016, 2017, 2018, 2019, 2020, 2021, 2022 and 2023, we issued approximately 520,000, 890,000, 960,000, 230,000, 530,000, 95,000, 3,000 and 1.6 million shares, respectively, of our common stock in the open market through Controlled Equity Offering sales agreements with Cantor Fitzgerald pursuant to effective registration statements. In 2023, we completed two registered direct offerings by selling an aggregate of approximately 4.7 million shares of common stock and accompanying warrants to purchase an aggregate of approximately 5.3 million shares of common stock. These transactions may also have resulted in a change of control as defined by Section 382 or could result in a change of control in the future upon the subsequent disposition of the shares.

We have not currently completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since our formation due to the significant complexity and cost associated with such a study and the fact that there could be additional changes in the future. If we have experienced a change of control at any time since our formation, utilization of our NOL or R&D credits carryforwards would be subject to an annual limitation under Sections 382 and 383 which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of our NOL or R&D credits carryforwards before utilization. Tax years 2000 to 2024 remain subject to future examination by the major tax jurisdictions in which we are subject to tax.

Liquidity and Capital Resources

Since our inception in 1998, we have generally had a history of operating losses and we expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. These losses have resulted primarily from costs incurred to research and develop our product candidates and, to a lesser extent, from selling, general and administrative costs associated with our operations and product sales. We had cash, cash equivalents and investments totaling $12.0 million at December 31, 2024, which includes $150,000 of interest-bearing marketable securities classified as restricted investments on our balance sheet as of December 31, 2024 as compared to cash, cash equivalents and investments totaling $29.8 million at December 31, 2023. At December 31, 2024, we had an accumulated deficit of $597.3 million.

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

As discussed below, we do not have sufficient cash resources to fund our planned operations, existing debt and contractual commitments and planned capital expenditures. Our auditors have issued a going concern opinion as of, and for the year ended, December 31, 2024. Unless we secure funding from collaborations, additional equity or debt financing, of which there can be no assurance, we may not be able to continue operations.

Cash Flows

We used $19.1 million and $34.4 million of cash in operating activities in the years ended December 31, 2024 and 2023, respectively. The decrease in cash used in operating activities in 2024 was primarily due to lower costs incurred to research and develop our product candidates and, to a lesser extent, from selling, general and administrative costs associated with our operations and product sales, partially offset by lower payments from our collaborators compared with 2023. The cash used in operating activities was primarily to fund operations as well as our working capital requirements, partially offset by the changes in accounts receivable, accounts payable and accrued liabilities.

We received $18.0 million cash from investing activities in the year ended December 31, 2024 and used $1.2 million of cash in investing activities in the year ended December 31, 2023, respectively. The increase in cash generated from investing activities in 2024 was primarily due to net proceeds from the sale of the ALZET product line and a decrease in purchases of available-for-sale securities, partially offset by a decrease in proceeds from maturities of available-for-sale securities in 2024 compared with 2023.

We used $16.3 million cash in financing activities in the year ended December 31, 2024 and generated $20.5 million of cash from financing activities in the year ended December 31, 2023, respectively. The increase in cash used in financing activities in the year ended December 31, 2024 was primarily used to make higher principal payments and a final payment on the term loan with Oxford Finance LLC ("Oxford Finance") as we fully paid off the term loan in 2024. Cash provided by financing activities in 2023 was primarily due to cash proceeds received from the registered direct offerings that were completed in February 2023 and in July 2023 and from the sale of our common stock in the open market pursuant to a sales agreement dated July 30, 2021 with Cantor Fitzgerald & Co. (the “2021 Sales Agreement”), partially offset by principal payments on the term loan with Oxford Finance.

Shelf Registration Statement

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

In 2023, we raised net proceeds (net of commissions) of approximately $1.6 million from the sale of our common stock in the open market under the 2021 Sales Agreement. In 2024, we raised net proceeds (net of commissions) of approximately $648,000 from the sale of our common stock in the open market under the 2021 Sales Agreement.

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

As of March 25, 2025, we had up to $250.0 million of our securities available for sale under the 2024 Registration Statement. However, due to the SEC’s “baby shelf” rules discussed above, only up to approximately $8.7 million of our securities are currently available for sale under the 2024 Registration Statement.

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

Term Loan

In July 2016, we entered into a Loan and Security Agreement (as amended, the "Loan Agreement") with Oxford Finance. In the event of default by us under the 2016 Loan Agreement, the lender would have been entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may have been required to repay all amounts then outstanding under the Loan Agreement. As a result, the term loan was reclassified to current liabilities from non-current liabilities on our balance sheet as of December 31, 2023 due to recurring losses, liquidity concerns and a subjective acceleration clause in the Loan Agreement. In November 2024, we completed the sale of our ALZET product line to Lafayette Instrument Co. ("LIC"), a portfolio company of Branford Castle Partners II, L.P., a North-American focused private equity firm. Under the terms of the agreement, LIC paid DURECT $17.5 million in exchange for certain assets and liabilities associated with the ALZET product line. Simultaneous with this transaction, we paid off all remaining obligations under the term loan agreement with Oxford Finance.

Going Concern

As of December 31, 2024, we had approximately $12.0 million in cash, cash equivalents and investments compared to cash, cash equivalents, and investments of $29.8 million at December 31, 2023. In 2024, we completed the sale of our ALZET product line, paid off all remaining obligations under the term loan agreement with Oxford Finance and raised net proceeds (net of commissions) of approximately $648,000 from the sale of our common stock in the open market under the 2021 Sales Agreement.

In 2023, we received approximately $22.7 million in net proceeds (net of placement agent fees and other offering expenses) from two registered direct offerings and we raised net proceeds (net of commissions) of approximately $1.6 million from the sale of our common stock in the open market under the 2021 Sales Agreement.

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

Cash used in our operating activities is heavily influenced by the timing and structure of new corporate collaborations. While one feature of our business strategy is seeking new corporate collaborations, assuming no new collaborations and no milestone payments, we anticipate that cash used in operating activities will decrease in the near term. In aggregate, we are required to make future payments pursuant to our existing contractual obligations as follows (in thousands):

Contractual Obligations	2025	2026 and thereafter	Total
Operating lease obligations	$ 1,150	$ 1,351	$ 2,501
Total contractual cash obligations	$ 1,150	$ 1,351	$ 2,501

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

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

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

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

implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

As a result, our independent registered public accounting firm included an explanatory paragraph regarding our ability to continue as a going concern in its report on our financial statements as of, and for the year ended, December 31, 2024.

Recent Accounting Pronouncements

See Note 1 “Summary of Significant Accounting Policies” – “Recent Accounting Pronouncements”, to our financial statements for a full description of recent accounting pronouncements, including the expected dates of adoption and estimated effects on financial condition and results of operations, which is incorporated herein by reference.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data.

DURECT CORPORATION
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
DURECT Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheet of DURECT Corporation (the “Company”) as of December 31, 2024, the related statements of operations and comprehensive loss, stockholders’ equity, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company’s Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion

on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of the February 2023 Common Warrants

Critical Audit Matter Description

As described in Notes 3 and 9 of the financial statements, in February 2023, the Company issued common warrants to purchase an aggregate of 2,000,000 shares of Common Stock, in a registered direct offering (the "February Offering"). At the date of issuance and as of December 31, 2024, the Company accounted for the common warrants as current liabilities on the balance sheet and are adjusted to estimated fair value at each reporting period. The common warrants are valued using a Monte-Carlo valuation model due to the presence of an alternative cashless settlement feature in the financing agreement that provides the warrant holders with an alternative settlement feature to receive a fixed percentage of the shares underlying the warrants for no consideration. Because this feature allows for the warrant holders to use an alternative mechanism to exercise their warrants in a manner that would yield different values, a Monte-Carlo valuation model was determined to be appropriate.

The valuation of the common warrants related to the February Offering requires a high degree of judgment and is subject to change based on various quantitative and qualitative factors. A high degree of auditor judgment and an increased extent of effort were required when performing audit procedures to evaluate the reasonableness of management’s estimates and assumptions related to the valuation of the transaction due to the use of complex valuation models to estimate the value of the common warrants, which included the need to involve our valuation specialists. Therefore, we identified the Company’s valuation of the common warrants related to the February Offering as a critical audit matter.

How We Addressed the Matter in Our Audit

We obtained an understanding of and evaluated the design of controls relating to the Company’s valuation of the common warrants related to the February Offering. We evaluated the significant accounting policies relating to the Company’s analyses, as well as management’s application of the policies, for appropriateness and reasonableness.

To test the accounting for the common warrants in the February Offering, we performed audit procedures that included, among other things, obtaining an understanding of the Company’s process to account for the issuance of the common warrants, inspecting the warrant agreements, evaluating the reasonableness of management’s assumptions used as inputs within the valuation model and testing the accuracy of the underlying data used in the valuation models by tracing the key inputs to relevant terms contained in the warrant agreements. We also involved a valuation specialist to assist in evaluating the valuation methodologies and significant assumptions used in the valuation model, as well as testing the mathematical accuracy of the calculations.

Accounting and disclosure of Business Disposal and Discontinued Operations

Critical Audit Matter Description

As described in Note 11 of the financial statements, on November 22, 2024 (the “Closing Date”), the Company entered into an Asset Purchase Agreement (the “APA”) with Alzet, LLC, a subsidiary of Lafayette Instrument Co. (the “Purchaser”). Under the terms of the APA, the Company agreed to sell to the Purchaser substantially all of the assets, and certain specified liabilities, related to the ALZET product line (the “Sale”). Pursuant to the terms of the APA, the Purchaser paid the Company $17,500,000 subject to certain adjustments, including for net working capital, and agreed to assume certain liabilities with respect to the transferred assets.

The accounting and disclosure of business disposals and discontinued operations is especially challenging and requires extensive effort to audit the subjective and complex judgments associated with those matters, including determination of whether the disposal was an asset or a business, determination of the allocation of goodwill that was disposed of in connection with the Sale and whether the disposal would be disclosed as a discontinued operation.

How We Addressed the Matter in Our Audit

We obtained an understanding of and evaluated the design of controls relating to the Company's accounting for significant unusual transactions and the presentation of discontinued operations. We assessed and evaluated management’s judgments in determining whether the disposed assets met the definition of a business or asset disposal. We assessed and evaluated management’s judgments in determining whether the Sale met the discontinued operations classification criteria and tested the gain recognized on the Sale through procedures performed, including, but not limited to, inspection of relevant supporting documentation and assessment of the accounting implications of the terms therein, tested the goodwill amount allocated to the Sale, tested the mathematical accuracy of the calculations, and inquired of management regarding specific assumptions made. We tested the recognition and classifications of the Company’s segregation of assets, liabilities and the results of operations that are classified as discontinued operations by inspecting the Company’s accounting data and related adjustments. We tested the accuracy and completeness of the Company’s disclosures as they relate to discontinued operations.

/s/ WithumSmith+Brown, PC

We have served as the Company’s auditor since 2024.

San Francisco, California
March 27, 2025

PCAOB ID No. 100

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of DURECT Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheet of DURECT Corporation (the Company) as of December 31, 2023, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has an accumulated deficit as well as negative cash flows from operating activities and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 1998 to 2024.

San Francisco, California

March 28, 2024

except for Note 11, as to which the date is

March 27, 2025

DURECT CORPORATION

BALANCE SHEETS
(in thousands, except per share amounts)

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,011	$ 28,400
Short-term investments	792	1,280
Accounts receivable (net of allowances of $0 at December 31, 2024 and $20 at December 31, 2023)	453	618
Inventories, net	106	132
Prepaid expenses and other current assets	813	1,465
Discontinued operations - current assets	—	2,777
Total current assets	13,175	34,672
Property and equipment, net	41	88
Operating lease right-of-use assets	2,135	3,079
Goodwill	2,725	6,169
Long-term restricted investments	150	150
Other long-term assets	123	123
Discontinued operations - non-current assets	—	908
Total assets	$ 18,349	$ 45,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 309	$ 1,723
Accrued liabilities	4,771	5,810
Term loan, current portion, net	—	16,663
Operating lease liabilities, current portion	1,082	1,171
Warrant liabilities	1,548	1,224
Discontinued operations - current liabilities	—	420
Total current liabilities	7,710	27,011
Operating lease liabilities, non-current portion	1,124	1,967
Other long-term liabilities	384	594
Discontinued operations - non-current liabilities	—	834
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.0001 par value: 350,000 and 150,000 shares authorized at December 31, 2024 and 2023, respectively; 31,042 and 30,334 shares issued and outstanding at December 31, 2024 and 2023, respectively	23	23
Additional paid-in capital	606,439	603,780
Accumulated other comprehensive loss	(1)	(14)
Accumulated deficit	(597,330)	(589,006)
Stockholders' equity	9,131	14,783
Total liabilities and stockholders' equity	$ 18,349	$ 45,189

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

DURECT CORPORATION

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

	Year ended December 31,	
	2024	**2023**
Collaborative research and development and other revenue	$ 1,896	$ 2,277
Product revenue, net	135	313
Total revenues	2,031	2,590
Operating expenses:		
Cost of product revenues	78	268
Research and development	10,383	29,351
Selling, general and administrative	10,482	12,653
Total operating expenses	20,943	42,272
Loss from operations	(18,912)	(39,682)
Other income (expense):		
Interest and other income	821	2,129
Change in fair value of warrant liabilities	(323)	13,583
Issuance cost for warrants	—	(1,627)
Loss on issuance of warrants	—	(2,033)
Other income, net	498	12,052
Loss from continuing operations	(18,414)	(27,630)
Income from discontinued operations (Note 11)	10,090	6
Net loss	(8,324)	(27,624)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	13	(1)
Total comprehensive loss	$ (8,311)	$ (27,625)
Net loss per share, basic		
Loss from continuing operations	$ (0.60)	$ (1.05)
Income from discontinued operations	$ 0.33	$ —
Net loss per common share	$ (0.27)	$ (1.05)
Net loss per share, diluted		
Loss from continuing operations	$ (0.60)	$ (1.20)
Income from discontinued operations	$ 0.33	$ —
Net loss per common share	$ (0.27)	$ (1.20)
Weighted-average shares used in computing net loss per share		
Basic	30,940	26,256
Diluted	30,940	26,520

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

DURECT CORPORATION

STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	22,785	$ 23	$ 586,357	$ (13)	$ (561,382)	$ 24,985
Issuance of common stock upon exercise of stock options and purchases of ESPP shares	11	—	34	—	—	34
Issuance of common stock in the February 2023 registered direct offering	1,700	—	—	—	—	—
Issuance of common stock in the July 2023 registered direct offering, net of issuance costs of $673	2,991	—	8,540	—	—	8,540
Issuance of common stock pursuant to the 2021 Sales Agreement, net of issuance costs of $32	1,623	—	1,564	—	—	1,564
Issuance of common stock upon warrant exercises	1,224	—	3,013	—	—	3,013
Stock-based compensation expense from stock options and ESPP shares	—	—	4,272	—	—	4,272
Net loss	—	—	—	—	(27,624)	(27,624)
Change in unrealized loss on available-for-sale securities, net of tax	—	—	—	(1)	—	(1)
Balance at December 31, 2023	30,334	$ 23	$ 603,780	$ (14)	$ (589,006)	$ 14,783
Issuance of common stock pursuant to the 2021 Sales Agreement, net of issuance costs of $13	702	—	648	—	—	648
Issuance of common stock upon exercise of stock options and from the ESPP	6	—	5	—	—	5
Stock-based compensation expense from stock options and ESPP shares			2,006			2,006
Net loss					$ (8,324)	(8,324)
Change in unrealized gain on available-for-sale securities, net of tax				$ 13		13
Balance at December 31, 2024	31,042	$ 23	$ 606,439	$ (1)	$ (597,330)	$ 9,131

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

DURECT CORPORATION
STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (8,324)	$ (27,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of ALZET product line	(11,539)	—
Loss on extinguishment of debt	130	—
Depreciation and accretion	84	31
Stock-based compensation	1,995	2,538
Change in fair value of warrant liabilities	323	(13,583)
Loss on issuance of warrants	—	2,033
Issuance cost for warrants	—	427
Other	169	422
Changes in assets and liabilities:		
Accounts receivable	371	2,162
Inventories	(214)	(107)
Prepaid expenses and other assets	630	796
Accounts payable	(1,380)	(1,329)
Accrued liabilities	(1,331)	(180)
Total adjustments	(10,762)	(6,790)
Net cash used in operating activities	(19,086)	(34,414)
Cash flows from investing activities		
Purchases of property and equipment	—	(52)
Proceeds from sales of fixed assets	—	84
Purchases of available-for-sale securities	(2,956)	(6,198)
Proceeds from maturities of available-for-sale securities	3,500	5,000
Proceeds from sale of ALZET product line	17,500	—
Net cash provided by (used in) investing activities	18,044	(1,166)
Cash flows from financing activities		
Payments on equipment financing obligations	—	(1)
Payments on term loan principal	(15,000)	(5,000)
Payment of final payment on term loan	(2,000)	—
Net proceeds from issuances of common stock pursuant to the 2021 Sales Agreement	648	1,564
Net proceeds from issuances of common stock upon exercise of stock options, and purchases of ESPP shares	5	34
Proceeds from issuances of warrants and common stock in the February 2023 registered direct offering	—	10,000
Net proceeds from issuances of warrants and common stock in the July 2023 registered direct offering	—	13,900
Net cash (used in) provided by financing activities	(16,347)	20,497
Net decrease in cash and cash equivalents	(17,389)	(15,083)
Cash, cash equivalents, and restricted cash, beginning of the period (1)	28,550	43,633
Cash, cash equivalents, and restricted cash, end of the period (1)	$ 11,161	$ 28,550
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,407	$ 2,332

(1) Includes restricted cash of $150,000 (presented as long-term restricted investments) on the balance sheets at each of December 31, 2024 and 2023.

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

DURECT CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Operations

DURECT Corporation (the “Company”) was incorporated in the state of Delaware on February 6, 1998. The Company is a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. Larsucosterol, the Company's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases ("DNMTs"), epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-associated hepatitis ("AH") patients. Larsucosterol is in clinical development for the potential treatment of AH, for which FDA has granted a Fast Track Designation and Breakthrough Therapy Designation; metabolic dysfunction-associated steatohepatitis (“MASH”), also known as non-alcoholic steatohepatitis or NASH is also being explored. The Company also manufactures and sells certain excipients for certain clients for use as raw materials in their products.

Basis of Presentation and Use of Estimates

The Company’s financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of the accompanying financial statements conforms to U.S. GAAP, which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, the period of performance, identification of performance obligations and evaluation of milestones with respect to our collaborations, the amounts of revenues, recoverability of inventory, certain accrued liabilities including accrued clinical costs, asset retirement obligations, and valuation of warrant liabilities. The Company bases its estimates on historical experience and on various other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Liquidity and Need to Raise Additional Capital

As of December 31, 2024, the Company had an accumulated deficit of $597.3 million as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans for the next twelve months following the issuance of these financial statements. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidates. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year from the issuance of these financial statements. Management’s plans in order to meet its operating cash flow requirements include seeking additional collaborative agreements for certain of its programs as well as financing activities such as public offerings and private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments.

There are no assurances that such additional funding will be obtained and that the Company will succeed in its future operations. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations. As further described in Note 8, the Company classified the remaining balance of its term loan as a current liability on the Company’s balance sheet as of December 31, 2023 due to the timing of repayment obligations and due to recurring losses, liquidity concerns and a subjective acceleration clause in the Company’s Loan Agreement.

In 2024, the Company completed the sale of its ALZET product line to Lafayette Instrument Co. ("LIC"), a portfolio company of Branford Castle Partners II, L.P., a North-American focused private equity firm. Under the terms of the agreement, LIC paid the Company $17.5 million in exchange for certain assets and liabilities associated with the ALZET product line. Simultaneous with this transaction, the Company paid off all remaining obligations under the term loan agreement with Oxford Finance LLC.

These financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event the Company can no longer continue as a going concern.

Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments with maturities of 90 days or less from the date of purchase to be cash equivalents. Investments with original maturities of greater than 90 days from the date of purchase but less than one year from the balance sheet date are classified as short-term investments, while investments with maturities in one year or beyond one year from the balance sheet date are classified as long-term investments. Management determines the appropriate classification of its cash equivalents and investment securities at the time of purchase and re-evaluates such determination as of each balance sheet date. Management has classified the Company’s cash equivalents and investments as available-for-sale securities in the accompanying financial statements. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive loss. Realized gains and losses are included in interest income. There were no material realized gains or losses in the periods presented. The cost of securities sold is based on the specific identification method.

The Company invests in debt instruments of government agencies, corporations, and money market funds with high credit ratings. The Company has established guidelines regarding diversification of its investments and their maturities with the objectives of maintaining safety and liquidity, while maximizing yield.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of interest-bearing investments and trade receivables. The Company maintains cash, cash equivalents and investments with various major financial institutions. The Company performs periodic evaluations of the relative credit standing of these financial institutions. In addition, the Company performs periodic evaluations of the relative credit quality of its investments.

The Company’s trade receivables derive largely from pharmaceutical clients. The Company provides credit in the normal course of business to its customers and collateral for these receivables is generally not required. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. The Company maintains reserves for estimated credit losses and, to date, such losses have been immaterial in all periods presented.

Customer and Product Line Concentrations (excluding the ALZET product line)

Indivior accounted for 78% and 65% of the Company's total revenue for 2024 and 2023, respectively.

Total revenue by geographic region for the years 2024 and 2023 are as follows (in thousands):

	Year ended December 31,	
	2024	2023
Europe	$ 1,592	$ 1,689
United States	189	514
Others	250	387
Total	$ 2,031	$ 2,590

Revenue by geography is determined by the location of the customer.

Inventories, net

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company may be required to expense previously capitalized inventory costs upon a change in management's judgment due to new information that suggests that the inventory will not be saleable.

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

	December 31,	
	2024	2023
Raw materials	$ 10	$ 10
Finished goods	96	122
Total inventories	$ 106	$ 132

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation, which is computed using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized using the straight-line method over the estimated useful lives of the assets, or the terms of the related leases, whichever are shorter.

Goodwill

Goodwill is periodically assessed and evaluated for impairment. The Company operates in one operating segment and also has only one reporting unit, which is the research, development and manufacturing of pharmaceutical products. The Company assesses the impairment of goodwill at least annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. To date, the Company has not recorded any impairment charge related to goodwill.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, intangible assets, and other long-term assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable.

If an indicator of impairment is present for any long-lived asset, the Company is required to determine whether the undiscounted future cash flows from the long-lived asset is less than its carrying amount. If so, impairment, if any, is calculated as the amount by which the long-lived asset's carrying value exceeds its estimated fair value. Through December 31, 2024, there have been no material impairment losses.

Leases

ASC 842 requires the Company to recognize an operating lease right-of-use asset and corresponding operating lease liability for the Company's leased properties. The Company's operating lease right-of-use

assets and liabilities are recognized under ASC 842 based on the present value of lease payments over the remaining lease term at the lease commencement date. In determining the net present value of lease payments, we estimate the incremental borrowing rate based on the information available, including remaining lease term. As of December 31, 2024, the weighted-average remaining lease term was 2.14 years for the Company’s leased properties.

Stock-Based Compensation

The Company accounts for share-based payments using a fair-value based method for costs related to all share-based payments, including stock options and stock issued under the Company’s employee stock purchase plan (ESPP). The Company estimates the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company recognizes compensation costs on a straight-line basis over the requisite service period and accounts for forfeitures as they occur. See Note 9 for further information regarding stock-based compensation.

Revenue Recognition

Product Revenue, Net

The Company manufactures and sells certain excipients used by pharmaceutical companies as raw materials in certain of their products, including Methydur and a marketed animal health product. Prior to the sale of the ALZET product line in November 2024, the Company also manufactured and sold ALZET miniature osmotic pumps used in laboratory research.

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

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

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

Collaborative Research and Development and Other Revenue

Royalties and Earn-outs: For the Company's arrangements that include sales-based royalties or earn-outs, including milestone payments based on first commercial sale or the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty or earn-out has been allocated has been satisfied (or partially satisfied).

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

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

Prepaid and Accrued Clinical Costs

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

Prepaid and Accrued Manufacturing Costs

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

Research and Development Expenses

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

Comprehensive Loss

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

Segment Reporting

The Company operates in one operating segment, which is the research, development and manufacturing of pharmaceutical products.

Common Stock Warrants

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

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

Net Loss Per Share

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. Certain warrants participate in distributions of the Company. The net loss attributable to common stockholders is not allocated to the warrant holders as the holders of warrants do not have a contractual obligation to share in losses. Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding and common stock equivalents (i.e., options and warrants to purchase common stock) outstanding during the period, if dilutive, using the treasury stock method for options.

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

	Year Ended December 31,	
	2024	2023
Basic loss per share computation:		
Net loss	$ (8,324)	$ (27,624)
Weighted average number of shares outstanding - basic	30,940	26,256
Net loss per share - basic	$ (0.27)	$ (1.05)
Diluted loss per share computation:		
Net loss	$ (8,324)	$ (27,624)
Change in fair value of pre-funded warrant liabilities	—	1,557
Change in fair value of common warrant liabilities	—	2,775
Net loss adjusted for change in fair value of warrant liabilities	$ (8,324)	$ (31,956)
Weighted average shares used to compute basic net loss per share	30,940	26,256
Dilutive effect of pre-funded warrants	—	168
Dilutive effect of common warrants	—	96
Weighted average shares used to compute diluted net loss per share	30,940	26,520
Net loss per share - diluted	$ (0.27)	$ (1.20)

The computation of diluted net loss per share for 2024 and 2023 excludes the impact of options to purchase 4.0 million and 3.4 million shares of common stock outstanding for the year ended December 31, 2024 and 2023, respectively, as such impact would be anti-dilutive.

Both the pre-funded warrants and the common warrants to purchase shares of common stock entitle the holders thereof to participate in dividends and other distributions of assets by the Company to its holders of common shares, but are not required to absorb losses incurred. As a result, all warrants were excluded from basic net loss per share calculations during 2024 and 2023, respectively. For diluted net loss per share purposes, warrants are included in the number of shares outstanding if the effect is dilutive. The dilutive effect of pre-funded warrants was zero and 168,000 shares during 2024 and 2023, respectively. Additional common warrants to purchase 3.6 million and 2.6 million shares were excluded from the denominator in the calculation of diluted net loss per share in 2024 and 2023, respectively, as the effect would be anti-dilutive.

Shipping and Handling

Costs related to shipping and handling are included in cost of revenues for all periods presented.

Discontinued Operations

In accordance with ASC 205-20 Presentation of Financial Statements: Discontinued Operations, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity’s operations and financial results when the component/s of an entity meets the criteria in paragraph 205-20-45-10. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net loss of continuing operations.

The Company disposed of its ALZET product line, a component of its business, in November 2024 and met the definition of a discontinued operation as of December 31, 2024. Accordingly, the Company has classified the results of the ALZET product line as discontinued operations in its statements of operations and comprehensive loss for all periods presented. All assets and liabilities associated with the ALZET product line were classified as assets and liabilities of discontinued operations in the balance sheets for the periods presented. All amounts included in the notes to the financial statements relate to continuing operations unless otherwise noted. For additional information, see Note 11, “Discontinued Operations” to the financial statements in this Annual Report on Form 10-K.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (“ASU 2023-07”), which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The Company adopted ASU 2023-07 effective December 31, 2024, on a retrospective basis. The adoption of 2023-07 did not change the way that the Company identifies its reportable segments and, as a result, did not have a material impact on the Company’s segment-related disclosures. Refer to Note 12 for further information on the Company's reportable segment.

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

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

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

2. Strategic Agreements

The collaborative research and development and other revenue associated with the Company's major collaborators or counterparties were $1.9 million and $2.3 million in 2024 and 2023, respectively. The collaborative research and development and other revenue included (a) amounts related to earn-out revenue from Indivior UK Limited ("Indivior") with respect to PERSERIS net sales, (b) feasibility programs and research and development activities funded by our collaborators or counterparties, (c) royalty revenue from Orient Pharma Co., Ltd. ("Orient Pharma") with respect to Methydur net sales and (d) royalty revenue from Innocoll Pharmaceuticals Limited ("Innocoll") with respect to POSIMIR net sales.

Agreement with Innocoll

On December 21, 2021, the Company entered into a license agreement (as amended, the "Innocoll Agreement") with Innocoll. Pursuant to the Innocoll Agreement, the Company granted Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize in the United States, POSIMIR®, the Company's FDA-approved post-surgical pain product, with respect to all uses and applications in humans. None of the additional milestones under the agreement have been met. On November 8, 2024, the Company received notice that Innocoll is terminating the Innocoll Agreement, effective May 6, 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to the Company, and the Company is evaluating next steps with respect to the commercialization of POSIMIR. We do not expect that this termination will have a material impact on our financial statements.

Patent Purchase Agreement with Indivior

In September 2017, we entered into an agreement with Indivior (the "Indivior Agreement"), under which we assigned to Indivior certain patents that may provide further intellectual property protection for PERSERIS, Indivior's extended-release injectable suspension for the treatment of schizophrenia in adults. In consideration for such assignment, Indivior made non-refundable upfront and milestone payments to DURECT totaling $17.5 million. Additionally, under the terms of the agreement with Indivior, the

Company receives quarterly earn-out payments into 2026 that are based on a single digit percentage of U.S. net sales of PERSERIS. Indivior commercially launched PERSERIS in the U.S. in February 2019. The Indivior Agreement contains customary representations, warranties and indemnities of the parties. Amounts recognized during the twelve months ended December 31, 2024 and 2023 related to earn-out revenues from PERSERIS were $1.6 million and $1.7 million, respectively, and were included in collaborative research and development and other revenue. In July 2024, Indivior announced discontinuation of sales and marketing for PERSERIS due to the highly competitive market and impending changes that are expected to intensify payor management in the treatment category in which PERSERIS participates.

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. The following table sets forth the fair value of the Company's financial assets that were measured at fair value on a recurring basis as of December 31, 2024 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$ 688	$ —	$ —	$ 688
Certificates of deposit	—	150	—	150
Commercial paper	—	8,913	—	8,913
Total	$ 688	$ 9,063	$ —	$ 9,751

The following table sets forth the fair value of our financial assets that were measured at fair value on a recurring basis as of December 31, 2023 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$ 951	$ —	$ —	$ 951
Certificates of deposit	—	150	—	150
Commercial paper	—	24,882	—	24,882
Total	$ 951	$ 25,032	$ —	$ 25,983

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 and commercial paper 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 may 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 December 31, 2023 is less than twelve months and these investments are rated by S&P and Moody's at AAA or AA- for securities and A1, A2, P1 or P2 for commercial paper.

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

	December 31, 2024			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 688	$ —	$ —	$ 688
Certificates of deposit	150	—	—	150
Commercial paper	8,914	—	(1)	8,913
	$ 9,752	$ —	$ (1)	$ 9,751
Reported as:				
Cash and cash equivalents	$ 8,810	$ —	$ (1)	$ 8,809
Short-term investments	792	—	—	792
Long-term restricted investments	150	—	—	150
	$ 9,752	$ —	$ (1)	$ 9,751

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

The following is a summary of the cost and estimated fair value of available-for-sale securities at December 31, 2024, by contractual maturity (in thousands):

	December 31, 2024	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 8,914	$ 8,913
Mature after one year through five years	150	150
	$ 9,064	$ 9,063

There were no securities that have had an unrealized loss for more than 12 months as of December 31, 2024.

As of December 31, 2024, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Warrant Liabilities

The following table summarizes the activity of the Company's Level 3 warrant liabilities as of December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	**2023**
Fair value at beginning of year - February 2023 issuance (Pre-funded warrants)	$ —	$ —
Initial fair value at the original issuance date	—	1,743
Change in fair value during the year	—	(1,557)
Fair value of liability classified warrants exercised	—	(186)
Fair value at end of year - February 2023 issuance (Pre-funded warrants)	$ —	$ —
Fair value at beginning of year - February 2023 issuance (Common warrants)	$ 312	$ —
Initial fair value at the original issuance date	—	10,290
Change in fair value during the year	102	(7,151)
Fair value of liability classified warrants exercised	—	(2,827)
Fair value at end of year - February 2023 issuance (Common warrants)	$ 414	$ 312
Fair value at end of year - February 2023 issuance	$ 414	$ 312
Fair value at beginning of year - July 2023 issuance	$ 912	$ —
Initial fair value at the original issuance date	—	5,788
Change in fair value during the year	222	(4,876)
Fair value of liability classified warrants exercised	—	—
Fair value at end of year - July 2023 issuance	$ 1,134	$ 912
Total fair value at end of year	$ 1,548	$ 1,224

February 2023 Warrants

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

Pre-Funded Warrants

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

estimated fair value of the pre-funded warrants using a Black-Scholes option pricing model with the following key assumptions:

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

Common Warrants

The common warrants are accounted for as current liabilities on the balance sheets and are adjusted to estimated fair value at period end through “other income (expense)” on the statements of operations. The estimated fair value of the outstanding common warrants was $10.3 million, $312,000 and $414,000 as of February 8, 2023 (i.e., the issuance date), December 31, 2023 and December 31, 2024, respectively. In September 2023, 1,400,000 shares of the common warrants were exercised through the alternative cashless exercise provision in accordance with the financing agreement, resulting in a net issuance of 924,000 shares to the holder. The aggregate number of shares of our common stock issuable in such alternative cashless exercise equals the product of (x) 17 the aggregate number of shares of our common stock that would be issuable upon exercise of the common warrant in accordance with the terms of such common warrant if such exercise were by means of a cash exercise rather than a cashless exercise and (y) 0.66. The Company calculated the estimated fair value of the common warrants using a Monte-Carlo simulation model with the following key assumptions. The Company took the likelihood of achieving certain events and related impact on the Company's common stock price into account, as appropriate.

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

	February 8, 2023 (issuance)	December 31, 2023	December 31, 2024
Common stock price	$ 5.81	$ 0.59	$ 0.75
Exercise price per share	$ 5.00	$ 0.51	$ 0.51
Volatility	86.60%	118.00%	132.00%
Risk-free interest rate	3.82%	3.93%	4.27%
Contractual term (in years)	5.00	4.10	3.00
Expected dividend yield	—%	—%	—%

July 2023 warrants

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

The common warrants are accounted for as current liabilities on the balance sheets and are adjusted to estimated fair value at period end through “other income (expense)” on the statements of operations. The estimated fair value of the outstanding common warrants was $5.8 million, $912,000 and $1.1 million as of July 21, 2023 (i.e., the issuance date), December 31, 2023 and December 31, 2024,

respectively. The Company calculated the estimated fair value of the common warrants using a Black-Scholes option pricing model with the following key assumptions:

	July 21, 2023 (issuance)	December 31, 2023	December 31, 2024
Common stock price	$ 3.05	$ 0.59	$ 0.75
Exercise price per share	$ 4.89	$ 4.89	$ 4.89
Volatility	88.60%	115.60%	124.49%
Risk-free interest rate	4.18%	3.88%	4.30%
Contractual term (in years)	5.00	4.60	3.50
Expected dividend yield	—%	—%	—%

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

4. Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Equipment	$ 5,971	$ 5,996
Leasehold improvements	8,059	8,113
	14,030	14,109
Less accumulated depreciation and amortization	(13,989)	(14,021)
Property and equipment, net	$ 41	$ 88

Depreciation expense was $49,000 and $148,000 in 2024 and 2023, respectively.

As of December 31, 2024 and 2023, the Company recorded $384,000 and $375,000, respectively, as a liability which was included in accrued liabilities and other long-term liabilities on its balance sheets for asset retirement obligations associated with the estimated restoration cost for its leased buildings.

5. Restricted Investments

As of December 31, 2024 and 2023, the Company had $150,000 recorded as restricted investments, which primarily served as collateral for letters of credit securing a leased facility in California.

6. Commitments

Operating Leases

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

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

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 $1.5 million and $2.0 million for the years ended December 31, 2024 and 2023. In determining the net present value of lease payments, the Company used its incremental borrowing rate of 11.5% based on the information available, including remaining lease term, at the adoption date of ASC 842. As of December 31, 2024 and 2023, the weighted-average remaining lease term was 2.14 years and 3.48 years, respectively, for the Company’s leased properties.

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

Year ending December 31,	Operating Leases
2025	$ 1,150
2026	1,185
2027	166
	2,501
Less present value adjustment	(295)
Operating lease liabilities recognized	$ 2,206

7. Accrued Liabilities

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

	December 31, 2024	December 31, 2023
Accrued compensation and benefits	$ 850	$ 1,206
Accrued clinical costs	204	1,578
Accrued contract research and manufacturing cost	2,841	2,340
Others	876	686
Total	$ 4,771	$ 5,810

8. Term Loan

In July 2016, the Company entered into a $20.0 million secured single-draw term loan (as amended, the “Loan Agreement”) with Oxford Finance LLC (“Oxford Finance”). The Company and Oxford Finance entered into five subsequent amendments to the Loan Agreement in February 2018, November 2018, December 2019, March 2021 and May 2021. For amendments 1-3 and 5, the Company paid Oxford Finance loan modification fees of $100,000, $900,000, $825,000 and $712,500, respectively. As amended, the Loan Agreement provided for interest only payments through June 1, 2023, followed by consecutive monthly payments of principal and interest in arrears starting on June 1, 2023 and continuing through the maturity date of the term loan of September 1, 2025. The Loan Agreement provided for a floating interest rate (7.95% initially and 12.75% as of December 31, 2023) based on an index rate plus a spread. In addition, a payment equal to 10% of the principal amount of the term loan was due when the term loan became due or upon the prepayment of the facility. If the Company elected to prepay the loan, there was 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 had been recorded as debt discount on the Company’s balance sheets and together with the final $2.0 million payment were being amortized to interest expense using the effective interest method over the revised term of the loan. The Company made principal payments of $5.0 million in 2023.

The term loan was secured by substantially all of the assets of the Company, except that the collateral did not include any intellectual property (including licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contained customary representations, warranties and covenants by the Company, which covenants limited 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 contained 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 was 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 was 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 was not material, but could become material in future periods if an event of default became more probable than is currently estimated.

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

In 2024, the Company completed the sale of our ALZET product line to Lafayette Instrument Co. (LIC), a portfolio company of Branford Castle Partners II, L.P., a North-American focused private equity firm. Under the terms of the agreement, LIC paid DURECT $17.5 million in exchange for certain assets and liabilities associated with the ALZET product line. Simultaneous with this transaction, the Company paid off all remaining obligations under the term loan agreement with Oxford Finance LLC.

9. Stockholders' Equity

Common Stock

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

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

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

Registered Direct Offerings

February 2023 Financing

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

The pre-funded warrants were exercisable immediately following the closing date of the February Offering and have an unlimited term and an initial exercise price of $0.00001 per share. The common warrants were immediately exercisable and have a five-year term and an initial exercise price of $5.00 per share, which was lowered to $4.89 per share as a result of an anti-dilution provision in the common warrants issued in the February Offering that was triggered by the July Offering (as defined below) and then lowered to $0.51 that was triggered by the sale of our common stock in the open market in November 2023. The combined offering price was $5.00 per share and accompanying common warrant, or in the case of pre-funded warrants, $4.99999 per pre-funded warrant and accompanying common warrant. A holder (together with its affiliates) may not exercise any portion of a pre-funded warrant or common warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company’s outstanding common stock immediately after exercise.

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

Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company’s common stock. Because liability-classified financial instruments are initially and subsequently carried at fair value, the Company’s financial results

will reflect the volatility in these estimate and assumption changes. Changes in estimated fair value are recognized as a component of other income (expense) in the statements of operations.

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

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

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

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

As of December 31, 2024 and 2023, common warrants to purchase 600,000 shares of the Company's common stock were outstanding.

At December 31, 2024, the Company updated the estimated fair value of the outstanding common warrants using a Monte-Carlo valuation model resulting in an estimated fair value of $414,000, an increase of $102,000 for these common warrants compared with December 31, 2023. At December 31, 2023, the Company updated the estimated fair value of the outstanding common warrants using a Monte-Carlo valuation model resulting in an estimated fair value of $312,000, a decrease of $2.8 million for these common warrants on the issuance date.

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

The total loss of $102,000 resulting from the change in the estimated fair value of the liabilities for the common warrants was recorded as a change in the estimated fair value of warrant liabilities in the accompanying statements of operations for the year ended December 31, 2024. The total gain of $7.2 million and $1.6 million resulting from the change in the estimated fair value of the liabilities for the common warrants and pre-funded warrants, respectively, was recorded as a change in the estimated fair value of warrant liabilities in the accompanying statements of operations for the year ended December 31, 2023.

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

July 2023 Financing

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

The common warrants were immediately exercisable and have a five-year term and an initial exercise price of $4.89 per share. The combined offering price was $5.015 per share and accompanying common warrant. A holder (together with its affiliates) may not exercise any portion of the common warrants to the extent that the holder would own more than 4.99% (or, at the election of the holder 9.99%) of the Company's outstanding common stock immediately after exercise.

The common stock and common warrants are separate freestanding instruments. The estimated fair value of the common stock issued in the July Offering as of the date of issuance (i.e., July 21, 2023) was $9.1 million, which was the number of shares of 2,991,027 multiplied by the price per share as of the date of issuance of $3.05 per share. The common stock issued in the July Offering was classified as equity on the Company's balance sheets. The Company allocated the offering expenses related to the July 2023 offering of $1.1 million based on the relative fair values of common stock and common warrants issued. The Company recognized an expense for the amount allocated to the common warrants of $427,000 (included within other expense, net) upon the closing of the offering in the year ended December 31, 2023. The Company recorded the amount allocated to the common stock of $673,000 as a reduction in additional paid-in capital on its balance sheets as of December 31, 2023.

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

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

Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company's common stock. Because liability-classified financial instruments are initially and subsequently carried at fair value, the Company's financial results

will reflect the volatility in these estimate and assumption changes. Changes in fair value are recognized as a component of other income (expense) in the statements of operations.

The Company valued the common warrants issued in the July Offering using the Black-Scholes option valuation model. The Black-Scholes method was determined to be appropriate given the lack of alternative mechanisms to settle the warrants in a manner that would yield different values, such as an alternative cashless settlement feature. The fair value of these warrants as of the issuance date, as of December 31, 2023 and December 31, 2024 were $5.8 million, $912,000 and $1.1 million, respectively. The loss of $221,000 resulting from the change in the fair value of the liability for these warrants was recorded as a change in estimated fair value of warrant liabilities in the accompanying statements of operations for the twelve months ended December 31, 2024.The gain of $4.9 million resulting from the change in the fair value of the liability for these warrants was recorded as a change in estimated fair value of warrant liabilities in the accompanying statements of operations for the twelve months ended December 31, 2023.

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

As of December 31, 2024, none of the warrants issued in the July Offering have been exercised. Common warrants to purchase 2,991,027 shares of the Company's common stock were outstanding with an exercise price of $4.89 per share.

ATM Financings

During the twelve months ended December 31, 2024, the Company raised net proceeds (net of commissions) of approximately $648,000 from the sale of 702,090 shares of the Company’s common stock in the open market at a weighted average price of $0.94 per share pursuant to the 2021 Registration Statement and the 2021 Sales Agreement.

During the twelve months ended December 31, 2023, there were no sales of the Company's common stock in the open market.

As of March 25, 2025, the Company had up to $250.0 million of the Company’s securities available for sale under the 2024 Registration Statement. However, due to the SEC’s “baby shelf” rules discussed above, only up to approximately $8.7 million of our securities are available for sale under the 2024 Registration Statement.

Description of Stock-Based Compensation Plans

2000 Stock Plan (Incentive Stock Plan)

In January 2000, the Company’s Board of Directors and stockholders adopted the DURECT Corporation 2000 Stock Plan, under which incentive stock options and non-statutory stock options and stock purchase rights may be granted to employees, consultants and non-employee directors. The 2000 Stock Plan was amended by written consent of the Board of Directors in March 2000 and written consent of the stockholders in August 2000.

In April 2005, the Board of Directors approved certain amendments to the 2000 Stock Plan. At the Company’s annual stockholders meeting in June 2005, the stockholders approved the amendments of the 2000 Stock Plan to: (i) expand the types of awards that the Company may grant to eligible service providers under the Stock Plan to include restricted stock units, stock appreciation rights and other similar types of awards (including other awards under which recipients are not required to pay any purchase or exercise price) as well as cash awards; and (ii) include certain performance criteria that may be applied to awards granted under the Stock Plan.

At the Company’s annual stockholders meeting in June 2010, the stockholders approved amendments of the 2000 Stock Plan to: (i) provide that the number of shares that remain available for issuance will be reduced by two shares for each share issued pursuant to an award (other than an option or stock appreciation right) granted on or after the date of the 2010 Annual Meeting; (ii) expand the types of transactions that might be considered repricings and option exchanges for which stockholder approval is required; (iii) provide that shares tendered or withheld in payment of the exercise price of an option or withheld to satisfy a withholding obligation, and all shares with respect to which a stock appreciation right is exercised, will not again be available for issuance under the Stock Plan; (iv) require that options and stock appreciation rights have an exercise price or base appreciation amount that is at least fair market value on the grant date, except in connection with certain corporate transactions, and that stock appreciation rights may not have longer than a 10-year term; (v) add new performance goals that may be used to provide “performance-based compensation” under the 2000 Stock Plan; (vi) extend the term of the 2000 Stock Plan to the date that is ten (10) years following the stockholders meeting; and (vii) expand the treatment of outstanding awards in connection with certain changes of control of the Company to cover mergers in which the consideration payable to stockholders is not solely securities of the successor corporation.

At the Company’s annual stockholders meeting in June 2011, June 2014, June 2016 and June 2018, the stockholders approved amendments of the 2000 Stock Plan to increase the number of shares of the Company’s common stock available for issuance by 550,000 shares, 400,000 shares, 500,000 shares, and 750,000 shares, respectively, each of which had previously been approved by the Board of Directors.

At the Company’s annual stockholders meeting in June 2019, the stockholders approved an amendment of the 2000 Stock Plan to extend the term of the 2000 Stock Plan to the date that is ten (10) years following the stockholders meeting.

In April 2013, the Board of Directors approved certain amendments to the 2000 Stock Plan to: (i) increase the number of stock options granted to a non-employee director on the date which such person first becomes a director from 3,000 to 7,000 shares of common stock; each option shall have a ten-year term, become exercisable in installments of one-third of the total number of options granted on each anniversary of the grant and have a two-year period following termination of Director status in which the former director can exercise the option; (ii) modify the exercise period for future option grants to a non-employee director in which a former director can exercise the option following termination of Director status from a one year period to a two-year period.

Options granted under the 2000 Stock Plan expire no later than ten years from the date of grant. Options may be granted with different vesting terms from time to time not to exceed five years from the date of grant. The option price of an incentive stock option granted to an employee or of a nonstatutory stock option granted to any person who owns stock representing more than 10% of the total combined voting power of all classes of stock of the Company (or any parent or subsidiary) shall be no less than 110% of the fair market value per share on the date of grant. The option price of an incentive stock option granted to any other employee shall be no less than 100% of the fair market value per share on the date of grant.

At the Company’s annual stockholders meeting in June 2022, the stockholders approved an amendment of the 2000 Stock Plan to increase the number of shares of the Company’s common stock available for issuance by 1,800,000 shares and to extend the term of the 2000 Stock Plan to the date that is ten (10) years following the stockholders meeting.

At the Company’s annual stockholders meeting in September 2024, the stockholders approved an amendment of the 2000 Stock Plan to increase the number of shares of the Company’s common stock available for issuance by 2,000,000 shares and to extend the term of the 2000 Stock Plan to the date that is ten (10) years following the stockholders meeting.

A total of 8,429,650 shares of common stock have been reserved for issuance under this plan. The plan expires in June 2034.

As of December 31, 2024, 1,844,180 shares of common stock were available for future grant and options to purchase 4,619,287 shares of common stock were outstanding under the 2000 Stock Plan.

2000 Employee Stock Purchase Plan

In August 2000, the Company adopted the 2000 Employee Stock Purchase Plan. This purchase plan is implemented by a series of overlapping offering periods of 24 months' duration, with new offering periods, other than the first offering period, beginning on May 1 and November 1 of each year and ending April 30 and October 31, respectively, two years later. The purchase plan allows eligible employees to purchase common stock through payroll deductions at a price equal to the lower of 85% of the fair market value of the Company's common stock at the beginning of each offering period or at the end of each purchase period. The initial offering period commenced on the effectiveness of the Company's initial public offering.

In April 2010, the Board of Directors approved certain amendments to the 2000 Employee Stock Purchase Plan. At the Company's annual stockholders meeting in June 2010, the stockholders approved the amendment of the 2000 Employee Stock Purchase Plan to: (i) increase the number of shares of our common stock authorized for issuance under the ESPP by 25,000 shares; (ii) extend the term of the ESPP to the date that is ten (10) years following the stockholders meeting; (iii) provide for six-month consecutive offering periods beginning on November 1, 2010; (iv) revise certain provisions to reflect the final regulations issued under Section 423 of the Code by the Internal Revenue Service; and (v) provide for the cash-out of options outstanding under an offering period in effect prior to the consummation of certain corporate transactions as an alternative to providing for a final purchase under such offering period.

In March 2015, the Board of Directors approved certain amendments to the 2000 Employee Stock Purchase Plan. At the Company's annual stockholders meeting in June 2015, the stockholders approved the amendments of the 2000 Employee Stock Purchase Plan to: (i) increase the number of shares of our common stock authorized for issuance under the ESPP by 35,000 shares; and (ii) extend the term of the ESPP to the date that is ten (10) years following the stockholders meeting. At each of the Company's annual stockholders meeting in June 2017 and in June 2020, the stockholders approved amendments of the 2000 Employee Stock Purchase Plan to increase the number of shares our common stock authorized for issuance under the ESPP by 35,000 shares and to re-approve its material terms. At the Company's annual stockholders meeting in June 2023, the stockholders approved amendments of the 2000 Employee Stock Purchase Plan to increase the number of shares of our common stock authorized for issuance under the ESPP by 40,000 shares and to re-approve its material terms.

The plan expires in June 2033. A total of 365,000 shares of common stock have been reserved for issuance under this plan. As of December 31, 2024, 49,667 shares of common stock were available for future grant and 315,333 shares of common stock have been issued under the 2000 Employee Stock Purchase Plan.

As of December 31, 2024, shares of common stock reserved for future issuance consisted of the following:

	December 31, 2024
Stock options outstanding	4,619,287
Restricted stock units outstanding	275,000
Stock options available for grant	1,844,180
Employee Stock Purchase Plan	49,667
	6,788,134

A summary of stock option activity under all stock-based compensation plans is as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2023	4,128,259	$ 9.37	6.22	$ —
Options granted	1,268,950	$ 1.30		
Options exercised	—	$ —		
Options forfeited	(176,318)	$ 9.02		
Options expired	(601,604)	$ 13.76		
Outstanding at December 31, 2024	4,619,287	$ 6.59	6.73	$ —
Exercisable at December 31, 2024	2,343,759	$ 10.34	4.44	$ —
Vested and expected to vest at December 31, 2024	4,619,287	$ 6.59	6.73	$ —

The weighted-average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $1.30 and $4.36 per share, respectively. The aggregate intrinsic value in the table above represents the total intrinsic value (i.e., the difference between the Company's closing stock price on the last trading day of 2024 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their in-the-money options on December 31, 2024. This amount changes based on the fair market value of the Company's common stock. The total value of options exercised was zero and $1,400 for the years ended December 31, 2024 and 2023, respectively.

Expenses for non-employee stock options are recorded over the vesting period of the options, which closely approximates the non-employee's performance period, with the value determined by the Black-Scholes option valuation method and remeasured over the vesting term.

As of December 31, 2024, the Company had two stock-based equity compensation plans, which are described above. The employee stock-based compensation cost that has been included in the statements of operations and comprehensive loss is shown as below (in thousands):

	Year ended December 31,	
	2024	2023
Research and development	$ 747	$ 1,163
Selling, general and administrative	1,173	1,310
	$ 1,920	$ 2,473

Because the Company had a net operating loss carryforward as of December 31, 2024, no excess tax benefits for the tax deductions related to stock-based compensation were recognized in the statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised during 2024, which would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities.

Determining Fair Value

Valuation and Expense Recognition. The Company estimates the fair value of stock options granted using the Black-Scholes option valuation model. The Company recognizes the expense on a straight-line basis. The expense for options is recognized over the requisite service periods of the awards, which is generally the vesting period.

Expected Term. The expected term of options granted represents the period of time that the options are expected to be outstanding. The Company determines the expected life using historical options experience. This develops the expected life by taking the weighted average of the actual life of

options exercised and cancelled and assumes that outstanding options are exercised uniformly from the current holding period through the end of the contractual life.

Expected Volatility. The Company estimates the volatility of its common stock at the date of grant based on the historical volatility of the Company's common stock.

Risk-Free Rate. The Company bases the risk-free rate that it uses in the Black-Scholes option valuation model on the implied yield in effect at the time of option grant on U.S. Treasury zero-coupon issues with substantially equivalent remaining terms.

Dividends. The Company has never paid any cash dividends on its common stock and the Company does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model.

The Company used the following assumptions to estimate the fair value of options granted and shares purchased under its stock plans and employee stock purchase plan for the years ended December 31, 2024 and 2023:

	Year ended December 31,	
	2024	2023
Stock Options		
Risk-free rate	3.7-4.2%	4.0-4.2%
Expected dividend yield	—	—
Expected term (in years)	7.3-7.50	7.0-7.5
Volatility	109-110%	87-88%
Forfeiture rate (1)	0.0%	0.0%

(1) The Company accounts for forfeitures as they occur.

	Year ended December 31,	
	2024	2023
Employee Stock Purchase Plan		
Risk-free rate	4.4-5.4%	4.6-5.1%
Expected dividend yield	—	—
Expected term (in years)	0.5	0.5
Volatility	95-246%	88-104%

There were 6,000 and 9,788 shares purchased under the Company's employee stock purchase plan during the years ended December 31, 2024 and 2023, respectively. Included in the statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023 was $1,600 and $5,300, respectively, in stock-based compensation expense related to the recognition of expenses related to shares purchased under the Company's employee stock purchase plan.

As of December 31, 2024, $2.5 million of total unrecognized compensation costs related to nonvested stock options is expected to be recognized over the respective vesting terms of each award through 2028. The weighted average term of the unrecognized stock-based compensation expense is 2.3 years.

The following table summarizes information about stock options outstanding at December 31, 2024:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options Outstanding	Weighted-Average Remaining Contractual Life (In years)	Weighted-Average Exercise Price	Number of Options Exercisable	Weighted-Average Exercise Price
$1.06-$1.22	36,000	8.25	$ 1.21	2,000	$ 1.06
$1.30-$1.30	1,231,950	9.49	$ 1.30	41,500	$ 1.30
$3.12-$3.12	88	0.10	$ 3.12	88	$ 3.12
$3.32-$3.32	650,000	8.64	$ 3.32	—	$ —
$4.00-$4.93	69,285	7.40	$ 4.53	42,160	$ 4.54
$5.07-$5.07	851,872	7.40	$ 5.07	576,086	$ 5.07
$5.29-$8.71	605,168	5.66	$ 7.06	518,183	$ 6.81
$8.80-$12.40	494,389	1.57	$ 11.13	494,389	$ 11.13
$12.60-$21.00	501,396	3.48	$ 16.33	490,214	$ 16.27
$21.10-$28.00	179,139	4.07	$ 22.67	179,139	$ 22.67
$1.06 - $28.00	4,619,287	6.73	$ 6.59	2,343,759	$ 10.34

The Company received zero and $5,500 in cash from option exercises under all stock-based compensation plans for the years ended December 31, 2024 and 2023, respectively.

10. Income Taxes

The Company accounts for income taxes using the liability method under ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on temporary differences resulting from the different treatment of items for tax and financial reporting purposes. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Additionally, the Company must assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The Company has provided a full valuation allowance on the Company's deferred tax assets because the Company believes it is more likely than not that its deferred tax assets will not be realized. The Company evaluates the realizability of its deferred tax assets on a quarterly basis. The Company recorded a deferred tax liability of zero and $244,000 on its balance sheets at December 31, 2024 and 2023, respectively, that arose from tax amortization of an indefinite-lived intangible asset. The Company recorded a tax expense of zero in the years ended December 31, 2024 and 2023, respectively.

The reconciliation of income tax expenses (benefit), at the statutory federal income tax rate of 21%, to net income tax benefit included in the statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023 is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
U.S. federal taxes benefit at statutory rate	$ (1,799)	$ (5,801)
Change in valuation allowance	(6,789)	3,733
Stock-based compensation	210	631
Research and development tax credits	2,041	(1,047)
Warrants	68	(2,084)
Expiring net operating losses	6,287	4,540
Adjustment for Uncertain Tax Positions	(760)	—
Sale of ALZET	455	—
Other	43	28
Total income tax (benefit) provision	$ (244)	$ —
Portion related to discontinued operations	244	—
Total income tax (benefit) provision	$ —	$ —

In 2024 and 2023, total income tax provision (benefit) expense was zero. Deferred tax assets and liabilities reflect the net tax effects of net operating loss, research and other credit carryforwards, and the temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

Significant components of the Company’s deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 82,229	$ 83,752
Research and other credits	19,906	21,679
Section 174 R&D capitalization	10,321	11,004
Stock-based compensation	2,738	3,076
Other	1,646	4,976
Total deferred tax assets	116,840	124,487
Valuation allowance for deferred tax assets	(116,276)	(123,393)
Deferred tax liabilities - right of use asset	(564)	(1,338)
Net deferred tax assets and liabilities	$ —	$ (244)

The Company recognizes deferred tax assets to the extent that the Company believes that these assets are more likely than not to be realized. In making such a determination, all available positive and negative evidence is considered, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If it is determined that the Company would be able to realize deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would cause a provision benefit to be recognized. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of tax benefit might change as new information becomes available. Given the Company’s history of operating losses, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by $7.1 million during 2024 and increased by $5.8 million during 2023, respectively.

As of December 31, 2024, the Company had net operating loss carryforwards for federal income tax purposes of approximately $303.9 million, of which approximately $197.0 million will expire in the years 2025 through 2037, and approximately $106.9 million which do not expire, and federal research and development tax credits of approximately $17.0 million, which expire at various dates beginning in 2025 through 2043, if not utilized.

As of December 31, 2024, the Company had net operating loss carryforwards for state income tax purposes of approximately $270.4 million, which expire in the years 2025 through 2043, if not utilized, and state research and development tax credits of approximately $17.8 million, which do not expire.

Utilization of the net operating losses may be subject to a substantial annual limitation due to federal and state ownership change limitations. The annual limitation may result in the expiration of net operating losses before utilization.

At December 31, 2024 and December 31, 2023, the Company had unrecognized tax benefits of approximately $12.8 million and $13.6 million, respectively (none of which, if recognized, would affect the Company's effective tax rate). The Company does not believe there will be any material changes in its unrecognized tax positions over the next twelve months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31,	
	2024	2023
Balance at beginning of the year	$ 13,568	$ 13,068
Decrease related to prior year tax positions	(799)	(170)
Increase related to current year tax positions	—	670
Balance at end of the year	$ 12,769	$ 13,568

Interest and penalty costs related to unrecognized tax benefits, if any, are classified as a component of interest and other income, net in the Statements of Operations and Comprehensive Loss. The Company did not recognize any interest and penalties expenses related to unrecognized tax benefits for the years ended December 31, 2024 and 2023.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to U.S. federal and state income tax examination for calendar tax years ending 2000 through 2024 due to unutilized net operating losses and research credits.

Beginning with 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenditures when incurred under Section 174 and requires taxpayers to capitalize and amortize domestic expenditures over five years and foreign expenditures over fifteen years. Therefore, based on enacted law, there is a deferred tax asset reflected in the deferred tax table for this item, which is offset by a valuation allowance.

11. Discontinued Operations

On November 22, 2024 (the "Closing Date"), the Company entered into an Asset Purchase Agreement (the "APA") with Alzet, LLC, a subsidiary of Lafayette Instrument Co. (the "Purchaser"). Under the terms of the APA, the Company agreed to sell to the Purchaser substantially all the assets, and certain specified liabilities, related to the ALZET product line (the "Sale"). The APA provided for, subject to certain terms and conditions, the entry into a Transition Services Agreement, pursuant to which the Company agrees to perform certain transition services related to the purchased assets for up to six months after the Closing Date, subject to potential extensions.

On the Closing Date, the Company completed the transaction contemplated by the APA. Pursuant to the terms of the APA, the Purchaser paid the Company $17,500,000 subject to certain adjustments, including for net working capital, and also agreed to assume certain liabilities with respect to the transferred assets.

As a result of the sale of the ALZET product line, the operating results from the Company's ALZET product line have been excluded from continuing operations and presented as discontinued operations in the accompanying Statements of Operations and Comprehensive Loss for all periods presented. During the twelve months ended December 31, 2024, the Company recorded a gain on sale of the ALZET product line of $11.5 million, upon the completion of sale to the Purchaser. The Company incurred transaction costs related to the sale of ALZET product line in the amount of $2.1 million that were recorded in selling, general and administrative expenses within discontinued operations. The results of operations and gain from discontinued operations presented below include certain allocations that management believes fairly reflect the utilization of services provided to the ALZET product line. The allocations do include interest expense of the Oxford term loan as the loan was required to pay off at the close of sale of ALZET product line for all periods presented. The allocations do not include amounts related to general corporate administrative expenses. Therefore, these results of operations do not necessarily reflect what the results of operations would have been had the ALZET product line operated as a stand-alone entity.

The components of income from discontinued operations as reported in the Company’s statements of operations were as follows (in thousands):

	Year ended December 31,	
	2024	2023
Total revenues	$ 5,106	$ 5,958
Operating expenses:		
Cost of product revenues	1,288	1,449
Selling, general and administrative	3,877	1,710
Total operating expenses	5,165	3,159
Other expense:		
Interest and other expenses	1,504	2,793
Loss on debt extinguishment	130	—
Total costs and expenses	6,799	5,952
Income (loss) from discontinued operations	(1,693)	6
Other income:		
Gain on sale of the ALZET product line	11,539	—
Pretax net income from discontinued operations	9,846	6
Income tax benefit	244	—
Net income from discontinued operations	$ 10,090	$ 6
Net income per share		
Basic	$ 0.33	$ 0.00
Diluted	$ 0.33	$ 0.00
Weighted-average shares used in computing net income per share		
Basic	30,940	26,256
Diluted	30,940	26,520

The following table presents information related to assets and liabilities reported as discontinued operations in the Company's balance sheets (in thousands):

	December 31, 2024	December 31, 2023
Accounts receivable	$ —	$ 643
Inventories, net	—	2,087
Prepaid expenses and other current assets	—	47
Discontinued operations – current portion	$ —	$ 2,777
Property and equipment, net	$ —	$ 2
Operating lease right-of-use assets	—	901
Other long-term assets	—	5
Discontinued operations – non-current portion	$ —	$ 908
Accounts payable	$ —	$ 54
Accrued liabilities	—	156
Operating lease liabilities, current portion	—	210
Discontinued operations – current portion	$ —	$ 420
Operating lease liabilities, non-current portion	$ —	$ 734
Other long-term liabilities	—	100
Discontinued operations – non-current portion	$ —	$ 834

The following table presents certain non-cash items related to discontinued operations, which are included in the Company's statements of cash flows (in thousands):

	Years ended December 31, 2024	Years ended December 31, 2023
Depreciation	$ 6	$ 10
Stock-based compensation expense	75	65
Goodwill	3,443	—
	$ 3,524	$ 75
Gain on sale of the ALZET product line	$ 11,539	$ —
Non-cash items, net	$ (8,015)	$ 75

12. Segment Information

The Company is committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. Larsucosterol, the Company's lead drug candidate, binds to and inhibits the activity of DNMTs, epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-AH patients. Larsucosterol is in clinical development for the potential treatment of AH, for which FDA has granted a Fast Track Designation; metabolic dysfunction-associated steatohepatitis ("MASH"), also known as non-alcoholic steatohepatitis or NASH is also being explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved and has been exclusively licensed to Innocoll Pharmaceuticals for commercialization in the United States. The Company also manufactures and sells certain excipients for certain clients for use as raw materials in their products.

The Company’s long-lived assets recognized on the Balance Sheets primarily consisted of property and equipment, net and operating lease right-of-use assets, which are located within the U.S.

The Company manages the business activities on a consolidated basis and operates in one reportable segment.

The Company's Chief Executive Officer is the Chief Operating Decision Maker (“CODM”). The CODM assesses operating performance and makes resource allocation decisions primarily based on net loss, cash on-hand and cash flows utilizing the Company’s product development timelines and cash balances as key inputs to resource allocation.

Significant expenses within loss from continuing operations, as well as within net loss, include cost of goods sold, research and development, and selling, general and administrative expenses, which are each separately presented on the Company’s Statement of Operations and Comprehensive Loss.

13. Subsequent Events

On January 9, 2025, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that for the last 30 consecutive business days the bid price for the Company’s common stock had closed below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market (“Nasdaq”) pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Minimum Closing Bid Price Requirement”). The deficiency letter does not result in the immediate delisting of the Company’s common stock from Nasdaq.

The Company has been provided an initial period of 180 calendar days from January 9, 2025, or until July 8, 2025, to regain compliance with the Minimum Closing Bid Price Requirement. If the Company is not in compliance with the Minimum Closing Bid Price Requirement by July 8, 2025, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards required by Nasdaq, except for the Minimum Closing Bid Price Requirement.

The Company intends to continue actively monitoring the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Minimum Closing Bid Price Requirement, which could include effecting a reverse stock split. However, there can be no assurance that the Company will be able to regain compliance with the Minimum Closing Bid Price Requirement.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

As required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15, DURECT's management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of DURECT's disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that DURECT's disclosure controls and procedures were effective as of the end of the period covered by this report.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision of our Chief Executive Officer and Chief Financial Officer and with the participation of our management, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during our last fiscal quarter that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Adjustment of certain items in our Unaudited Condensed Balance Sheet as of December 31, 2024 and Unaudited Condensed Statements of Operations and Comprehensive Loss for the year ended December 31, 2024 included within our Fourth Quarter and Full Year 2024 Financial Results earnings release.

Subsequent to the issuance of the Company's earnings announcement on March 26, 2025, the Company recorded an adjustment in its Unaudited Condensed Statements of Operations and Comprehensive Loss for the year ended December 31, 2024 to record an additional $450,000 in accrued liabilities due to recognition of unbilled expenses. The adjustment resulted in an increase of $450,000 in total liabilities and a corresponding decrease in stockholders' equity as of December 31, 2024. The effects of this adjustment increased the Company's net loss by $450,000 in its previously reported Unaudited Condensed Statements of Operations and Comprehensive Loss for the year ended December 31, 2024.

During the fiscal quarter ended December 31, 2024, none of our directors or officers informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The names of the executive officers of the Company and their ages, titles and biographies as of the date hereof are incorporated by reference from Part I, Item 1, above.

DIRECTORS

Our Certificate of Incorporation provides that our Board of Directors is divided into three classes, with staggered three-year terms.

Our Class I director, whose term expires at our 2025 annual meeting, is Gail J. Maderis. Our Class II directors, whose terms expire at our 2026 annual meeting, are Peter S. Garcia and Judith J. Robertson. Our Class III directors, whose terms expire at our 2027 annual meeting, are Mohammad Azab, James E. Brown and Gail M. Farfel. Only one class of directors is elected at each annual meeting. The other classes continue to serve for the remainder of their three-year terms. Additionally, the Company plans to re-classify one of our Class III directors from Class III to Class I in connection with our 2025 annual meeting in order to re-balance the class sizes of our Board of Directors to be as nearly equal in number as reasonably possible as required by our certificate of incorporation.

Directors

The names of our directors, their ages as of March 25, 2025 and certain other information about them are set forth below.

Name	Age	Position
James E. Brown, D.V.M.	68	President, Chief Executive Officer and Director
Mohammad Azab, M.D., M. Sc., M.B.A. (1) (3)	69	Director
Gail M. Farfel, Ph.D. (1) (3)	61	Director
Peter S. Garcia, M.B.A. (1) (2)	63	Director, Chair of the Audit Committee
Gail J. Maderis, M.B.A. (1) (2)	67	Chair of the Board and Director Nominee, Chair of the Compensation Committee
Judith J. Robertson (2) (3)	65	Director, Chair of the Nominating and Corporate Governance Committee

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and Corporate Governance Committee

James E. Brown, D.V.M. for the biography of Dr. Brown, please see “Part I, Item 1” – “Executive Officers of the Registrant” above.

Mohammad Azab, M.D., M. Sc., M.B.A. has served on our Board of Directors since January 2021. Dr. Azab served as President and Chief Medical Officer of Astex Pharmaceuticals, Inc. ("Astex") from January 2014 to November 2020 after holding the position of Chief Medical Officer there commencing in July 2009. Upon retirement from his management role, Dr. Azab served as the chair of the board of directors for Astex, a subsidiary of Otsuka pharmaceuticals Co. Ltd, till May 2022. Previously, Dr. Azab served as President and Chief Executive Officer of Intradigm Corporation, a developer of small interfering RNA cancer therapeutics. Prior to this, Dr. Azab served as Executive Vice President of Research and Development, and Chief Medical Officer of QLT Inc., and in several drug development leadership positions at Astra Zeneca in the UK and Sanofi Pharmaceuticals in France. Dr. Azab holds his M.D. degree (M.B., B.Ch.) from Cairo University and a Master of Business Administration from the Richard Ivey School of Business, University of Western Ontario. He received post-graduate training and degrees in oncology research from the University of Paris-Sud and biostatistics from the University of Pierre et Marie Curie in Paris, France. Dr. Azab has more than 30 years of experience in clinical research, global drug development, and business management and led the global development of several drugs currently approved in oncology and other therapeutic areas. Dr. Azab currently serves on the board of directors of Lisata Therapeutics. Dr. Azab previously served on the board of directors of Xenon Pharmaceuticals Inc. until June 2024. Dr. Azab's scientific background including his senior management experience in the pharmaceutical industry and his service as a board member on multiple publicly traded companies are among the qualifications he brings to our Board of Directors.

Gail M. Farfel, Ph.D. has served on our Board of Directors since April 2019. Dr. Farfel served as the Chief Executive Officer of ProMIS Neurosciences Inc. from September 2022 through December 2023. Prior to that, Dr. Farfel served as the Executive Vice President and Chief Development Officer of Zogenix, Inc. ("Zogenix") from July 2015 and on the board of directors of Zogenix International Ltd., a wholly owned subsidiary of Zogenix, Inc. until the acquisition of Zogenix by UCB Pharma S.A. in March 2022, where she oversaw Nonclinical and Clinical Development and Regulatory Affairs. Before joining Zogenix, Dr. Farfel was Chief Clinical and Regulatory Officer of Marinus Pharmaceuticals Inc., a biopharma engaged in development of treatment for neurological disorders. Prior to her entry into the biotech space, Dr. Farfel served as Vice President and Therapeutic Area Head for Neuroscience at Novartis Pharmaceuticals Corporation, where she oversaw their portfolio of neurology and psychiatry products. Dr. Farfel began her career in pharmaceutical drug development at Pfizer Inc., where she worked in Clinical Development and Global Medical Affairs, directing programs through all stages of clinical development and regulatory submissions. Additionally, Dr. Farfel previously served on the board of directors of AVROBIO, Inc. from October 2020 to June 2024. Dr. Farfel is the author of over 50 scientific articles and presentations in the areas of neuropsychopharmacology and drug effects and is a Director on the Boards of the Dravet Syndrome Foundation and the American Society for Experimental Neurotherapeutics. She holds a Ph.D. in Neuropsychopharmacology from the University of Chicago. Dr. Farfel also holds a bachelor's degree in Biochemistry from the University of Virginia. Dr. Farfel's pharmaceutical industry experience relating to executive management, strategic planning, medical and scientific expertise and pharmaceutical industry experience as it relates to drug development and regulatory affairs are among the qualifications she brings to our Board of Directors.

Peter S. Garcia, M.B.A. has served on our Board of Directors since December 2021. Mr. Garcia has worked as a Chief Financial Officer in the life sciences industry for over 30 years and raised over $2 billion in capital during that period. Since November 2024 he has been Chief Financial Officer of Bluejay Therapeutics. He served as the Chief Financial Officer of ALX Oncology Holdings Inc. ("ALX") from January 2020 to November 2024 and led their initial public offering in July 2020 and follow on offering in December 2020. Prior to ALX, he served as Vice President and Chief Financial Officer from 2013 until 2019 at PDL BioPharma, Inc. ("PDL"), an acquirer of royalties and pharmaceutical assets. Before his time at PDL, Mr. García served as Chief Financial Officer at BioTime, Inc., a clinical-stage biotechnology company now known as Lineage Cell Therapeutics. He previously served as Chief Financial Officer of Marina Biotech, Nanosys, Nuvelo, Novacept, IntraBiotics Pharmaceuticals and Dendreon, and began his life science career at Amgen where he served in a number of financial roles of increasing responsibility. Mr. García holds an M.B.A. from the University of California, Los Angeles and a B.A. in Economics and Sociology from Stanford University. Mr. Garcia's pharmaceutical industry experience relating to finance and accounting, executive management, treasury, employee benefits and audit matters are among the qualifications he brings to our Board of Directors.

Gail J. Maderis, M.B.A. has served on our Board of Directors since January 2021 and as Chair of our Board of Directors since March 2023. Ms. Maderis has served as Chair of the board of Antiva Biosciences, Inc. ("Antiva"), a venture funded biopharma company developing topical therapies to treat the pre-cancerous lesions caused by human papillomavirus, since April 2023. From 2015 to April 2023, Ms. Maderis served as President and Chief Executive Officer of Antiva. From 2009 to 2015, Ms. Maderis led BayBio, the industry organization representing and supporting Northern California's life science community, as its President and Chief Executive Officer. From 2003 to 2009, Ms. Maderis served as President and Chief Executive Officer of Five Prime Therapeutics, Inc., a protein discovery and development company focused on immuno-oncology. Prior to FivePrime, Ms. Maderis held senior executive positions at Genzyme Corporation, including Founder and President of Genzyme Molecular Oncology. Ms. Maderis also practiced management and strategy consulting with Bain & Co. She currently serves on the boards of directors of Antiva and Valitor, Inc., as well as on the nonprofit boards of The Termeer Foundation and the University of California Berkeley Foundation Board of Trustees. Ms. Maderis previously served on the board of directors of Allarity Therapeutics, Inc. ("Allarity") from July 2021 until January 2023 and on the board of directors of Allarity Therapeutics A/S, Allarity's predecessor, since October 2020. She received a Bachelor of Science in business from the University of California at Berkeley and a Master of Business Administration from Harvard Business School. Ms. Maderis' operational, industry and leadership experience in the biopharmaceutical industry as Chief Executive Officer of Five Prime Therapeutics, Inc., Founder and President of Genzyme Molecular Oncology and her current position at Antiva, and her insight into business and policy trends impacting the biopharma industry are among the qualifications she brings to our Board of Directors.

Judith J. Robertson has served on our Board of Directors since April 2019. Since January 2022, Ms. Robertson has served as the Chief Commercial Officer of Opthea Limited ("Opthea") and previously was the Chief Commercial Officer of Aerie Pharmaceuticals Inc. ("Aerie") from December 2016 to December 2018, during which time she built the commercial organization and led the successful commercial launch of Rhopressa® (netarsudil) for glaucoma. Ms. Robertson joined Aerie from the Janssen Pharmaceutical Companies of Johnson & Johnson ("Janssen"), where she was the Vice President and Global Commercial Strategy Leader of Immunology, Ophthalmology, and Commercial Analytics from June 2013 to November 2016. Part of her duties at Janssen included evaluating all external licensing and acquisition opportunities. Prior to Janssen, she was Vice President Global Business Franchise Head of Ophthalmology at Novartis Pharma AG ("Novartis") (f/k/a Alcon Laboratories, Inc.), Vice President Global Franchise Head of Respiratory at Novartis, Vice President of Sales & Marketing of Respiratory and Dermatology at Novartis, and President of Bristol Myers Squibb Canada Co. Ms. Robertson previously served on the board of directors of Opthea from June 2021 to January 1, 2022. Ms. Robertson holds a Master of Management from the Kellogg School of Business at Northwestern University and holds a Bachelor of Arts in social science from Ryerson University. Ms. Robertson's pharmaceutical industry experience relating to executive leadership experience with pharmaceutical companies and her expertise with respect to sales, marketing and commercialization of pharmaceutical products are among the qualifications she brings to our Board of Directors.

There are no family relationships among any of our directors or executive officers.

Code of Ethics

In December 2024, the Board approved an amended Code of Ethics applicable to all of our employees, officers and directors. The purpose of the Code of Ethics is to deter wrongdoing and, among other things, promote compliance with applicable laws, fair dealing, proper use and protection of our assets, prompt and accurate public company reporting, reporting of accounting complaints or concerns and avoidance of conflicts of interest and usurpation of corporate opportunities.

Our Code of Ethics can be found on our corporate website at www.durect.com under "Investors—Corporate Governance—Documents & Charters." If we make any substantive amendments to the Code of Ethics or grant any waiver from a provision of the Code of Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver by a method selected by the Board of Directors and in conformity with applicable SEC and Nasdaq rules.

Whistleblower Policy

In compliance with Section 301 of the Sarbanes-Oxley Act, the Audit Committee of the Board of Directors maintains procedures for the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and confidential, anonymous employee submissions of concerns regarding questionable accounting or auditing matters ("Whistleblower Policy"). In December 2024, the Board approved an amended Whistleblower Policy. Our Whistleblower Policy can be found on our corporate website at www.durect.com under "Investors—Corporate Governance—Documents & Charters."

Audit Committee

Audit Committee The Audit Committee has been established in accordance with Section 3(a)(58)(A) of the Exchange Act. In accordance with its charter, the Audit Committee assists the Board in its general oversight of our financial reporting, internal controls and audit functions, and is directly responsible for the appointment, retention, compensation and oversight of the work of our independent registered public accounting firm. At the end of the last fiscal year, the Audit Committee was composed of the following directors: Peter S. Garcia, Gail J. Maderis and Judy J. Robertson. Mr. Garcia has served as Chair of the Audit Committee since June 2023.

Among other matters, the Audit Committee monitors the activities and performance of our external auditors, including the audit scope, external audit fees, auditor independence matters and the extent to which the independent registered public accounting firm may be retained to perform non-audit services. Our independent registered public accounting firm, WithumSmith+Brown, PC ("Withum"), provides the Audit Committee with the written disclosures and the letter required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent accountant's communications with the Audit Committee concerning independence, and the Audit Committee discusses with the independent registered public accounting firm and management that firm's independence.

In accordance with Audit Committee policy and the requirements of law, all services to be provided by Withum are pre-approved by the Audit Committee. Pre-approval includes audit services, audit-related services, tax services and other services. In its pre-approval and review of non-audit service fees, the Audit Committee considers, among other factors, the possible effect of the performance of such services on the auditor's independence. To avoid certain potential conflicts of interest in maintaining auditor independence, the law prohibits a publicly traded company from obtaining certain non-audit services from its auditing firm.

As required by Nasdaq rules, the members of the Audit Committee each qualify as "independent" under special standards established for members of audit committees. The Audit Committee also includes at least one member who has been determined by the Board to meet the qualifications of an "audit committee financial expert" in accordance with SEC rules. Peter S. Garcia has been determined by the Board of Directors to be "audit committee financial experts." Stockholders should understand that this designation is a disclosure requirement of the SEC related to Mr. Garcia's experience and understanding with respect to certain accounting and auditing matters. The designation does not impose upon Mr. Garcia any duties, obligations or liability that are greater than are generally imposed on either of them as members of the Audit Committee and the Board, and their designation as an audit committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the Audit Committee or the Board.

Insider Trading, Hedging and Stock Ownership Policies

We have adopted an Insider Trading Policy governing the purchase, sale, and other dispositions of our securities by our directors, officers, employees and other individuals associated with us that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. Our insider trading policy provides that all officers and employees

of the Company, all members of the Board, and any consultants and contractors to the Company that the Company designates, as well as, to the extent controlled by or benefiting any of the foregoing persons, members of the immediate families (spouse, parents, grandparents, children, grandchildren and siblings, including any such relationships that arise through marriage or adoption) sharing a household with the officer, employee, director, consultant or contractor, and any other member of the households of persons directly subject to this Policy, and family trusts (or similar family entities) may not engage in any transactions that suggest speculation in our stock (that is, an attempt to profit in short-term movements, either increases or decreases, in the stock price). The policy notes that many “hedging” transactions, such as “collar” transactions, contingent or forward sales, and other similar or related arrangements, are prohibited. Specifically, our insider trading policy precludes any employee or Officer from engaging in any “short” sale, “sale against the box” or any equivalent transaction involving our stock (or the stock of any of our business partners in any of the situations described above). A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

We do not have a stock ownership policy.

Delinquent Section 16(A) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and any persons who own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. Based solely on our review of the copies of such forms filed with the SEC and written representations from the directors and executive officers, we believe that all Section 16(a) filing requirements were timely met in the year ended December 31, 2024 except as otherwise disclosed in our previous filings with the SEC, with the following exception: a late (due to an administrative error) Form 4 filing for one transaction that was made on behalf of Dr. Norman Sussman immediately upon such finding on September 11, 2024.

Item 11. Executive Compensation.

Compensation Discussion and Analysis

The Compensation Committee (for purposes of this analysis, the "Committee") of the Board has responsibility for establishing, implementing and continually monitoring adherence with our compensation practices. The Committee makes all decisions regarding the compensation of our Chief Executive Officer (our "CEO") and Chief Financial Officer (our "CFO"), as well as the other individuals included in the Summary Compensation Table below (together with our CEO and CFO, our "Named Executive Officers") and all of our Vice Presidents. In this proxy, we refer to those persons as our "Officers."

Philosophy and Elements

All of our compensation programs are designed to attract and retain key employees, motivating them to achieve corporate and individual objectives and rewarding them appropriately for their performance. Different programs are geared to short and longer-term performance with the goal of increasing stockholder value over the long term. Executive compensation programs impact all employees by setting general levels of compensation and helping to create an environment of goals, rewards and expectations. Because we believe the performance of every employee is important to our success, we consider the effect of executive compensation and incentive programs on all of our employees.

We believe that the compensation of our Officers should reflect the extent of their success as a management team and in addition, their individual performance in attaining key operating objectives, such as advancing our product pipeline, entering into strategic collaborative agreements and maintaining our financial strength, and ultimately, increasing stockholder value. We believe that the performance of our Officers in managing the Company, considered in light of general economic and specific Company, industry and competitive conditions, should be the basis for determining their overall compensation. We also believe that their compensation should not be based on the short-term performance of our stock, whether favorable or unfavorable, but rather that the price of our stock will, in the long-term, reflect our operating performance, and ultimately, the management of the Company by our Officers. We seek to have the long-term performance of our stock reflected in executive compensation through our stock option and other equity incentive programs.

Elements of compensation for our executives include: salary, bonus, stock incentive awards and perquisites. We choose to pay each element of compensation to our executives in order to attract and retain the necessary executive talent, reward performance and provide incentive for their balanced focus on long-term strategic goals as well as short-term performance. The amount of each element of compensation is determined by or under the direction of the Committee, which uses the following factors to determine the amount of salary and other benefits to pay each executive:

- performance against corporate and individual objectives for the previous year;
- value of their unique skills and capabilities to support our long-term performance;
- performance of their general management responsibilities;
- contribution as a member of our executive management team;
- difficulty of achieving desired results in the coming year and years to follow; and
- compensation paid by companies deemed by the Committee to be comparable to us.

These elements fit into our overall compensation objectives by helping to secure the future potential of our products and operations, continuing to meet our business objectives, providing proper compliance and regulatory guidance, and helping to create an effective and cohesive team. Our policy for allocating between long-term and currently paid compensation is to ensure adequate base compensation to attract and retain personnel, while providing incentives to maximize long-term value for us and our stockholders. Likewise, we provide cash compensation in the form of base salary to meet competitive salary norms and reward performance on an annual basis and in the form of bonus compensation to reward superior performance against specific annual goals. We provide non-cash compensation (i.e., stock options) to reward superior performance against specific objectives and long-term strategic goals. Our compensation package for our Named Executive Officers for fiscal year 2024 ranged from 42% to 72% in cash compensation and 28% to 58% in non-cash compensation, including benefits and equity-related awards. We believe that this structure is competitive within the marketplace and appropriate to fulfill our stated policies. There is no pre-established policy or target for the allocation between either cash and non-cash or short-term and long-term incentive compensation. Rather, the Committee reviews information from relevant peer companies, and such other information as it considers appropriate, to determine the appropriate level and mix of incentive compensation.

Setting Officer Compensation

Process

At one or more meetings at the end of each fiscal year (usually in December) or early in the following fiscal year (usually in January or February), the Committee reviews our performance during the fiscal year against established corporate objectives, individual Officer performance and history of all the elements of each Officer's total compensation in comparison with the compensation of executive officers in an appropriate peer group as described below. After due consideration of the foregoing, the Committee:

- sets the base salaries for our Officers for the following fiscal year;
- approves individual Officer bonus payments for performance for the prior fiscal year;
- approves stock options that will be granted to each Officer for performance for the prior fiscal year;
- adopts the management incentive plan (including objectives and weighting) for the following fiscal year; and
- decides upon general compensation guidelines and overall salary, bonus and stock option budgets for all employees.

The specific basis for the determination of base salaries, bonuses and stock option grants to Officers is detailed below.

Role of Executive Officers

The CEO annually reviews the performance of each Officer (other than his own performance, which is reviewed by the Committee) with the assistance and input from our head of Human Resources. The conclusions reached and recommendations made based on these reviews, including with respect to salary adjustments and annual award amounts, are presented to the Committee. Officers, other than the CEO, are not present at the time of these deliberations. The Committee can exercise its discretion in modifying any recommended adjustments or awards to executives and ultimately makes the final decision with respect to the compensation of all our Officers. The CEO is not present during the Committee's deliberations and discussion on their individual compensation.

Benchmarking

To assist the Committee in benchmarking executive compensation in 2023, the Committee retained Larry Setren & Associates, an independent compensation consulting firm, to collect and synthesize data from several sources as detailed below.

The Committee reviewed compensation information as reported in the definitive proxies for fiscal year 2022 from the following public life sciences companies: 89bio, Axcella, Atreca, Cymabay Therapeutics, CytomX Therapeutics, Eiger Biopharma, Gritstone bio, Harpoon Therapeutics, Magenta Therapeutics, Ovid Therapeutics, Spero Therapeutics, Surrozen, Syros Pharmaceuticals, Unity Biotechnology and Viking Therapeutics (the "Peer Companies"). The Committee selected the Peer Companies as a relevant comparison group for us based on various criteria including similarity of business, employee headcount, market capitalization and revenue, and reviewed the proposed Peer Companies with Larry Setren & Associates for appropriateness as a comparison group. Where such source did not provide sufficient information with respect to the bonus and equity compensation of certain officer positions, the Committee used compensation information from The Radford Global Life Sciences Survey (2022) (the "2022 Radford Survey") as a supplement. The Committee took into consideration the summarized compensation data from the Peer Companies along with the data from the 2022 Radford Survey when setting base salaries applicable for fiscal year 2024 and determining the cash bonus opportunities and stock option awards for our Officers for fiscal year 2024.

Base Salary

It is the goal of the Committee to establish salary compensation for our Officers that is competitive with comparable peer companies. In setting Officer base salaries for fiscal year 2024 (which were set in July 2023), the Committee reviewed the salary compensation of officers with comparable qualifications, experience and responsibilities as reported in the 2022 Radford Survey and definitive proxies of the Peer Companies. It is not our policy to pay our CEO or other Officers at the highest level relative to their respective counterparts at the Peer Companies. In setting target compensation for our Officers, the Committee uses as a reference point the 50th percentile of compensation paid to similarly situated executives at the Peer Companies. Variations to this objective may occur as dictated by the experience and performance level of the individual and market factors. We believe that this gives us the opportunity to attract and retain talented managerial employees both at the senior executive level and below, yet conserves our financial resources, to the benefit of our stockholders.

The following table summarizes the annual base salary rates of our Named Executive Officers at fiscal year-end in 2024 compared to 2023. There were no salary increases to the Officers in 2024.

Name	2024 Base Salary ($)	2023 Base Salary ($)
James E. Brown	597,914	597,914
Timothy M. Papp	431,600	431,600
Norman L. Sussman	429,865	429,865

Bonus (Non-Equity Incentive Plan Compensation)

The cash bonus element of our executive compensation is designed to reward our Officers for the achievement of shorter-term corporate goals, measurable on an annual basis, as well as, with certain exceptions noted below for the CEO, individual Officer performance. Our general process for determining the bonus element of our Officer compensation for fiscal year 2024 performance is set forth below.

In setting the target bonus for which each Officer would be eligible for fiscal 2024 performance, the Committee reviewed the bonuses of officers with comparable qualifications, experience and responsibilities at companies as reported in the 2022 Radford Survey and definitive proxies of the Peer Companies.

For performance in fiscal year 2024, the Committee set the target bonus for the CEO at 60% of such individual's base notional salary, and for all other Officers at 30%–40% of such individual's base notional salary. The two factors used by the Committee to determine the percentage of the target amount to be awarded to any individual Officer other than the CEO are the individual performance of such Officer during the relevant fiscal year and the Company's performance as a whole against pre-set corporate objectives for fiscal year 2024 (the "Corporate Objectives"). The Committee retains the discretion to adjust actual bonus payments based on other factors, as discussed below.

The Corporate Objectives for each fiscal year are typically established by the Committee in consultation with our Officers in the first quarter of such fiscal year. The Corporate Objectives comprise product development, financial, business development and operational goals with varying degrees of difficulty and have associated target dates for accomplishment. Each objective is weighted based on its importance to the accomplishment of the Company's plans. At the end of each fiscal year, the Committee makes a determination of the overall percentage of the Corporate Objectives accomplished by the Company as a whole during the fiscal year. The Committee exercises its reasonable discretion in determining the percentage of Corporate Objectives accomplished by the Company, including, for example, taking into account the achievement of any listed objective above expectations or the accomplishments of the Company that were not listed in the Corporate Objectives.

For fiscal year 2024, the Corporate Objectives against which Officer performance was evaluated consisted of, among others, the following goals.

- Financial
    - The principal financial goals were to operate within the approved corporate budget, meet revenue and cash contribution targets for the ALZET® product line and obtain financing commitments or other capital resources to fund the Company through Phase 3 topline data for larsusocosterol.
- Product Development of Larsucosterol and Research and Development
    - The primary goals related to initiating the Phase 3 trial.

The Committee believes that the accomplishments of the Company as a whole are an important measure of the performance of all of our Officers, including the effectiveness of their leadership and teamwork. In particular, the percentage of the total eligible amount that is normally awarded to the CEO as a bonus is based entirely on the Company's overall performance and accomplishment of the Corporate Objectives because the Committee believes that the paramount duty of this individual is leadership. Thus, the bonus awarded to the CEO for a fiscal year is typically computed by multiplying the percentage determined by the Committee based on Corporate Objectives accomplished and the Company's overall performance by 60% of the CEO base salary (the target bonus amount that he is eligible to receive as set by the Committee).

For a fiscal year, the Committee typically applies a weighting of Corporate Objectives (80% for Vice Presidents; 90% for Senior Vice Presidents; and 95% for the Chief Financial Officer, Chief Medical Officer and Executive Vice Presidents) and applies a weighting of individual performance (20% for Vice Presidents; 10% for Senior Vice Presidents; and 5% for the Chief Financial Officer, Chief Medical Officer and Executive Vice Presidents) for Officers other than the CEO.

The individual performance of each Officer, except for the CEO, is assessed as part of an annual written performance appraisal performed typically at the end of each fiscal year. At the end of each fiscal year or early in the following fiscal year, each Officer, together with his or her supervisor (e.g., the CEO), agrees upon a written set of objectives for the following fiscal year pertinent to the Officer individually (which includes goals for the functional area or business managed by such Officer). The supervisor also assesses the accomplishments of the Officer in the most recently completed fiscal year against the applicable pre-established objectives for that Officer in such year, and arrives at a percentage of goals accomplished. Thus, the bonus of each Officer other than the CEO is typically determined as follows:

Bonus Amount = (A% * B% + C% * D%) * E% * Base Salary

A = the percentage (5%, 10% or 20%) of individual performance applicable to the Officer

B = the percentage of personal objectives accomplished by the Officer as determined by the Officer's supervisor

C = the percentage (80%, 90% or 95%) of weighting of Corporate Objectives

D = the percentage of Corporate Objectives accomplished and overall performance by the Company as determined by the Committee

E = the percentage (30%, 35% or 40%) of the base salary set as the maximum bonus target applicable to the Officer

Notwithstanding the general practice with respect to determination of Officer bonuses set forth above, the Committee retains complete discretion to adjust the result obtained using the general approach for individual variations in performance or business considerations.

The Board tracked performance against these corporate goals throughout fiscal year 2024. At the end of the year, the Committee determined that no corporate bonuses would be paid to all employees (including our Named Executive Officers) relative to 2024 performance, and thus did not come to a formal determination of the exact percentage of corporate goals that had been achieved.

The total calculated bonus award for the Named Executive Officers for 2024 are set forth in the table below.

Name	2024 Base Salary ($)	Annual Incentive Opportunity Target (as % of base salary)	Target ($)	Actual 2024 Earned Award ($)
James E. Brown	597,914	60%	358,748	—
Timothy M. Papp	431,600	40%	172,640	—
Norman L. Sussman	429,865	40%	171,946	—

Equity Incentive Program

We intend that our equity incentive program is the primary vehicle for offering long-term incentives and rewarding our Officers and key employees. We also regard our equity incentive program as a key retention tool. This is a very important factor in our determination of the type of award to grant and the number of underlying shares that are granted in connection with that award. Because of the direct relationship between the value of an option and the market price of our common stock, we have always believed that granting stock options is the best method of motivating our Officers to manage the Company in a manner that is consistent with our interests and those of our stockholders. It is our typical practice to grant stock options to our Officers and all employees annually in connection with our annual employee performance appraisal.

At the same meeting(s) during which the Committee determines our Officer base salaries for the following fiscal year and bonuses for performance in the previous fiscal year, the Committee also determines the ranges of stock options for which our Officers are eligible by rank. The Committee sets these ranges after consideration of (a) the value of equity incentive awards of officers with comparable qualifications, experience and responsibilities at the then-current peer companies, (b) the dilution that would be created by the stock options awards for that fiscal year (the "Burn Rate"), (c) the overall value of equity held by our employees as a retention incentive, and (d) the Company's prior year performance. The Committee's general philosophy is that the value of our equity incentive awards to our Officers should be competitive with the then-current peer companies subject to the Company maintaining a Burn Rate for its equity incentive programs that is not overly dilutive to our stockholders and comparable to other companies in the then-current peer group.

In determining the annual grant amounts of stock options to our employees and Officers, the Committee considers a review of market data for comparable positions and each individual's accumulated vested and unvested awards, current and potential realizable value over time using stock appreciation assumptions, vesting schedules, comparison of individual awards between Officers and in relation to other compensation elements, stockholder dilution and accounting expense, and corporate performance as well as each individual's performance. The factors used by the Committee to determine the specific number of shares underlying any stock option grant to any individual Officer other than the CEO include the individual performance of such Officer during the prior fiscal year and the performance of the Company as a whole against the Corporate Objectives. The specific number of shares underlying the stock option grants to our CEO is determined based on the performance of the Company as a whole against the Corporate Objectives and may include a review of option grants by Peer Companies.

For our annual stock option grant, which occurred on October 14, 2024, the Committee targeted a Burn Rate (computed as total shares subject to the annual option grants to all employees including Officers for the 2024 fiscal year divided by total outstanding shares as of December 31, 2023) of approximately 4.1%.

In addition to annual grants, our Board of Directors and Committee may grant equity compensation to our Officers and employees at any time for incentive and retention purposes in keeping with our non-cash equity compensation practices.

On July 26, 2024, pursuant to the recommendation of the Committee, the Board of Directors approved a restricted stock unit ("RSU") grant of 275,000 shares of common stock to Mr. Papp.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

Our executive officers are not permitted to choose the grant date for their individual stock option grants. Stock option grants to our employees, including our executive officers, are generally made annually at a meeting of the Committee that is held during the first quarter of each year (after the conclusion of our annual Company-wide performance appraisal of all employees for the previous fiscal year), and the grants are effective on the date of the meeting (or on the next trading day following such date if it is not a trading day). Additionally, non-employee directors generally receive grants of initial and annual equity awards, at the time of a director's initial appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, as further described under the heading, "Director Compensation" above.

We do not otherwise maintain any written policies on the timing of awards of stock options or similar instruments with option-like features. The Compensation Committee considers whether there is any material nonpublic information about our Company when determining the timing of stock option grants and does not seek to time the award of stock options in relation to our Company's public disclosure of material nonpublic information. During fiscal year 2024, we did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. In addition,

during fiscal year 2024, none of our Named Executive Officers were awarded options with an effective grant date during any period beginning four business days before the filing or furnishing of a Form 10-Q, Form 10-K, or Form 8-K that disclosed material nonpublic information (other than a Form 8-K that disclosed a material new option award grant under Item 5.02(e)), and ending one business day after the filing or furnishing of such reports.

Post-Employment Compensation

Pension Benefits

We do not provide pension arrangements or post-retirement health coverage for our executives or employees. Our executive officers, as with all eligible employees, are eligible to participate in our 401(k) plan. We do not provide matching contributions for any of our employees including our Officers.

Nonqualified Deferred Compensation

We do not provide any nonqualified deferred contribution or other deferred compensation plans.

Other Post-Employment Payments

All of our employees, including our Officers, are employees-at-will and as such do not have employment contracts with us. We also do not provide post-employment health coverage or other benefits, except in connection with the change of control agreements, details of which are included below under “Change of Control Agreements.”

Anti-Hedging Policy

Our insider trading policy provides that all officers and employees of the Company, all members of the Board, and any consultants and contractors to the Company that the Company designates, as well as, to the extent controlled by or benefiting any of the foregoing persons, members of the immediate families (spouse, parents, grandparents, children, grandchildren and siblings, including any such relationships that arise through marriage or adoption) sharing a household with the officer, employee, director, consultant or contractor, and any other member of the households of persons directly subject to the policy, and family trusts (or similar family entities) may not engage in any transactions that suggest speculation in our stock (that is, an attempt to profit in short-term movements, either increases or decreases, in the stock price). The policy notes that many “hedging” transactions, such as “collar” transactions, contingent or forward sales, and other similar or related arrangements, are prohibited. Specifically, our insider trading policy precludes any employee or Officer from engaging in any “short” sale, “sale against the box” or any equivalent transaction involving our stock (or the stock of any of our business partners in any of the situations described above).

Compensation Recovery Policy

In accordance with the final rules adopted by the SEC and Nasdaq implementing the incentive-based compensation recovery provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”), in the event the Company is required to restate any of its financial statements that have been filed with the SEC, then the Compensation Committee will seek to recover any erroneously awarded performance-based incentive-based compensation (including any performance-based cash and equity awards and salary increases earned wholly or in part based on the attainment of financial performance goals) received by any person who is or was a Section 16 officer during the three-fiscal year recovery period.

Most Recent Advisory Vote on Executive Compensation

The Committee noted that at the 2024 Annual Meeting held on September 25, 2024, the Company’s executive compensation was approved on a non-binding, advisory basis based upon the following votes:

For	Against	Abstain	Broker Non-Vote
5,895,423	913,798	234,524	15,119,441

The Board of Directors and the Committee reviewed these final vote results and determined that, given the significant level of support, no changes to our executive compensation philosophy, policies and decisions were necessary based solely on the vote results.

Tax and Accounting Implications

Deductibility of Executive Compensation

While Section 162(m) of the Internal Revenue Code of 1986, as amended, places a limit of $1 million on the amount of compensation that we may deduct as a business expense in any year with respect to certain of our executive officers, except with respect to certain grandfathered “performance-based” arrangements, the Committee retains the discretion to award compensation that is not deductible as it believes that it is in the best interests of our stockholders to maintain flexibility in our approach to executive compensation in order to structure a program that we consider to be the most effective in attracting, motivating and retaining key executives.

Accounting for Stock-Based Compensation

Stock-based compensation is estimated at the date of grant based on the stock award’s fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite period in a manner similar to other forms of compensation paid to employees and directors. Our financial statements include more information regarding accounting for stock-based compensation.

COMPENSATION OF EXECUTIVE OFFICERS

The following table shows for the fiscal years ended December 31, 2024 and 2023, compensation awarded to or paid to, or earned by, our Chief Executive Officer and our other Named Executive Officers.

In 2024 and 2023, we did not grant any stock awards and we do not currently offer pension or nonqualified deferred compensation plans.

Summary Compensation Table for Fiscal 2024

Name and Principal Position	Year	Salary ($)		Bonus ($)	Stock Awards (1)($)	Option Awards (2)($)	Non-Equity Incentive Plan Compensation (3)($)	All Other Compensation (4)($)	Total ($)
James E. Brown, D.V.M.	2024	597,914	(5)	—	—	430,538	—	44,136	1,072,588
President and Chief Executive Officer	2023	586,416		—	—	812,320	—	47,048	1,445,784
Timothy M. Papp	2024	431,600	(6)	—	459,250	126,291	—	4,316	1,021,457
Chief Financial Officer	2023	423,300		—	—	243,696	—	4,316	671,312
Norman L. Sussman	2024	429,865	(7)	—	—	119,402	—	51,697	600,964
Chief Medical Officer	2023	421,599		—	—	182,772	—	50,107	654,478

(1) Amounts in this column reflect the aggregate grant date fair value of RSUs granted in the applicable year as computed in accordance with FASB ASC Topic 718. These amounts reflect our accounting expense for these stock awards and do not represent the actual economic value that may be realized by each Named Executive Officer. There can be no assurance that these amounts will ever be realized. For more information, please see Note 9 of the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2024 regarding assumptions underlying the valuation of equity awards.

(2) Amounts in this column reflect the aggregate grant date fair value of stock options granted in the applicable year as computed in accordance with FASB ASC Topic 718. The grant date fair value of the options was determined using the Black-Scholes option pricing model based on the fair market value on the date of grant. These amounts reflect our accounting expense for these stock options and do not represent the actual economic value that may be realized by each Named Executive Officer. There can be no assurance that these amounts will ever be realized. For more information, please see Note 9 of the financial statements in our Annual Report on Form 10-K for the years ended December 31, 2023 and 2024 regarding assumptions underlying the valuation of equity awards.

(3) There were no bonuses awarded to our Named Executive Officers relative to their 2023 and 2024 performance.

(4) Includes amounts associated with insurance premiums we pay for Accidental Death and Dismemberment, Life, Medical, Dental, Vision, short-term and long-term disability insurance and medical insurance waiver incentives.

(5) Dr. Brown’s salary increased from $574,918 to $597,914 effective July 1, 2023. There was no salary increase for Dr. Brown in 2024.

(6) Mr. Papp’s salary increased from $415,000 to $431,600 effective July 1, 2023. There was no salary increase for Mr. Papp in 2024.

(7) Dr. Sussman’s salary increased from $413,332 to $429,865 effective July 1, 2023. There was no salary increase for Dr. Sussman in 2024.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR—EXECUTIVE OFFICERS

The following table shows for the fiscal year ended December 31, 2024, certain information regarding outstanding stock awards and option awards at fiscal year-end for our Named Executive Officers. All options and RSUs were granted under our 2000 Stock Plan.

Outstanding Equity Awards at December 31, 2024

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Grant Date	Option Expiration Date (1)	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
James E. Brown	24,999	—	—	8.80	1/09/2015(4)	1/09/2025		
	3,703	—	—	17.50	3/26/2015(5)	3/26/2025		
	19,999	—	—	11.60	1/28/2016(4)	1/28/2026		
	4,807	—	—	13.50	3/31/2016(5)	3/31/2026		
	16,720	—	—	11.60	1/28/2016(3)	1/28/2026		
	14,567	—	—	13.10	1/9/2017(3)	1/9/2027		
	22,499	—	—	13.10	1/9/2017(4)	1/9/2027		
	4,717	—	—	14.00	6/19/17(5)	6/19/2027		
	18,821	—	—	12.40	1/26/2018(3)	1/26/2028		
	24,999	—	—	12.40	1/26/2018(4)	1/26/2028		
	22,175	—	—	5.77	1/23/2019(3)	1/23/2029		
	14,999	—	—	5.77	1/23/2019(4)	1/23/2029		
	22,499			21.10				
		—	—		1/21/2020(4)	1/21/2030		
	19,593	1,306	—	20.30	1/15/2021(4)	1/15/2031		
	65,731	29,879	—	8.71	1/6/2022(4)	1/6/2032		
	50,665	—	—	5.07	2/21/2023(3)	2/21/2033		
	87,500	112,500	—	5.07	2/21/2023(4)	2/21/2033		
	—	—	250,000	3.32	8/23/2023(7)	8/23/2033		
	—	375,000	—	1.30	10/14/2024(4)	10/14/2034		
Timothy M. Papp	33,750	26,250	—	4.52	7/1/2022(2)	7/1/2032		
	12,377	—	—	5.07	2/21/2023(3)	2/21/2033		
				5.07				
	26,250	33,750	—		2/21/2023(4)	2/21/2033		
	—	—	50,000	3.32	8/23/2023(7)	8/23/2033		
	—	110,000	—	1.30	10/14/2024(4)	10/14/2034		
							275,000 (8)	206,250 (9)
Norman L. Sussman	20,000	—	—	17.70	11/2/2020(2)	11/2/2030		
	—	—	5,000	17.70	11/2/2020(7)	11/2/2030		
	9,375	625	—	20.30	1/15/2021(4)	1/15/2031		
	27,388	12,449	—	8.71	1/6/2022(4)	1/6/2032		
	24,557	—	—	5.07	2/21/2023(3)	2/21/2033		
	19,687	25,313	—	5.07	2/21/2023(4)	2/21/2033		
	—	—	50,000	3.32	8/23/2023(7)	8/23/2033		
	—	104,000	—	1.30	10/14/2024(4)	10/14/2034		

(1) The original term of these option grants is 10 years from the date of grant.

(2) The vesting schedule associated with these option grants is as follows: one-fourth (1/4) of the total shares subject to such option shall vest on the one-year anniversary of the date of grant, and one-sixteenth (1/16) of the total shares subject to the option shall vest quarterly over three years following the one-year anniversary, subject to continued service on each applicable vesting date.

(3) The vesting schedule associated with these option grants is as follows: 100% of the total shares subject to such option vested on the date of grant.

(4) The vesting schedule associated with these option grants is as follows: one-sixteenth (1/16) of the total shares subject to the option shall vest quarterly over four years following the date of grant, subject to continued service on each applicable vesting date.

(5) The vesting schedule associated with these option grants is as follows: one-fourth (1/4) of the total shares subject to the option shall vest quarterly over one year following the date of grant, subject to continued service on each applicable vesting date.

(6) The vesting schedule associated with the option grant is as follows: one forty-eighth (1/48) of the total shares subject to the option shall vest monthly over four years following the date of grant, subject to continued service on each applicable vesting date.

(7) The vesting schedule associated with these option grants is as follows: the performance-based stock option grants will vest upon meeting certain specified development and regulatory milestones within specified time frames related to larsucosterol for severe AH, with such vesting also subject to the optionee providing continuous service to the Company through the date of the applicable vesting event.

(8) The vesting schedule associate with the RSU grant is as follows: the RSUs vested as to 50% of the total number of shares on January 26, 2025, and the remaining 50% of the total number of shares will vest on July 26, 2025, subject to continued service on each applicable vesting date.

(9) Each RSU represents the right to receive a share of our common stock. The market value of our common stock is based on the per share price of $0.75, which was the closing stock price of the Company’s common stock on December 31, 2024, the last trading day of the fiscal year 2024.

CHANGE OF CONTROL AGREEMENTS

We maintain a change of control policy applicable to our Officers who hold the rank of Vice President and above (who are not party to any other change of control agreement with us) which provides that, in the event that such Officer's employment is terminated without cause or constructively terminated, in connection with and prior to a change in our control, or within 24 months following a change in our control, then: (1) the unvested portion of any stock options or stock awards held by such Officer shall automatically accelerate so as to become completely vested as of the effective date of the termination, and (2) such Officer shall receive a lump sum cash payment equal to one year of such Officer's then current notional salary, provided that such cash payment will be equal to two years of such Officer's then current notional salary in the case of Dr. Brown.

The change of control policy provides any such severance benefits are conditioned upon such Officer delivering to us an effective release of claims against us, complying with certain non-disparagement covenants, and cooperating with the Company in order to ensure an orderly transfer of his or her duties and responsibilities. If the Officer breaches any of these requirements, the Company will have no further obligation to pay to the Officer any benefit under the policy, and the Officer will be obligated to repay to the Company all benefits previously paid to, or on behalf of, the Officer under the policy.

The policy contains a "better after-tax" provision, which provides that if any of the payments to an executive constitutes a parachute payment under Code Section 280G, the payments will either be (i) reduced or (ii) provided in full to the executive, whichever results in the executive receiving the greater amount after taking into consideration the payment of all taxes, including the excise tax under Code Section 4999.

Had a change of control occurred during fiscal 2024 and had their employment been terminated on December 31, 2024, our Named Executive Officers would have been eligible to receive the payments set forth in the columns under the heading "Terminations Within 24 Months of a Change of Control" in the table below without taking into account the impact of the "better after-tax" provision.

	Terminations Within 24 Months of a Change of Control		
Name	**Severance Payments ($)**	**Value of Accelerated Unvested Options (1)($)**	**Value of Accelerated Unvested Stock Awards (2)($)**
James E. Brown	1,195,828	—	—
Timothy M. Papp	431,600	—	206,250
Norman L. Sussman	429,865	—	—

(1) The value of accelerated vesting of the options is based solely on the excess, if any, of $0.75 per share, the closing market price of our common stock on December 31, 2024, over the exercise price of the unvested portion (as of December 31, 2024) of our Named Executive Officers' stock options. Because many of our stock options have exercise prices higher than our current stock price, if our stock value was higher at the time of any actual termination of employment, additional stock options could have considerable value.

(2) The value of accelerated vesting of stock awards is based on the closing market price of our common stock of $0.75 on December 31, 2024. Mr. Papp held 275,000 unvested RSUs on December 31, 2024 that would be subject to acceleration .

DIRECTOR COMPENSATION

Overview of Compensation and Procedures

The Compensation Committee reviews the level of compensation of our non-employee directors on an annual basis. To determine how appropriate the current level of compensation for our non-employee directors is, we have historically obtained data from a number of different sources including:

- publicly available data describing director compensation in peer companies;
- survey data collected by our human resources department; and
- information obtained directly from other companies.

We compensate non-employee members of the Board through a mixture of cash and equity-based compensation. Effective January 1, 2024, each non-employee director became eligible to receive a cash retainer fee equal to $40,000 per year in addition to annual cash retainer fees for serving on the following committees: (a) Audit Committee (retainer of $8,000 or $22,500 for the chairperson), (b) Compensation Committee (retainer of $6,000 or $15,000 for the chairperson), (c) Nominating and Corporate Governance Committee (retainer of $5,000 or $12,000 for the chairperson), and (d) Research and Development Committee ($7,500 or $15,000 for the chairperson), (d) Research and Development Committee which was disbanded on July 12, 2024 ($7,500 or $15,000 for the chairperson), and (e) Transaction Committee (retainer of $8,000 for all members). The cash retainer fees are eligible to be paid on a quarterly basis in arrears. In connection with her appointment as the Chair of the Board, effective March 17, 2023, Ms. Maderis receives a cash retainer fee of $70,000 per year.

All of our current non-employee directors are also eligible to receive stock option grants under our 2000 Stock Plan as part of their compensation for their service. Pursuant to the Compensation Committee's most recent review of non-employee director compensation, when each non-employee director first became a director, he or she received nonstatutory options to purchase 7,000 shares of our common stock . These options have a ten-year term and become exercisable in installments of one-third of the total number of shares granted on each anniversary of the grant. Additionally, each director who had served for at least 6 months as of the date of our annual stockholder meeting in 2024 received options to purchase 5,500 additional shares of our common stock on the date of our annual stockholder meeting (Annual Grant), with such Annual Grant vesting on the day before the first anniversary of the date of grant of the Annual Grant.

Options granted on or after June 24, 2013 may be exercised only (1) while the individual is serving as a director on the Board, (2) within 12 months after termination by death or disability or (3) within 24 months after the individual's term as director ends for any other reason. In 2019, the Board extended the post termination exercise period of approximately 238,644 vested options held by non-employee directors who served on the Board for more than 10 years based on a policy adopted by the Board. The policy stipulated that upon retirement of any member of the Board who has served on the Board for at least 10 years prior to the effective date of such retirement, all options held by such directors shall continue to be exercisable until the earlier of (a) the termination date of such option or (b) 10 years after such director's retirement date.

Employee directors receive no additional compensation for serving on our Board of Directors.

From January 1, 2024 to June 30, 2024, four directors (Dr. Azab, Dr. Farfel, Mr. Garcia and Ms. Maderis) voluntarily elected to forego receiving their director's fees. Transaction Committee members (Dr. Azab, Dr. Farfel, Mr. Garcia and Ms. Maderis) voluntarily elected to receive their FY2024 committee fee in 2025.

The following table sets forth certain information regarding the compensation of each non-employee member of our Board of Directors for the fiscal year ended December 31, 2024.

Director Compensation for Fiscal 2024

Name	Fees Earned or Paid in Cash ($)	Option Awards (1)($)	All Other Compensation ($)	Total ($)
Mohammad Azab, M.D., M. Sc., M.B.A.	25,742	5,893	—	31,635
Terrence F. Blaschke, M.D.	52,984	5,893	—	58,877
Gail M. Farfel, Ph.D.	23,242	5,893	—	29,135
Peter S. Garcia, M.B.A.	34,250	5,893	—	40,143
Gail J. Maderis, M.B.A.	46,500	5,893	—	52,393
Judith J. Robertson	60,000	5,893	—	65,893

(1) Amounts in this column reflect the aggregate grant date fair value of stock options granted in the applicable year as computed in accordance with FASB ASC Topic 718. The grant date fair value of the options was determined using the Black-Scholes option pricing model based on the fair market value on the date of grant. These amounts reflect our accounting expense for these stock options and do not represent the actual economic value that may be realized by each non-employee director. There can be no assurance that these amounts will ever be realized. For more information, please see Note 9 of the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2024 regarding assumptions underlying the valuation of equity awards.

(2) In September 2024, an option to purchase 5,500 shares of our common stock at $1.22 per share was granted under our 2000 Stock Plan to each of the directors (with a fair value of $5,893 for each option grant).

The following table sets forth certain information regarding outstanding equity awards at December 31, 2024 of all of our non-employee directors:

	Number of Securities Underlying Unexercised Options (#)	
Name	Exercisable	Unexercisable
Mohammad Azab, M.D., M. Sc., M.B.A.	20,750	5,500
Terrence F. Blaschke, M.D.	49,656	5,500
Gail M. Farfel, Ph.D.	29,000	5,500
Peter S. Garcia, M.B.A.	18,000	5,500
Gail J. Maderis, M.B.A.	20,750	5,500
Judith J. Robertson	29,000	5,500

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

COMMON STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table presents information concerning the beneficial ownership of the shares of our common stock as of March 25, 2025 by:

- each stockholder whom we know to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our Named Executive Officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined under the rules and regulations of the SEC. Shares of common stock subject to options, warrants and conversion privileges that are currently exercisable or exercisable within 60 days of March 25, 2025 are deemed to be outstanding and beneficially owned by the person holding such options, warrants or convertible securities for the purpose of computing the number of shares beneficially owned and the percentage ownership of that person, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Except as indicated in the footnotes to this table, and subject to applicable community property laws, these persons have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The number and percentage of shares beneficially owned are based on 31,041,981 shares of common stock outstanding as of March 25, 2025. Except as otherwise noted, the address of each person listed in the table is c/o DURECT Corporation, 10240 Bubb Road, Cupertino, California 95014.

Name of Beneficial Owners	Amount and Nature of Beneficial Ownership	Percent of Common Stock
Holders of 5% or more of our common stock		
Asen and Co. (1)	3,080,000	9.9%
Ingalls & Snyder, LLC (2)	2,681,770	8.5%
Directors and Named Executive Officers		
James E. Brown, D.V.M. (3)	679,876	2.2%
Timothy M. Papp (4)	238,627	*
Norman L. Sussman (5)	125,239	*
Mohammad Azab, M.D., M. Sc., M.B.A. (6)	26,750	*
Gail M. Farfel, Ph.D. (7)	39,000	*
Peter S. Garcia, M.B.A. (8)	22,667	*
Gail J. Maderis, M.B.A. (9)	40,750	*
Judith J. Robertson (10)	64,613	*
All executive officers and directors as a group (8 persons) (11)	**1,237,522**	**3.9%**

* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) Based upon a Schedule 13G/A filed by Asen and Co. on January 8, 2025. Asen and Co. is deemed to be the beneficial owner with sole voting and dispositive power over 2,580,000 shares of our common stock and shared voting and dispositive power over 500,000 shares of our common stock. The stockholder's address is 222 1/2 East 49th Street, New York, NY 10017.

(2) Based upon a Schedule 13G/A filed by Ingalls & Snyder, LLC on February 21, 2025. Ingalls & Snyder, LLC is deemed to be the beneficial owner with shared dispositive power over 2,681,770 shares of our common stock. The stockholder's address is 1 Rockefeller Plaza, New York, NY 10020.

(3) Includes 176,453 shares of our common stock held by James E. Brown and 8,000 shares of our common stock held by the James & Karen Brown 2006 Trust U/A. Also includes 495,423 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(4) Includes 101,127 shares of our common stock issuable upon exercise of options within 60 days of March 25, 2025 and 137,500 shares of our common stock issuable upon exercise of restricted stock units exercisable by Timothy M. Papp.

(5) Includes 125,239 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(6) Includes 6,000 shares of our common stock held by Mohammad Azab. Also includes 20,750 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(7) Includes 10,000 shares of our common stock held by Gail M. Farfel. Also includes 29,000 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(8) Includes 7,000 shares of our common stock held by Peter S. Garcia. Also includes 15,667 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(9) Includes 20,000 shares of our common stock held by the Gail J. Maderis Revocable Trust dated April 8, 2013 Gail Maderis TTEE. Also includes 20,750 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(10) Includes 35,613 shares of our common stock held by Judith J. Robertson. Also includes 29,000 shares of our common stock issuable upon exercise of options exercisable within 60 days of March 25, 2025.

(11) Includes an aggregate of 836,956 shares of our common stock issuable pursuant to the exercise of outstanding stock options exercisable within 60 days of March 25, 2025 held by all of our executive officers and directors as a group.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information as of December 31, 2024 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)	
Equity compensation plans approved by security holders (1)	4,894,287	$ 6.31	1,844,180	(2)
Equity compensation plans not approved by security holders	—	—	—	
Total	4,894,287	$ 6.31	1,844,180	

(1) Consists of the following equity compensation plans: (i) our 2000 Stock Plan and (ii) our 2000 Employee Stock Purchase Plan.

(2) Includes 1,844,180 shares of our common stock reserved under our 2000 Stock Plan for future issuance, and includes 49,667 shares of our common stock reserved under our 2000 Employee Stock Purchase Plan for future issuance, including shares that will be purchased during the most recent purchase period under the 2000 Employee Stock Purchase Plan commencing on November 1, 2024 and ending on April 30, 2025.

Item 13. Certain Relationships, Related Transactions and Director Independence.

CERTAIN RELATIONSHIPS

In accordance with the Audit Committee charter, the Audit Committee is responsible for reviewing and approving the terms and conditions of all related party transactions (as defined in Item 404 of Reg. S-K), other than compensation transactions, which are subject to the auspices of the Compensation Committee. Although we have not entered into any financial transactions with any immediate family member of any of our directors or executive officers, if we were to do so, any such material financial transaction would need to be approved by the Audit Committee before we enter into such a transaction. The Audit Committee also reviews and approves our proxy statement and the information contained therein.

INDEPENDENCE OF BOARD OF DIRECTORS AND ITS COMMITTEES

Under Nasdaq listing standards, independent directors must comprise a majority of a listed company’s board of directors within a specified period of the closing of the Company's initial public offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and corporate governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. We currently satisfy the audit committee independence requirements of Rule 10A-3. Additionally, Compensation Committee members must not have a relationship with us that is material to the director’s ability to be independent from management in connection with the duties of a Compensation Committee member.

Our Board has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board determined that each of our directors who served during 2024 or is currently serving, other than Dr. Brown, was or is an independent director as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq.

OTHER TRANSACTIONS

During the last fiscal year, we granted options to purchase common stock to our employees and directors as reported in this Annual Report on Form 10-K.

We have entered into indemnification agreements with each of our directors and executive officers. Such agreements require us, among other things, to indemnify our officers and directors, other than for liabilities arising from willful misconduct of a culpable nature, and to advance their expenses incurred as a result of any proceedings against them as to which they could be indemnified.

Item 14. Principal Accountant Fees and Services.

FEES BILLED FOR SERVICES RENDERED BY PRINCIPAL ACCOUNTANT

On June 28, 2024, the Audit Committee dismissed Ernst & Young LLP ("EY") as the Company's independent registered public accounting firm and appointed WithumSmith+Brown, PC ("Withum") as the Company's new independent registered public accounting firm commencing with the Company's fiscal year ended December 31, 2024.

All Audit Fees, Audit-Related Fees, Tax Fees and Other Fees for 2024 were pre-approved by the Audit Committee according to the policies and procedures described above under the caption "The Board, Board Committees and Meetings—Audit Committee." The following table depicts the fees for services provided by Withum and EY during the fiscal years ended December 31, 2024 and December 31, 2023, respectively. Withum did not provide any services during the fiscal year ended December 31, 2023.

	Years Ended December 31,	
	2024 (1)	2023 (2)
Audit Fees	$ 518,956	$ 1,303,024
Tax Fees	15,100	83,298
Total	$ 534,056	$ 1,386,322

(1) Represents fees billed by Withum for the year ended December 31, 2024.

(2) Represents fees billed by EY for the year ended December 31, 2023.

Audit Fees

Audit Fees include fees for audit services associated with the 2024 and 2023 audits of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q. Audit Fees also include fees for advice on audit and accounting matters that arose during, or as a result of, the audit or the review of annual and interim financial statements, respectively. Additionally, the 2023 Audit Fees include approximately $135,000 related to the review of SEC registration statements, issuance of comfort letters, and issuance of consents.

Tax Fees

Tax fees include tax compliance services related to preparation of tax returns, assistance with filing of employee retention credits with the Internal Revenue Service and other tax matters.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this report:

(1) *Financial Statements*

The Index to financial statements in Item 8 of this report is incorporated herein by reference as the list of the financial statements required as part of this report.

(2) *Financial Statement Schedules*

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the financial statements or notes thereto.

(3) The list of exhibits are filed as part of or furnished with this annual report on Form 10-K as applicable.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 4, 2010).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2018).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 16, 2021).
3.4	Certificate of Correction to the Charter Amendment of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K/A, as filed with the SEC on June 25, 2021).
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 16, 2022).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.8 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 8, 2023).
3.7	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 000-31615), as filed with the SEC on December 17, 2014).
3.8	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Company (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-3, as amended (File No. 333-128979), as initially filed with the SEC on October 13, 2005).
3.9	Certificate of Amendment to Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Company (incorporated by reference to Exhibit 3.7 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on August 5, 2010).
3.10	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 14, 2024).
4.1	Description of Securities of the Registrant Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K (File No. 000-31615), as filed with the SEC on March 28, 2024).

Exhibit Number	Description
4.2	Form of Warrant (February 2023) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 7, 2023).
4.3	Form of Warrant (July 2023) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 21, 2023).
10.1+	Form of Indemnification Agreement between the Company and each of its Officers and Directors (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, as amended (File No. 333-35316), as initially filed with the SEC on April 20, 2000).
10.2+	DURECT Corporation 2000 Stock Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 26, 2024).
10.3+	Form of Employee Restricted Stock Unit Award Agreement for use with the DURECT Corporation 2000 Stock Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 30, 2024).
10.4+	2000 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-31615) filed on June 22, 2023).
10.5	Modified Net Single Tenant Lease Agreement between the Company and DeAnza Enterprises, Ltd. dated as of February 18, 1999 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, as amended (File No. 333-35316), as initially filed with the SEC on April 20, 2000).
10.6	Second Amendment to Lease between De Anza Enterprises and the Company dated as of August 6, 2009 (incorporated by reference to Exhibit 10.56 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 2, 2009).
10.7	Third Amendment to Lease between De Anza Enterprises and the Company dated as of December 21, 2010 (incorporated by reference to Exhibit 10.63 to the Company's Annual Report on Form 10-K (File No. 000-31615), as filed with the SEC on March 3, 2011).
10.8	Fourth Amendment to Lease between De Anza Enterprises and the Company dated as of August 20, 2013 (incorporated by reference to Exhibit 10.71 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 5, 2013).
10.9	Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated December 5, 2012 (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K (File No. 000-31615), as filed with the SEC on November 8, 2018).
10.10	Fifth Amendment to Lease between De Anza Enterprises and the Company dated as of August 15, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 17, 2018).

Exhibit Number	Description
10.11++	Amendment No. 1 to Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated July 2, 2015 (incorporated by reference to Exhibit 10.34 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 14, 2024).
10.12++	Amendment No. 2 to Exclusive License Agreement between the Company and Virginia Commonwealth University Intellectual Property Foundation dated March 6, 2018 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 14, 2024).
10.13++	License agreement by and between the Company and Innocoll Pharmaceuticals Limited dated December 21, 2021 (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K (File No. 000-31615), as filed with the SEC on March 8, 2022).
10.14	First Amendment to License Agreement by and between the Company and Innocoll Pharmaceuticals Limited dated September 19, 2022 (incorporated by reference Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615) filed with the SEC on November 3, 2022).
10.15+	Offer letter between Timothy M. Papp and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 5, 2022).
10.16+	Offer letter between Norman L. Sussman and the Company dated October 12, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 2, 2022).
10.17+	Employment Agreement with James E. Brown (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, as amended (File No. 333-35316), as initially filed with the SEC on April 20, 2000).
10.18	Form of Securities Purchase Agreement, dated February 3, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 7, 2023).
10.19	Addendum IV to Lease between the Company and Wescove Vacaville, LLC dated as of May 11, 2023 (incorporated by reference Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615) filed with the SEC on August 10, 2023).
10.20	Securities Purchase Agreement, dated July 19, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 21, 2023).
10.21	Sixth amendment to Lease between the Company and De Anza Enterprises LLC dated as of September 6, 2023 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 000-31615), as filed with the SEC on November 14, 2023).
10.22*++	Asset purchase agreement by and between the Company and ALZET, LLC dated as of November 22, 2024.

Exhibit Number	Description
19.1*	Insider Trading Policy.
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1*	Rule 13a-14(a) Section 302 Certification.
31.2*	Rule 13a-14(a) Section 302 Certification.
32.1**	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Company Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K (File No. 000-31615), as filed with the SEC on March 28, 2024).
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL: (i) Balance Sheets as of December 31, 2024 and 2023, (ii) Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023, (iii) Statements of Stockholders' Equity for the years ended December 31, 2024 and 2023, (iv) Statements of Cash Flows for the years ended December 31, 2024 and 2023 and (v) Notes to Financial Statements, tagged as blocks of text and including detailed tags.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished, not filed.
+ Indicates a management contract or compensatory plan or arrangement.
++ Certain portions of this exhibit (indicated by "[***]") have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

Item 16. Form 10-K Summary.

The Company has elected not to include summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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
President and Chief Executive Officer

Date: March 27, 2025

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ James E. Brown **James E. Brown**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2025
/s/ TIMOTHY M. PAPP **Timothy M. Papp**	Chief Financial Officer (Principal Accounting Officer)	March 27, 2025
/s/ MOHAMMAD AZAB **Mohammad Azab**	Director	March 27, 2025
/s/ Gail M. Farfel **Gail M. Farfel**	Director	March 27, 2025
/s/ PETER S. GARCIA **Peter S. Garcia**	Director	March 27, 2025
/s/ GAIL J. MADERIS **Gail J. Maderis**	Director, Chair of the Board	March 27, 2025
/s/ Judith j. Robertson **Judith J. Robertson**	Director	March 27, 2025