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, 2023

OR

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

Commission File Number 001-38981

Mirum Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**83-1281555**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
950 Tower Lane, Suite 1050, Foster City, California	**94404**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (650) 667-4085

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, par value $0.0001 per share	MIRM	Nasdaq Global 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 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 that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Exchange Act). YES ☐ NO ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $830.1 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $25.87 per share.

The number of shares of registrant's common stock, par value $0.0001 per share, outstanding as of March 8, 2024 was 47,003,329.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the “Annual Report”) may contain “forward-looking statements” within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Part I, Item 1A, “Risk Factors” in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as “may,” “will,” “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate” or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Such statements may include, but are not limited to, statements concerning the following:

- the commercialization of our approved medicines and our other product candidates, if approved;
- our ability to obtain and maintain regulatory approval for our products and product candidates or any of our future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- our plans to research, develop and commercialize our product candidates, including the timing of our ongoing clinical trials of Livmarli and volixibat;
- our expectations regarding the size of target patient populations for our approved medicines and our product candidates, if approved for commercial use, and any additional product candidates we may develop;
- the size and growth potential of the markets for our approved medicines and our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our approved medicines and our product candidates, as well as third-party payor coverage and reimbursement for our approved medicines and our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our approved medicines and our product candidates;
- regulatory and legal developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to obtain funding for our operations; and
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should be aware that the occurrence of any of the events discussed under Part I, Item 1A, “Risk Factors” and elsewhere in this Annual Report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this Annual Report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part I, Item 1A, "Risk Factors" in this Annual Report.

- The success of our business depends, in part, on our ability to commercialize our approved medicines profitably.
- If we are unable to adequately grow, maintain and scale our marketing and sales capabilities or enter into or maintain rights pursuant to agreements with third parties to market and sell our approved medicines, we may not be able to generate sufficient revenues.
- Our approved medicines or any one of our product candidates, if approved, may fail to achieve the market acceptance among physicians, patients and others in the medical community necessary for commercial success.
- We rely completely on third parties to manufacture and distribute our clinical and commercial drug supplies, including certain sole-source suppliers and manufacturers. These third parties may fail to obtain and maintain regulatory approval for their facilities, fail to provide us with sufficient quantities of drug substance, drug product, or labeled finished product in a timely fashion, or fail to do so at acceptable quality levels or prices.
- Our business depends, in part, on the success of our product candidates, each of which requires significant clinical testing before we can seek regulatory approval and potentially launch commercial sales.
- We have encountered and may continue to encounter delays and difficulties enrolling patients in our clinical trials, and as a result, our clinical development activities could be delayed or otherwise adversely affected.
- Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.
- Any delays in the commencement or completion, or termination or suspension, of our clinical trials could result in increased costs for us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- We face significant competition from other biotechnology and pharmaceutical companies with products that may directly or indirectly compete with ours, and our operating results will suffer if we fail to compete effectively.
- We may fail to realize all of the anticipated benefits of the Bile Acid Portfolio Acquisition (defined below) or those benefits may take longer to realize than expected.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We may need substantial additional financing to continue our commercialization efforts for our approved medicines, develop our product candidates and implement our operating plans. If we fail to obtain additional financing when needed, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We do not currently have patent protection or regulatory exclusivity for certain of our approved medicines or rely solely upon regulatory exclusivity. If we are unable to obtain and maintain sufficient intellectual property protection for our approved medicines and our product candidates, or if the scope of the

intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our approved medicines and our other product candidates, if approved, may be adversely affected.

- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which could adversely impact our investors' confidence in our financial reports and our stock price could be adversely affected.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the identification, acquisition, development and commercialization of novel therapies for debilitating rare and orphan diseases.

We have three approved medicines: LIVMARLI® (maralixibat) oral solution (“Livmarli”), Cholbam® (cholic acid) capsules (“Cholbam”), and Chenodal® (chenodiol) tablets (“Chenodal”).

Livmarli is a novel, orally administered, minimally-absorbed ileal bile acid transporter (“IBAT”) inhibitor (“IBATi”) that is approved for the treatment of cholestatic pruritus in patients with Alagille syndrome (“ALGS”) in the United States and various other countries around the world and for cholestatic pruritus in patient with progressive familial intrahepatic cholestasis (“PFIC”) in the United States. We market and commercialize Livmarli in the United States and certain countries in Europe through our specialized and focused commercial team. We have also entered into license and distribution agreements with several rare disease companies for the commercialization of Livmarli in additional countries. We submitted a marketing authorization variation to the European Medicines Agency (“EMA”) in April 2023 for cholestatic pruritus in patients with PFIC, for which we expect an approval decision in the first half of 2024 based on positive data from our MARCH Phase 3 clinical trial of Livmarli in patients with PFIC. In February 2024, we submitted an additional Supplemental New Drug Application (“sNDA”) to the U.S. Food and Drug Administration (“FDA”) for cholestatic pruritus in patients with PFIC to introduce a higher concentration formulation of Livmarli used during the MARCH Phase 3 clinical trial intended to enable a label expansion for younger patients with PFIC and we expect an approval decision later in 2024.

On August 31, 2023, we completed the acquisition of assets of Travere Therapeutics, Inc. (“Travere”) that are primarily related to the development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of Chenodal and Cholbam (also known as Kolbam, and together with Chenodal, the “Bile Acid Medicines”) pursuant to an asset purchase agreement dated July 16, 2023 (such acquisition, the “Bile Acid Portfolio Acquisition”). The FDA approved Cholbam in March 2015 as the first FDA-approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects and for adjunctive treatment of patients with peroxisomal disorders, including peroxisome biogenesis disorder-Zellweger spectrum disorder (“PBD-ZSD”) and Smith-Lemli-Opitz syndrome (“SLOS”). Chenodal is approved for the treatment of radiolucent stones in the gallbladder and has received medical necessity recognition by the FDA for the treatment of cerebrotendinous xanthomatosis (“CTX”). We commercialize Chenodal and Cholbam in the United States through our specialized and focused commercial team. We have also assumed several license and distribution agreements with several rare disease companies for the commercialization of Chenodal and Cholbam in additional countries. In October 2023, we reported positive topline data from our RESTORE clinical trial evaluating Chenodal in patients with CTX. We plan to submit a new drug application for Chenodal for the treatment of CTX to the FDA in the first half of 2024.

We are also advancing our product candidate, volixibat, a novel, oral, minimally-absorbed agent designed to inhibit IBAT, for the treatment of adult patients with cholestatic liver diseases. We are developing volixibat in the setting of primary sclerosing cholangitis (“PSC”) and primary biliary cholangitis (“PBC”). Volixibat has been studied in over 400 adults for up to 48 weeks. Clinical trials of volixibat have shown significant activity on IBAT and bile acid markers such as 7αC4, fecal bile acids and cholesterol, demonstrating potent biological activity. We expect to conduct an interim analysis of our VISTAS Phase 2b clinical trial in PSC and report interim data from our VANTAGE Phase 2b clinical trial in PBC, both in the first half of 2024.

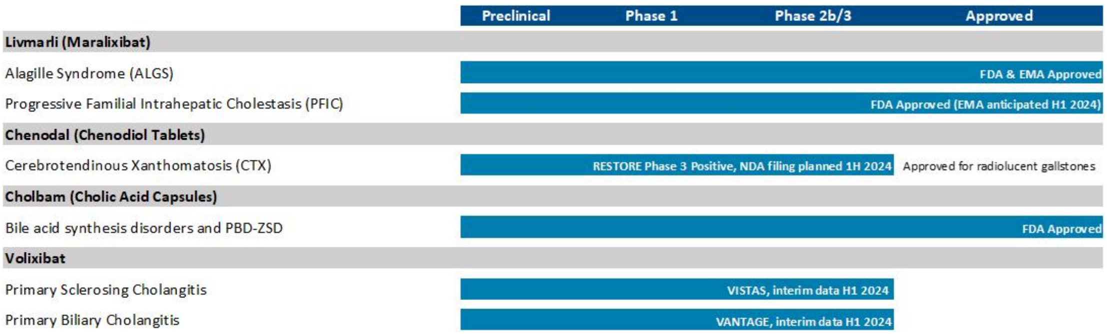
Our Strategy

Our goal is to strengthen our leadership position in rare and orphan diseases for which the unmet medical need is high. The key components of our strategy include:

- ***Commercialize and advance regulatory approvals of Livmarli for the treatment of ALGS internationally.*** Livmarli is approved by the FDA and the European Commission for the treatment of cholestatic pruritus in patients with ALGS three months of age and older and two months of age and older, respectively. We are commercializing Livmarli in the United States through one specialty pharmacy and certain countries in Europe through direct sales. Additionally, we have entered into several distributor and licensing agreements to advance Livmarli in numerous territories outside of the markets where we commercialize Livmarli directly.
- ***Commercialize Livmarli for the treatment of PFIC in the United States, and, if approved, internationally.*** Livmarli has been granted breakthrough therapy designation by the FDA for PFIC type 2. We submitted an sNDA to the FDA in February 2023, which was approved on March 13, 2024, and we submitted a marketing authorization variation to the EMA in April 2023, for which we expect an approval decision in the first half of 2024, each based on positive data from our MARCH Phase 3 clinical trial of Livmarli in patients with PFIC. In February 2024, we submitted an additional sNDA to the FDA to introduce a higher concentration formulation of Livmarli used during the MARCH Phase 3 clinical trial intended to enable a label expansion for younger patients with PFIC and we expect an approval decision later in 2024.
- ***Commercialize and further develop Chenodal and Cholbam.*** Chenodal is standard of care in the U.S. for the treatment of CTX under a medical necessity recognition from the FDA. We plan to submit an NDA for Chenodal for the treatment of CTX in the first half of 2024. Cholbam is approved for the treatment of bile acid synthesis disorders and adjunctive treatment of patients with peroxisomal disorders, including PBD-ZSD and SLOS and we expect to continue to commercialize the medicine for these indications. We are commercializing Chenodal and Cholbam in the United States through one specialty pharmacy.
- ***Develop and commercialize volixibat for the treatment of adults with PSC and PBC.*** We plan to further leverage our understanding of cholestatic liver disease with volixibat in adult settings. We are conducting adaptive, potentially registrational, Phase 2b clinical trials of volixibat in PSC and PBC.
- ***Actively manage our product portfolio and expand our pipeline of novel product candidates.*** We have assembled a team of scientific, clinical and business leaders with highly relevant experience to enable the advancement of therapeutics for rare and orphan diseases. We intend to leverage our collective expertise to identify, acquire, in-license and advance additional product candidates for the treatment of rare and orphan diseases.

Our Product Pipeline

The following graphic depicts each of our approved medicines and product candidates, the respective indications we are pursuing, the expected next milestones and regulatory designations:



Our Approved Medicines

Livmarli for cholestatic pruritus in patients with ALGS

Livmarli is a novel, orally administered, minimally-absorbed solution approved by the FDA as a once daily medicine for cholestatic pruritus in patients with ALGS three months of age and older and by the EMA as a once daily medicine for cholestatic pruritus in patients with ALGS two months of age and older. Livmarli is an IBATi that prevents absorption of bile acids in the ileum, thereby lowering serum bile acid ("sBA") levels in settings of cholestasis where excess bile acids cause symptomatic and progressive disease burden.

ALGS is a rare genetic disorder of severe cholestasis in which bile ducts are abnormally narrow, malformed and reduced in number, which leads to bile accumulation in the liver and ultimately progressive liver disease. In patients with ALGS, multiple organ systems may be affected by the mutation, including the liver, heart, kidneys and central nervous system. The accumulation of bile acids prevents the liver from working properly to eliminate waste from the bloodstream and leads to progressive liver disease. Signs and symptoms arising from cholestasis in ALGS may include jaundice, pruritus, xanthomas and growth deficit. The pruritus experienced by patients with ALGS is among the most severe in any chronic liver disease and is present in most affected children by the third year of life. In children with cholestasis due to ALGS, it is estimated that six in 10 of children progress to transplant or death by adulthood. Furthermore, it is reported that the majority of liver transplants in ALGS are due to cholestatic symptoms rather than progressive liver damage. In patients who have not received a liver transplant, 75% have active scratching, with 32% having destruction of skin, bleeding or scarring. Children with ALGS experience a markedly impaired quality of life largely due to the intense pruritus and associated skin lesions and disruptions in sleep and mood. A study to assess the health-related quality of life in ALGS patients indicated a significant burden in physical, psychological and social health accompanies the disease.

We believe the prevalent patient population in the United States and Europe is approximately 4,000 - 5,500 pediatric ALGS patients, which, based on our current expectations and beliefs, represents a greater than $500.0 million market opportunity. ALGS is estimated to impact one out of every 30,000 births globally.

Livmarli for cholestatic pruritis in patients with PFIC

Livmarli is a novel, orally administered, minimally-absorbed solution approved by the FDA as a once daily medicine for cholestatic pruritus in patients with PFIC five years of age and older.

PFIC is a group of rare autosomal recessive liver diseases characterized by canalicular bile transport defects, resulting in disrupted bile formation, progressive cholestasis with elevation of sBA, and pruritus. In children, PFIC represents 10% to 15% of indications for liver transplant, either due to intractable pruritus or end-stage liver disease. The most prevalent PFIC types are bile salt export pump ("BSEP") deficiency, also known as PFIC2 (50%–60%), multidrug resistance protein 3 (MDR3) deficiency, also known as PFIC3 (30%–40%), and familial intrahepatic cholestasis-associated protein 1 (FIC1) deficiency, also known as PFIC1 (10%–20%). Other types include tight junction protein 2 (TJP2) deficiency, also known as PFIC4 and myosin VB (MYO5B) deficiency, also known as PFIC6. In addition, a minority of patients with PFIC phenotype elude genetic diagnosis using current methods, and are diagnosed clinically.

Severe pruritus is a common feature of PFIC, greatly affecting quality of life, and leading to liver transplant when symptoms are refractory. The accumulation of bile acids in PFIC is an important mediator of pruritus and driver of liver disease progression. Patients suffer from growth impairment and require fat-soluble vitamin supplementation. Interruption of the enterohepatic bile acid recirculation has the potential to alleviate pruritus and prevent liver damage. Surgical biliary diversion ("SBD") has been performed to interrupt the enterohepatic circulation of bile acids in pruritic children who are not responsive to clinical management. In a large retrospective analysis in BSEP deficiency, reduction of sBA levels by ≥75% or to <102 μmol/L after SBD was associated with long-term native liver survival.

We believe the prevalent patient population in the United States and Europe is approximately 1,000 pediatric PFIC patients.

Chenodal

Chenodal (chenodeoxycholic acid or CDCA) is a naturally occurring bile acid that is approved for the treatment of people with radiolucent stones in the gallbladder. While indicated for radiolucent stones in the gallbladder, Chenodal has received medical necessity recognition by the FDA for the treatment of CTX, and is the standard of care for CTX, although it is not currently labeled or promoted for this indication. CTX is a rare, progressive and underdiagnosed bile acid synthesis disorder affecting many parts of the body. We estimate there are 1,000 - 2,000 prevalent CTX patients in the United States, however only 10% are currently diagnosed. In September 2022, Chenodal was granted Fast Track designation by the FDA for the treatment of CTX. In October 2023, we presented positive top line results from the Phase 3 RESTORE Study to evaluate the effects of Chenodal in adult and pediatric patients with CTX. The study objective was to evaluate the safety and efficacy of Chenodal by measurement of urine bile alcohols and other secondary measures. The primary endpoint of reduction in bile alcohols (urine 23S-pentol) was highly statistically significant ($p<0.0001$). The difference between placebo and active Chenodal at the end of the randomized double-blind withdrawal period was 20-fold.

In CTX, a deficiency of the bile acid CDCA leads to a buildup of bile alcohols which precedes a toxic accumulation of cholestanol. Cholestanol is the key driver of symptomatic burden and disease progression, including irreversible neurologic dysfunction. Results from the RESTORE study demonstrated that treatment with Chenodal not only improved urine bile alcohols but also serum cholestanol. Additionally, a greater proportion of patients receiving placebo required blinded rescue therapy, demonstrating the robustness of the effect.

The most commonly reported adverse events while on Chenodal were diarrhea and headache. The majority of adverse events reported were mild or moderate in severity and not considered to be treatment-related. We expect to submit an NDA for the treatment of CTX to the FDA in the first half of 2024.

Cholbam for the treatment of bile acid synthesis disorders and peroxisomal disorders, including PBD-ZSD and SLOS

The FDA approved Cholbam (cholic acid capsules) in March 2015, as the first FDA-approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects and for adjunctive treatment of patients with peroxisomal disorders, including PBD-ZSD and SLOS. The effectiveness of Cholbam has been demonstrated in clinical trials for bile acid synthesis disorders and the adjunctive treatment of peroxisomal disorders. An estimated 200 to 300 patients in the United States are current candidates for therapy.

Our Clinical Product Candidates

Livmarli in PFIC outside of the United States

We submitted a marketing authorization variation to the EMA in April 2023, for which we expect an approval decision in the first half of 2024, based on positive data from our MARCH Phase 3 clinical trial of Livmarli in patients with PFIC.

Volixibat

We are advancing our product candidate, volixibat, a novel, oral, minimally-absorbed agent designed to inhibit IBAT, for the treatment of adult patients with cholestatic liver diseases. We are developing volixibat for the treatment of PSC and PBC. Volixibat has been studied in over 400 adults for up to 48 weeks. Clinical trials of volixibat have shown significant activity on IBAT and bile acid markers such as 7αC4, fecal bile acids and cholesterol, demonstrating potent biological activity.

PSC is a serious, idiopathic chronic cholestatic liver disease characterized by the progressive inflammation and destruction of bile ducts, which can lead to life-threatening complications. It is estimated that approximately 54,000 people in the United States and Europe suffer from PSC. Up to approximately 65% of PSC patients suffer from pruritus during the course of the disease. Liver transplantation is the only treatment shown to improve clinical outcomes in PSC but is expensive, requires long-term administration of immunosuppressants and only a portion of the patients who require a liver transplant are able to match with a suitable donor organ. Ursodeoxycholic acid (“UDCA”), is used off-label in PSC with conflicting evidence. We are conducting the VISTAS Phase 2b clinical trial of volixibat in patients with pruritus and PSC. VISTAS is an adaptive, randomized Phase 2b clinical trial evaluating the effect of volixibat on pruritus, sBA and fibrosis markers in patients with PSC and pruritus. We expect an interim analysis from VISTAS in the first half of 2024.

PBC is a chronic, rare, cholestatic liver disease characterized by progressive liver bile flow impairment caused by immune-mediated destruction of intrahepatic bile ducts. This results in increased hepatic bile acid concentrations, which leads to a local inflammatory response in the liver that progresses to hepatic fibrosis, cirrhosis, and hepatic decompensation. The incidence rates for PBC in Europe, North America, Asia, and Australia are reported as ranging from 0.33 to 5.8 per 100,000 people, with a prevalence ranging from 1.91 to 40.2 per 100,000 people, resulting in approximately 230,000 patients across the United States and Europe suffering from PBC. Up to approximately 60% of PSC patients suffer from pruritus during the course of the disease. We are conducting the VANTAGE Phase 2b clinical trial of volixibat in patients with pruritus and PBC and we expect interim results from VANTAGE in the first half of 2024.

There are no approved therapies for PSC in the United States. A variety of licensed and off-label therapies are currently used to reduce the impact of the progressive nature of PBC. These include UDCA, obeticholic acid, peroxisome proliferator activator receptors like bezafibrate and fenofibrate, and others. However, the few therapeutic options available to manage PBC associated pruritus are temporary and/or suboptimal.

License, Finance, Royalty Agreements and Asset Purchases

Assignment and License Agreement with Shire International GmbH (Takeda)

In November 2018, we entered into an assignment and license agreement (“Shire License Agreement”) with Shire International GmbH (“Shire”), which was subsequently acquired by Takeda Pharmaceutical Company Limited. Pursuant to the Shire License Agreement, Shire assigned, transferred and conveyed all of its right, title and interest in and to the Pfizer Agreement, Satiogen Agreement and Sanofi Agreement, (collectively, the “Assigned License Agreements”), each of which is defined below.

In addition, Shire granted us an exclusive, royalty bearing, sublicensable, worldwide license under certain regulatory materials as well as patents and know-how, which we refer to collectively as the Shire IP, relating to the Livmarli compound and the volixibat compound in development by Shire as of that date, which we collectively refer to as the Shire Licensed Products, to develop, have developed, make, have made, use, sell, have sold, offer for sale or import the Shire Licensed Products worldwide for the therapeutic or prophylactic application in human health. We have sole authority and responsibility over development and commercialization activities for the Shire Licensed Products, and we are required to use commercially reasonable efforts to perform certain development, regulatory and commercialization activities with respect to the PFIC and ALGS indications for Livmarli and unspecified indications with respect to volixibat. We will solely own all inventions and discoveries arising out of activities conducted by us under the Shire License Agreement. We will also be responsible for the preparation, filing, prosecution and maintenance of patents under the Shire License Agreement and the cost thereof. We have the first right, but are not obligated, to enforce any patent licensed under the Shire License Agreement.

We are required to pay Shire up to an aggregate of $109.5 million upon the achievement of certain other clinical development and regulatory milestones for Livmarli in the PFIC and ALGS indications, and a $25.0 million payment upon regulatory approval of Livmarli for each and every other indication. Each such milestone payment will be paid only once for each such indication during the term of the Shire License Agreement, the first time Livmarli reaches such milestone event, regardless of the number of times such milestone is reached by Livmarli for the same indication. In addition, we are required to pay up to an aggregate of $30.0 million upon the achievement of certain clinical development and regulatory milestones for volixibat solely for the first indication sought. Each such milestone payment will be paid only once for the first indication for which volixibat is developed during the term of the Shire License Agreement, the first time volixibat reaches such milestone event, regardless of the number of products or the number of indications for which volixibat is developed.

Under the Shire License Agreement and Assigned License Agreements, to date, we have met clinical development, regulatory and sales milestones resulting in the payment of an aggregate of $71.0 million related to our Livmarli and volixibat programs.

Upon achievement of certain thresholds for aggregate worldwide net sales for all Shire Licensed Products, we are required to pay Shire, on a one-time, non-refundable and non-creditable basis, up to an aggregate of $30.0 million in tiered sales milestone payments. In the fourth quarter of 2023, we paid Shire $5.0 million based on the achievement of a sales milestone. Lastly, upon certain annual worldwide net sales of all Shire Licensed Products, we are required to pay Shire, on a non-refundable and non-creditable basis, tiered royalties with rates ranging from low double-digits to mid-teens ("Shire royalties"). As we make royalty payments to Satiogen, which is defined below, under the Satiogen Agreement, the Shire royalties will be reduced by a low single digit percentage of net sales. Similarly, if we actually make royalty payments to Sanofi, which is defined below, under the Sanofi Agreement, the Shire royalties will be reduced by low to high single digit percentages of certain net sales thresholds.

Under the Shire License Agreement, we are prohibited from developing any competing product prior to the five-year anniversary of the first commercial sale of a Shire Licensed Product, or commercializing any competing product prior to the eight-year anniversary of the first commercial sale of a Shire Licensed Product. For purposes of the Shire License Agreement, a competing product is any product that is or contains a compound (A) where the primary method of action is ASBT inhibition activity, which is another term for IBAT inhibition, or (B) that is commercialized or developed for any PFIC, ALGS, or BA indication, except (B) shall not apply with respect to (1) a given indication if a product failure has occurred with respect to such indication (e.g., if a product failure has occurred for a Shire Licensed Product for the BA indication, we may thereafter develop and commercialize a product for the BA indication if such product uses a different primary method of action than ASBT inhibition activity) or (2) a given product if such product is a product that is not deleterious to the sales or pricing of a Shire Licensed Product.

The Shire License Agreement will remain in effect on a country-by-country and Shire Licensed Product-by-Shire Licensed Product basis and will continue on such basis until the later of the (i) expiration of the last patent or patent application licensed under the Shire License Agreement that covers a Shire Licensed Product, (ii) expiration of any regulatory exclusivity period, and (iii) tenth anniversary of the first commercial sale of such Shire Licensed Product in such country. The term of the last patent or patent application licensed under the Shire License Agreement ends on October 26, 2032, absent patent term adjustment or extension. We may unilaterally terminate the Shire License Agreement for any reason or no reason upon 90 days' written notice to Shire. In addition, we may also terminate the Shire License Agreement if we reasonably determine that we are precluded from further development due to materially adverse pre-clinical or clinical pathology or toxicology data. Either party may terminate the Shire License Agreement in the event of the other party's insolvency or for the other party's material breach of the Shire License Agreement that remains uncured after 90 days of receiving written notice of such breach. Shire may terminate the Shire License Agreement upon our or our affiliates' challenge to the validity of the patents licensed under the Shire License Agreement.

License Agreement with Pfizer Inc.

Through the Shire License Agreement, we were assigned the rights to the license agreement ("Pfizer Agreement"), with Pfizer Inc. ("Pfizer"), pursuant to which we obtained an exclusive, worldwide license to Pfizer's know-how related to Livmarli, ("the Pfizer Know-How"). Under the Pfizer Agreement, we are permitted to research, develop, manufacture and commercialize products utilizing the Pfizer Know-How for the diagnosis, treatment, prevention, mitigation and cure of human diseases and disorders, and to sublicense such rights. Pfizer retained the right to use the Pfizer Know-How to conduct internal research and to use a third party to conduct research on Pfizer's behalf.

We have sole responsibility and control over development and commercialization activities for the Pfizer Know-How and products utilizing the Pfizer Know-How, and we are obligated to use commercially reasonable efforts to develop and commercialize products utilizing the Pfizer Know-How. In the event we determine to sublicense to a third party our right to commercialize the Pfizer Know-How or products utilizing the Pfizer Know-How under the Pfizer Agreement, Pfizer has the first right to negotiate such a commercial license with us.

Ownership of inventions and discoveries under the Pfizer Agreement will be determined in accordance with the rules of inventorship under United States patent laws. We will own and bear all expenses incurred in preparing, filing, prosecuting and maintaining all patents for inventions that are solely invented by us.

As consideration, upon commercialization of any product utilizing the Pfizer Know-How, we are required to pay to Pfizer a low single-digit royalty on net sales of such products sold by us, our affiliates or sublicensees. Our royalty obligations continue on a licensed product-by-licensed product basis until the eighth anniversary of the first commercial sale of such licensed product anywhere in the world. We currently pay royalties to Pfizer on our sales of Livmarli.

We may unilaterally terminate the Pfizer Agreement for any reason or no reason upon 90 days' written notice to Pfizer. Either party may terminate the Pfizer Agreement in the event of the other party's insolvency or for the other party's material breach of the Pfizer Agreement which remains uncured after 60 days of receiving written notice of such breach, or 30 days in the case of a payment breach. Absent early termination, the Pfizer Agreement will automatically expire on a country-by-country basis upon the expiration of our royalty payment obligations.

License Agreement with Sanofi-Aventis Deutschland GmbH

Through the Shire License Agreement, we were assigned the rights to the license agreement, as amended ("Sanofi Agreement"), with Sanofi-Aventis Deutschland GmbH ("Sanofi"), under which we obtained an exclusive, worldwide license to certain patents and know-how controlled by Sanofi related to volixibat ("Sanofi Technology"). Under the Sanofi Agreement, we are permitted to develop and commercialize products containing volixibat utilizing the Sanofi Technology. Additionally, under the Sanofi Agreement, we are permitted to manufacture products containing volixibat utilizing the Sanofi Technology and to sublicense such rights. In addition, Sanofi granted to us, under certain conditions, an exclusive option to obtain an exclusive license to manufacture volixibat during the term of the Sanofi Agreement. We exercised this option in May 2020 and are transferring manufacturing of volixibat to a third-party contract manufacturer. Sanofi retained the right to practice the Sanofi Technology outside the scope of the license granted to us under the Sanofi Agreement and to make and use for internal research purposes, provided that upon our request, Sanofi is obligated to provide us with a written summary of the results of any such research to the extent such results relate to the use of volixibat as an ASBT inhibitor ("ASBTi").

Under the Sanofi Agreement, we have sole authority and responsibility over development and commercialization activities for licensed products, and we are required to use diligent efforts to perform certain development, regulatory and commercialization activities.

With the exception of Sanofi's rights on its further optimization of the process of manufacturing of the product utilizing the Sanofi Technology, we will own all inventions and discoveries arising out of activities conducted by us under the Sanofi Agreement and we will be responsible for the preparation, filing, prosecution and maintenance of patents under the Sanofi Agreement. Further, we will have the first right, but will not be obligated, to enforce patents under the Sanofi Agreement. If we do not exercise our right to enforce patents under the Sanofi Agreement, Sanofi will be able to enforce the patents.

We are required to pay to Sanofi up to an aggregate of $36.0 million upon the achievement of certain regulatory, commercialization and product sales milestones. Upon commercialization of any product utilizing the Sanofi Technology, we will be required to pay to Sanofi tiered royalties in the mid to high single-digit range based upon net sales of licensed products sold by us and our affiliates and sublicensees in a calendar year, subject to adjustments in certain circumstances. Our royalty obligations continue on a licensed product-by-licensed product and country-by-country basis until the later to occur of the expiration of the last valid claim in a licensed patent or patent application covering the applicable licensed product in such country and ten years after the first commercial sale of a licensed product following regulatory approval in such country. The term of the last patent or patent application licensed under the Sanofi Agreement ends on May 26, 2030, absent patent term adjustment or extension. In the event we sublicense our right to commercialize a product utilizing the Sanofi Technology, we are obligated to pay to Sanofi a fee based on a percentage of sublicense fees received by us, which percentage ranges from the mid-teens to low-thirties, depending on the stage of development of such licensed product, and is subject to adjustment in certain circumstances.

For three years after the first commercial sale of a product utilizing the Sanofi Technology, on a licensed product-by-licensed product basis, we may not, through our own efforts or with an affiliate or third party, commercialize any product for specified indications with a method of action that reduces the reabsorption of bile acids in the intestinal tract, except for the commercialization of products utilizing the Sanofi Technology under the Sanofi Agreement.

We may unilaterally terminate the Sanofi Agreement for any reason or no reason upon 60 days' written notice to Sanofi. We may also terminate the Sanofi Agreement on a country-by-country or licensed product-by-licensed product basis upon written notice to Sanofi (1) if we reasonably determine that we are precluded from proceeding with the first Phase 2b clinical trial for a product utilizing the Sanofi Technology in certain major markets due to certain safety failures or (2) after using diligent efforts, we reasonably determine that we are precluded from proceeding with a Phase 3 clinical trial for a product utilizing the Sanofi Technology in certain major markets due to certain safety or efficacy failures. Either party may terminate the Sanofi Agreement in the event of the other party's insolvency or for the other party's material breach of the Sanofi Agreement which remains uncured after 90 days of receiving written notice of such breach, or ten business days in the case of a payment breach. Absent early termination, the Sanofi Agreement will remain in effect on a country-by-country and licensed product-by-licensed product basis until the expiration of our royalty payment obligations for such licensed product in such country.

License Agreement with Satiogen Pharmaceuticals, Inc.

Through the Shire License Agreement, we were assigned the rights to the license agreement, as amended ("Satiogen Agreement"), with Satiogen Pharmaceuticals, Inc. ("Satiogen"), now a wholly-owned Mirum entity, under which we obtained an exclusive, worldwide license to certain patents and know-how controlled by Satiogen related to ASBTis ("ASBTi Technology"), and TGR5 agonists ("TGR5 Technology"). Under the Satiogen Agreement, we are permitted to develop, manufacture and commercialize products utilizing the ASBTi Technology or TGR5 Technology for the diagnosis, treatment, prevention, mitigation and cure of human diseases and disorders, other than diabetes, obesity or a combination thereof, and to sublicense such rights. In March 2017, the Satiogen Agreement was amended to terminate the license of certain patents related to the ASBTi Technology and TGR5 Technology as each relates to diabetes and obesity. In May 2022, we completed the merger and acquisition of Satiogen in which Satiogen became our wholly-owned subsidiary.

We have sole responsibility and control over development and commercialization activities for products utilizing the ASBTi Technology or TGR5 Technology under the Satiogen Agreement and we are required to use commercially reasonable efforts to develop and commercialize such licensed products.

We are required to pay to Satiogen a low single-digit royalty on net sales of products utilizing the ASBTi Technology or TGR5 Technology sold by us and our affiliates. Our royalty obligations continue on a licensed product-by-licensed product and country-by-country basis until the expiration of the last valid claim in a licensed patent or patent application covering the applicable licensed product in such country. The term of the last patent or patent application licensed under the Satiogen Agreement ends on August 30, 2031, absent patent term adjustment or extension.

In the event we sublicense any of our rights under the ASBTi Technology or TGR5 Technology to a third party, we are obligated under the Satiogen Agreement to pay to Satiogen a fee based on a percentage of sublicense revenue received by us, which percentage ranges from the mid-teens to mid-twenties, depending on whether the right granted is in connection with the ASBTi Technology or TGR5 Technology, and the stage of development of such sublicensed technology. In addition, we are obligated under the Satiogen Agreement to pay to Satiogen a percentage of royalties we receive in consideration for the grant of such sublicense based on a percentage of revenue generated by such sublicensee for sales of products utilizing the ASBTi Technology or TGR5 Technology, which percentage is in the low-fifties and is subject to adjustment in certain circumstances. This payment will not exceed an amount that is one-half of our low single-digit royalty obligation to Satiogen.

We may unilaterally terminate the Satiogen Agreement for any reason or no reason upon 90 days' written notice to Satiogen. If we cease all research, development and commercialization efforts with respect to all licensed products related to the ASBTi Technology or the TGR5 Technology for over one year, or we determine to cease all such efforts, Satiogen may elect to terminate the Satiogen Agreement with respect to the license under the ASBTi

Technology or the TGR5 Technology, respectively. Either party may terminate the Satiogen Agreement for the other party's material breach of the Satiogen Agreement which remains uncured after 90 days of receiving written notice of such breach. Absent early termination, the Satiogen Agreement will automatically terminate upon the expiration of our royalty obligations.

Commercial Agreements related to Cholbam

Asset Purchase Agreement with Asklepion Pharmaceuticals, LLC

Through the Bile Acid Portfolio Acquisition, we were assigned the rights to the Asset Purchase Agreement ("Asklepion APA"), dated January 10, 2015, between Travere and Asklepion Pharmaceuticals, LLC ("Asklepion"), pursuant to which we acquired all right, title and interest to certain assets of Asklepion aimed at the development of products related to cholic acid ("Cholic Acid Products"). Pursuant to the Asklepion APA, we are required to pay Asklepion high single-digit to low double-digit tiered royalties on worldwide net revenues of Cholic Acid Products.

Master Services Agreement with The Aliceanna Group LLC

Through the Bile Acid Portfolio Acquisition, we were assigned Travere's rights and obligations under the Master Services Agreement ("Aliceanna MSA"), dated January 10, 2015, between Travere and The Aliceanna Group LLC ("Aliceanna") related to the performance of certain development services by Aliceanna related to Cholic Acid Products. Pursuant to the Aliceanna MSA, we are obligated to pay Aliceanna a low single-digit royalty on net revenues of Cholic Acid Products.

Commercial Agreements related to Chenodal

License and Manufacturing Agreement with LGM Pharma

Through the Bile Acid Portfolio Acquisition, we were assigned the rights to the License and Manufacturing Agreement, dated November 4, 2009, between LGM Pharma, formerly Nexgen Pharma, Inc. ("LGM"), and Manchester Pharmaceuticals, Inc. (together with its affiliates, "Manchester") related to the manufacture of Chenodal, pursuant to which we obtained an exclusive, perpetual license to market Chenodal in the U.S. under the terms of an abbreviated new drug application approved by the FDA and owned by LGM, which grants to LGM the authority to manufacture and sell Chenodal in the U.S.

International Rights Purchase Agreement with Manchester Pharmaceuticals LLC

Through the Bile Acid Portfolio Acquisition, we were assigned the rights to the International Rights Purchase Agreement ("Manchester IRPA"), dated March 26, 2014, between Travere and Manchester, pursuant to which we acquired all right, title and interest to certain products of Manchester related to chenodiol ("Chenodiol Products"). Pursuant to the Manchester IRPA, we are obligated to pay Manchester a mid-single-digit to low double-digit royalty on net sales of certain Chenodiol Products outside of the U.S.

Membership Interest Purchase Agreement with Loring Creek Holdings LLC et al.

Through the Bile Acid Portfolio Acquisition, we were assigned Travere's rights and obligations under the Membership Interest Purchase Agreement ("Manchester MIPA"), dated March 26, 2014, among, on the one hand, Travere, and on the other, Loring Creek Holdings LLC and certain individuals (collectively, the "MIPA Sellers"), pursuant to which Travere had acquired from the MIPA Sellers all issued and outstanding membership interests in Manchester Pharmaceuticals LLC. Pursuant to the Manchester MIPA, we are obligated to pay the MIPA Sellers a mid-single-digit to low double-digit royalty on net sales of certain Chenodiol Products in the U.S.

Asklepion APA

Pursuant to the Asklepion APA, we are required to pay Asklepion a low single-digit royalty on net sales of Chenodal in the U.S.

Revenue Interest Purchase Agreement with Oberland

In December 2020, we entered into a Revenue Interest Purchase Agreement (“RIPA”) with Mulholland SA LLC, an affiliate of Oberland Capital LLC, as agent for the purchasers party thereto (the “Purchasers”), and the Purchasers. Pursuant to the RIPA, the Purchasers paid us $50.0 million on closing and $65.0 million in April 2021, less certain transaction expenses. In April 2023, we exercised our option to terminate the RIPA and repurchase all future revenue interests from the Purchasers in exchange for a payment of $192.7 million. Upon repurchase of the revenue interests from the Purchasers, the RIPA, in accordance with its terms, was terminated with no further payments due to the Purchasers and the $100.0 million of previously restricted cash equivalents was no longer restricted from use.

Convertible Notes

In April 2023, we completed an offering of $316.3 million aggregate principal of 4.00% Convertible Senior Notes due 2029 (the “Notes”), which includes the exercise of the initial purchasers’ option in full. The offering resulted in net proceeds of $305.3 million after deducting the initial purchasers’ discounts and commissions and offering expenses. We used a portion of the net proceeds to repurchase the revenue interests pursuant to the RIPA, entered into in December 2020, as amended in September 2021.

Asset Purchase Agreement with Travere Therapeutics, Inc.

On August 31, 2023, we completed the Bile Acid Portfolio Acquisition. We paid $210.4 million upon closing of the transaction, and up to an additional $235.0 million is payable upon the achievement of certain milestones based on specified amounts of annual net sales of the Bile Acid Medicines.

We concurrently entered into a transitional services agreement with Travere, pursuant to which Travere is obligated to perform certain services for a period of time, not anticipated to last beyond 12 months post-close, with respect to our use and operation of the assets purchased.

In connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, we completed the private placement of 8,000,000 shares of our common stock at a price per share of $26.25, resulting in net proceeds of approximately $202.2 million.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights. A comprehensive discussion on risks relating to intellectual property is provided under “Risk Factors” under the subsection “Risks Related to Our Intellectual Property.”

We have developed and continue to develop patent portfolios around our product candidates, Livmarli (maralixibat) and volixibat. We have rights to pending patent applications in the United States, Europe, South Korea, Hong Kong, Mexico and Singapore covering the methods of treating various cholestatic liver indications using maralixibat and/or volixibat which, if issued, would expire in October 2032, absent any patent term adjustments or extensions. We have rights to an issued United States Patent No. 11,376,251 in the United States directed to treating ALGS in a pediatric subject with maralixibat, expiring in October 2032. This patent is listed in the FDA’s Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for Livmarli. We have rights to two issued patents in the United States directed to treating or ameliorating PFIC2 and treating or ameliorating a pediatric disorder characterized by having a non-truncating BSEP mutation selected from PFIC2, BRIC2, and drug induced cholestasis in a pediatric subject comprising administering Livmarli, both of which expire in October 2032. We have rights to two issued United States Patents Nos. 11,229,647 and 11,497,745 in the United States directed to treating ALGS in a pediatric subject comprising administering Livmarli to the subject expiring in February 2040. Both of these patents are listed in the Orange Book for Livmarli. We have rights to granted and/or issued patents in Australia, Brazil, Canada, China, Israel, Japan, Mexico, South Korea, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Turkmenistan, South Africa and Macau covering the methods of treating cholestasis using IBATis that have limited systemic exposure, which expire in October 2032. We also have rights to pending patent applications in United States, Europe, Eurasia,Hong Kong and Singapore, covering methods of treating pediatric cholestatic liver diseases using IBATis that have limited systemic exposure, which, if issued, would expire in October 2032, absent any patent term adjustments or extensions. We have rights to granted and/or issued patents in Australia, Brazil, Canada, China, Israel, Japan, Mexico, South Korea, South Africa, Singapore, Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Macau and Turkmenistan covering methods of treating pediatric cholestatic liver diseases using IBATis that have limited systemic exposure, which expire in October 2032. We also have rights to a granted patent in South Africa covering pediatric dosage forms of IBATis that have limited systemic exposure, which expires in October 2032. We have rights to pending patent applications in the United States, Europe, Canada, China, Japan, South Korea, Israel, Brazil, Russia, Mexico, Australia, New Zealand, UAE, and Saudi Arabia directed to methods for modulating a dosage of an IBATi and to methods for using patient genotype to predict response to IBATi administration in patients with BSEP deficiency. We have rights to pending applications in the United States, Europe, Canada, China, Japan, South Korea, Israel, Brazil, Russia, Mexico, Australia, New Zealand, UAE, and Saudi Arabia directed to methods for treating cholestatic liver disease comprising administering higher dosages of IBATis. We have rights to pending applications in the United States, Europe, Canada, China, Japan, South Korea, Israel, Brazil, Russia, Mexico, Australia, New Zealand, UAE, and Saudi Arabia directed to methods of increasing growth in pediatric subjects having cholestatic liver disease by administering IBATis. Any patents issuing from these applications would expire in February 2040, absent any patent term adjustments or extensions. We have rights to pending applications in the United States, Argentina, Taiwan and Patent Cooperation Treaty (“PCT”) directed to formulations of Livmarli which, if issued, would expire in October 2042, absent any patent term adjustments or extensions. We have rights to pending applications in the United States, Taiwan and PCT directed to treatment with IBATis in the fasted state which, if issued, would expire in October 2042, absent any patent term adjustments or extensions. We have rights to pending applications in the United States, Taiwan and PCT directed to increased event-free survival of long-term maralixibat patients which, if issued, would expire in November 2042, absent any patent term adjustments or extensions. We have rights to pending applications in the United States, Argentina, Taiwan, Uruguay, Paraguay and PCT directed to highly pure maralixibat forms and intermediates which, if issued, would expire in September 2043, absent any patent term adjustments or extensions. We have rights to pending applications in the United States and PCT directed to maralixibat compositions and solid dosage forms which, if issued, would expire in October 2043, absent any patent term adjustments or extensions. We have rights to pending applications in the United States, Taiwan, and PCT directed to treatment of PFIC with maralixibat which, if issued, would expire in October 2043, absent any patent term adjustments or extensions. We have licensed patent applications in the United States and a pending application in Europe from Satiogen covering therapeutic uses of IBATis that have limited systemic exposure for treating inflammatory intestinal conditions, which, if issued, would expire in May 2031, absent any patent term adjustments or extensions. Two of these Satiogen applications have issued as United States Patent No. 10,251,880 and 11,260,053, the latter being Orange-Book listed for Livmarli. We have licensed an issued United States patent, as well as issued foreign counterparts in Argentina, Austria, Australia, Belgium, Canada, Switzerland, China, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Ireland, Israel, India, Italy, Japan, South Korea, Liechtenstein, Mexico, Malaysia, Netherlands, Norway, Portugal, Russia, Sweden, Singapore, Taiwan, Turkey, and Brazil from Sanofi, that cover the composition and methods of making volixibat and salts thereof, expiring in December 2027. Patents related to Livmarli and volixibat may be eligible for patent term extensions in certain jurisdictions, including the United States, upon approval of a commercial use of the corresponding product by a regulatory agency in the jurisdiction where the patent was granted and/or issued. Similar to the patent term-extensions in the United States, Supplementary Protection Certificates (“SPCs”) serve as an extension to a patent right in the European Union (“EU”) for up to five years. SPCs have been granted for maralixibat for EP2771003 in Austria, Denmark, Italy, Netherlands, and Portugal, and are pending in Belgium, Czech Republic, Germany, Estonia, Spain, Finland, France, United Kingdom, Ireland, Norway, Poland, Sweden, and Slovakia.

We do not have patents or patent applications covering Livmarli as a composition of matter. Therefore, the primary patent-based intellectual property protection for our Livmarli program will be any patents granted on the pending method-of-use and dosage form patent applications.

In addition to patent protection, we rely on trade secret protection, trademark protection and know-how to expand our proprietary position around our chemistry, technology and other discoveries and inventions that we consider important to our business. We are a party to a number of license agreements under which we are granted intellectual property rights to know-how that are important to our business. We have licensed know-how related to Livmarli in the United States, Europe and other countries from Pfizer. We have licensed know-how related to ASBTi Technology and TGR5 Technology from Satiogen. We have licensed know-how related to volixibat from

Sanofi. Our existing license agreements as related to Livmarli and volixibat impose various development, regulatory and/ commercial diligence obligations, payment of milestones and/or royalties and other obligations.

In addition, we currently have orphan drug designation for Livmarli for the treatment of ALGS, PFIC, PSC and PBC in the United States and the EU, providing the opportunity to receive seven years of market exclusivity in the United States, which can be extended to seven and a half years if trials are conducted in accordance with an agreed-upon pediatric investigational plan, and ten years of market exclusivity in the EU, which can be extended to 12 years in the EU if trials are conducted in accordance with an agreed-upon pediatric investigational plan.

In the United States, maralixibat has been granted new chemical entity ("NCE") exclusivity until September 29, 2026. This five years of post-FDA approval exclusivity runs concurrently with its seven years orphan drug exclusivity for the treatment of ALGS. Upon approval in the United States, as volixibat has not previously been approved in the United States for any indication, it may be eligible for five years of NCE exclusivity, which would run concurrently with its seven years of orphan drug exclusivity if we obtain orphan drug designation for its approved uses.

We also seek to protect our intellectual property in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators and other contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ.

Furthermore, we seek trademark protection in the United States and internationally where available and when we deem appropriate.

Sales, Marketing and Distribution

We believe we have built the commercial infrastructure necessary to effectively support the commercialization of our approved medicines, and volixibat, if approved, in North America and certain countries in Europe and are using strategic partners, and distributors to assist in the commercialization of our approved medicines and volixibat in other markets.

The commercial infrastructure for orphan products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group and distribution support. Additional capabilities important to the marketplace include the management of key accounts such as managed care organizations, group-purchasing organizations, specialty pharmacies, government accounts and reimbursement support. Based on the number of physicians that treat cholestatic liver diseases, we have designed our commercial organization to target the relevant audience for our approved medicines and volixibat, if approved, in North America and certain countries in Europe primarily through an internal sales force. To maintain and further develop the appropriate commercial infrastructure, we have invested and expect to continue to invest significant amounts of financial and management resources in our commercial organization.

In addition, we have built a medical affairs organization and multiple capabilities across North America and Europe to meet the scientific and medical educational needs of the healthcare providers and patients in the rare disease community that are focused on providing accurate disease state and balanced product information for appropriate management of patients with rare disorders. Medical affairs is comprised of medical information, patient advocacy, patient diagnosis, medical science liaisons, research and educational grants.

We have entered into a services agreement with Eversana, a leading provider of commercial support services to the life science industry, to provide integrated nationwide distribution, specialty pharmacy, medical information, patient services and hub support for our approved medicines in the United States. For Livmarli, we have entered into a service agreement with Movianto to provide integrated distribution outside the United States.

Our approved medicines are currently distributed in the U.S. and Canada, through a single specialty pharmacy. Sales of our approved medicines outside of the U.S., Canada and certain EU countries are sold either directly by us, or to our authorized distributors or license partners. Both the specialty pharmacy and the authorized distributors act as intermediaries between us and the end-users and generally do not stock significant quantities of our products. In certain countries, governments place large periodic orders. The timing of these orders can be inconsistent and can create quarter-to-quarter variation in revenue.

Further, in 2023, we began selling Livmarli to pharmacies in certain European countries which act as intermediaries between us and end-users. These pharmacies do not stock significant amounts of inventory.

Manufacturing

We do not own or operate manufacturing facilities for the production of our approved medicines and volixibat or other product candidates that we may develop, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient and finished products, including clinical supplies. Over the course of the development of our IBATis we have used and continue to use multiple third-party contract manufacturers. We have entered into and expect to continue to enter into agreements for commercial production of our approved medicines. We do not have any current contractual arrangements for the manufacture of commercial supplies of volixibat. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

Competition

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our products and product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do.

Competition may also arise from, among other things, new drug development technologies, new or improved treatment options for preventing or reducing the incidence of disease in diseases our products treat and new small molecule or other classes of therapeutic agents. Such developments by competitors could reduce or eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

We are aware of two other companies pursuing clinical development of therapies that reduce sBA levels via the IBAT pathway. GlaxoSmithKline plc and Ipsen Pharma (“Ipsen”) have IBATis in clinical development for cholestatic liver diseases.

We are aware Ipsen has received approval for odevixibat for the treatment of pruritus in patients with PFIC, and pruritus in patients with ALGS 12 months and older, in the U.S., and for the treatment of PFIC in certain European countries. Ipsen has been granted orphan designation for PFIC in certain European countries and if Livmarli is deemed similar, it could prevent the approval of Livmarli in PFIC or result in a refusal by the European Commission to maintain orphan designation for Livmarli for PFIC in the European Economic Area (“EEA”). We are aware that Ipsen has submitted a marketing application to the EMA seeking approval for odevixibat for the treatment of cholestatic pruritus in patients with ALGS. Ipsen is also conducting a study of odevixibat in BA and plans to pursue other cholestatic liver diseases. Other off-label medications are also used in ALGS and PFIC for cholestatic pruritus such as Ursodeoxycholic acid (“UDCA”), cholestyramine and other bile salt resins, rifampin, naltrexone and other agents, such as selective serotonin reuptake inhibitors. Despite the lack of FDA approval, these older, generic agents are perceived as part of the standard of care for treating ALGS and PFIC patients suffering from cholestatic pruritus. Further, we may compete with companies that are developing gene therapy for the treatment of PFIC. Additionally, surgical interventions, such as partial external biliary diversion and nasobiliary drainage, and extracorporeal liver support, such as Molecular Adsorbent Recirculation System, are also employed in an attempt to lower bile acid levels, manage pruritus and improve measures of liver function.

In adult settings of cholestasis, similar to pediatric settings, cholestyramine, UDCA, rifampin and naltrexone are commonly used agents. We are aware that Intercept Pharmaceuticals, Inc.’s Ocaliva is approved as a second-line treatment for PBC. We are aware of several agents in clinical development for the treatment of PBC including Intercept’s Ocaliva and bezafibrate, Cymabay’s seladelpar, Ipsen’s elafibranor, Zydus Therapeutics Inc.’s saroglitazar magnesium, Escient Pharmaceuticals Inc.’s EP547, NGM Biopharmaceuticals, Inc.’s NGM282, Calliditas Therapeutics AB’s setanaxib, COUR Pharmaceuticals’ CNP-104, Ascletis Pharma’s ASC42, Umecrine Cognition’s golexanolone, and GlaxoSmithKline’s linerixibat, another IBATi.

We are not aware of FDA or European Commission approved therapeutics for the treatment of PSC. We are aware of several agents in clinical development for the treatment of PSC, including Cymabay’s seladelpar, DURECT Corporation’s DUR928, HighTide Biopharmaceutical Inc.’s HTD1801, Immunic Therapeutics’ IMU-838, Intercept’s Ocaliva, or obeticholic acid, Ipsen’s elafibranor and IPN60250 NGM Biopharmaceuticals Inc.’s NGM282, Escient Pharmaceuticals’s EP547, Chemomab Therapeutics Ltd.’s CM-101, and Pliant Therapeutics’ bexotegrast.

Symptomatic treatment with antipruritics, such as cholestyramine, typically provides only modest relief. Bristol Myers Squibb Company has discontinued its brand name cholestyramine, but generic versions of the drug are marketed by Upsher-Smith Laboratories, Inc., Par Pharmaceutical Companies, Inc., Sandoz Inc., the generic pharmaceuticals division of Novartis AG and others. UDCA, also known as ursodiol, is marketed by a number of generic pharmaceutical companies such as Mylan Inc., Actavis Inc., Lannett Company, Inc. and Par Pharmaceutical Companies, Inc.

There are other approved chenodeoxycholic acid products available outside of the U.S. Both Dr. Falk Pharma GmbH and Leadiant Biosciences, Inc. have FDA Orphan Drug Designations granted for the treatment of CTX (granted in 2004 and 2007, respectively); however, neither company, based on publicly available information, has initiated any prospective clinical studies in CTX.

There are currently no FDA-approved treatments in the U.S. that compete with Cholbam. There are other approved cholic acid products available outside of the U.S. and Laboratoires CTRS has received approval from the EMA for a version of cholic acid.

Under the Hatch-Waxman Amendments of the Federal Food, Drug, and Cosmetic Act, a pharmaceutical manufacturer may file an abbreviated new drug application (“ANDA”) seeking approval of a generic copy of an approved innovator product or an NDA under Section 505(b)(2) that relies on the FDA’s prior findings of safety and effectiveness in approving the innovator product. A Section 505(b)(2) NDA may be for a new or improved version of the original innovator product. Certain of our approved medicines, including Chenodal and Cholbam, are subject to immediate competition from compounded and generic entrants, as the ANDA and NDA for these drug products have no remaining or current patent or non-patent exclusivity.

In December 2019, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the “CREATES Act”) was enacted, which provides a legislatively defined private right of action under which generic companies can bring suit against companies who refuse access to product for the bioequivalence testing needed to support approval of a generic product. It is our policy, which is in compliance with the CREATES Act, to evaluate requests for samples of our branded products, and to provide samples in response to bona fide requests from qualified third parties, including generic manufacturers, subject to specified conditions. We have provided samples to certain generic manufacturers.

Government Regulation and Product Approval

As a pharmaceutical company that operates globally, we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Generally, our activities in other countries are or will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (“FDCA”), and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP"), regulations and other applicable regulations;
- submission to the FDA of an investigational new drug ("IND"), which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practice ("GCP"), regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA advisory committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice ("cGMP"), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA inspection of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase 4 trials. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows the advisory committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also determine that a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Orphan drug status in the EU has similar but not identical benefits in that jurisdiction.

Expedited Development and Review Programs

The FDA has a Fast Track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy for a serious condition where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, 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. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

A sponsor may seek FDA designation of a drug candidate as a "breakthrough therapy" if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and 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 includes intensive FDA interaction and guidance. If a drug is designated as breakthrough therapy, the FDA will expedite the development and review of such drug. Breakthrough therapy designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, this designation may not provide a material commercial advantage.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the drug product. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time during the patent's term between the effective date of an IND and the submission date of an NDA plus the time during the patent's term between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a NCE. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity and/or non-infringement to one of the patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity for the approved indication, except in certain circumstances. Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

We are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. In the United States, such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and health care provider transparency or "sunshine" laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. 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 and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an 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 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 of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute and the criminal healthcare fraud statutes (discussed below) was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The federal False Claims Act, as well as the civil monetary penalty law, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or 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. As a result of a modification to the federal False Claims Act made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies have also been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-covered, uses.

The Health Insurance Portability and Accountability Act ("HIPAA") also created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, certain ownership and investment interests held by physicians and their immediate family members.

We may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We also are or will become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in relation to clinical trials in Europe, we are subject to Regulation (EU) 2016/679, the General Data Protection Regulation and similar laws in European countries outside of the EU (collectively, the “GDPR”), in relation to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the European Economic Area, including the health and medical information of these participants. The GDPR also provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal data is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EU rules with respect to cross-border transfers of personal data out of the EU and European Economic Area. We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR, and we maintain an office in Switzerland, which has similar privacy and data protection laws and regulations. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation.

In addition, California recently enacted the California Consumer Privacy Act (“CCPA”), which requires covered companies to provide new disclosures to California residents and honor their requests to access, delete and opt-out of certain sharing of their personal data. The CCPA, which took effect on January 1, 2020, provides for civil penalties for violations and private right of action for certain data breaches. The CCPA has expanded substantially as a result of the California Privacy Rights Act of 2020, which, among other things, creates a new administrative agency to implement and enforce California’s privacy laws effective January 1, 2023. While certain clinical trial activities are exempt from the CCPA’s requirements, other personal data that we handle may be subject to the CCPA, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, imprisonment, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. In the United States and other countries, sales of pharmaceuticals, including Livmarli, depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Third party payors may require pharmaceutical companies to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of their products, in addition to the costs required to obtain the FDA approvals. Nonetheless, payors may determine that such products may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available for Livmarli and other drug products we may develop to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

If we elect to participate in certain governmental programs, we may be required to participate in discount and rebate programs, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. For example, drug manufacturers participating under the Medicaid Drug Rebate Program must pay rebates on prescription drugs to state Medicaid programs. Under the Veterans Health Care Act ("VHCA"), drug companies are required to offer certain drugs at a reduced price to a number of federal agencies, including the U.S. Department of Veterans Affairs and Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs, including Medicare and Medicaid. Recent legislative changes require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA also requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of Livmarli and any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for Livmarli or any other products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, in March 2010, the Affordable Care Act was enacted, which affected existing government healthcare programs and resulted in the development of new programs.

Among other things, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports 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 the 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 Act was enacted, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the current administration will impact the Affordable Care Act and our business.

Other legislative changes have also been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, 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, President Biden signed the American Rescue Plan Act of 2021 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, effective January 1, 2024.

There has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products

At the federal level, the previous administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in July 2021 the current administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to the current administration's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology 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.

At the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product 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 proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear if and how this program will be implemented and whether it will be subject challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. Any such approved importation plans, if 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 which suppliers will be included in their prescription drug and other healthcare programs.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign 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 similar process that requires the submission of an application for a clinical trial authorization ("CTA"), much like the IND prior to the commencement of human clinical trials.

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 ("CTD").

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the “EU portal”, the Clinical Trials Information System(“CTIS”); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

EU Review and approval process

In the EU, medicinal products can only be commercialized after a related marketing authorization has been granted. To obtain a marketing authorization for a product in the EU, an applicant must submit a Marketing Authorization Application (“MAA”), either under a centralized procedure administered by the EMA or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA’s Committee for Medicinal Products for Human Use (“CHMP”), conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the

EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

A marketing authorization has, in principle, an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original marketing authorization was granted. To support the application, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized marketing authorization) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional marketing authorization for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional marketing authorization is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will cease to be renewed.

A marketing authorization may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional marketing authorization, a marketing authorization granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard marketing authorization. However, unlike the conditional marketing authorization, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the marketing authorization will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC") if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Orphan Designation in the EU

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. A marketing authorization for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization Requirements in the EU

Where a marketing authorization is granted in relation to a medicinal product in the EU, the holder of the marketing authorization is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan (“RMP”) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States’ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics (“SmPC”), which may require approval by the competent national authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Pricing, Coverage and Reimbursement in the EU

In the EU, pricing and reimbursement schemes vary widely from country to country. Some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA Regulation") was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the EU.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Human Capital Management

As of December 31, 2023, we employed 264 employees, all of whom are full time, consisting of clinical, research, operations, finance and business development personnel. Forty of our employees hold Ph.D. or M.D. degrees. Further, 202 of our employees are located in the United States, and 56 in Europe and six in Canada. As of December 31, 2023, none of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We expect to continue to add employees in 2024, with a focus on clinical, research and development and commercialization activities. We continually evaluate the business need and opportunity to expand our team and balance in-house expertise and capacity with outsourced expertise and capacity. Currently, we outsource substantial clinical trial work to clinical research organizations and drug manufacturing to contract manufacturers.

We maintain a safety culture grounded on the premise of eliminating workplace incidents, risks and hazards. We have implemented and continue to enhance safety measures in all our facilities, including establishing clear and regular policies, safety protocols and updates to all employees.

We believe our success depends on our ability to attract, develop and retain key personnel. We invest in the growth and development of our employees through various training and development programs that build and strengthen employees' leadership and professional skills. We also have processes in place to conduct activities like performance management, succession and workforce planning in order to support our employees in their growth and development and ensure we provide learning opportunities.

To continually assess and improve our employee retention and engagement, we conduct an engagement survey on a regular basis, the results of which are discussed with our board of directors, at all-hands employee meetings and in individual functions. We take actions to address areas of employment concern and follow up routinely to share with employees what we are doing.

We strive toward having a diverse team of employees and are committed to equality, inclusion and workplace diversity. To accomplish this, we have included questions in our engagement survey to measure employee perception of inclusive culture. In 2020, we established a Culture Team that now consists of two sub-teams, one internationally and one in the United States with over 15 employees across a representative cross-section of departments. Amongst other initiatives, our Culture Team engages in continual discussions across the various business functions to identify potential actions to address areas of improvement and is focused on building accountability across the organization to ensure we meet our diversity objectives.

Corporate Information

We were incorporated in Delaware in May 2018. Our principal executive offices are located at 950 Tower Lane, Suite 1050, Foster City, California 94404, and our telephone number is (650) 667-4085. Our corporate website address is www.mirumpharma.com. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this report is an inactive textual reference only. Our design logo, “Mirum,” and our other registered and common law trade names, trademarks and service marks are the property of Mirum Pharmaceuticals, Inc.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to Commercialization of our Approved Medicines and Development of our Product Candidates

The success of our business depends, in part, on our ability to commercialize our approved medicines profitably.

Livmarli, Chenodal, and Cholbam are our approved medicines. The success of our business depends, in part, on our ability to commercialize our approved medicines profitably. Our successful commercialization of our approved medicines depends on a number of factors, including, among others, the following:

- our ability to grow and maintain our sales team in the United States ("U.S."), Canada, and certain countries in Europe, as well as scale our distribution capabilities in these locations and others where our products are available;
- the availability of adequate reimbursement and a commercially viable sales price of our approved medicines;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our approved medicines, including relative to alternative and competing treatments;
- a continued acceptable safety profile of our approved medicines;
- the effect of recent or forthcoming health care legislation and regulatory changes in the locations where our approved medicines are authorized;
- our ability to successfully obtain the substances and materials used in manufacturing our medicines from third parties and to have finished product manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for our commercial needs;
- our ability to establish and enforce intellectual property rights in and to our approved medicines and avoid third-party patent interference or intellectual property infringement claims;
- our ability to compete successfully with the marketing and sale of compounded and generic versions of our medicines; and
- sufficient patient population that would benefit from our approved medicines as they are intended for use in rare diseases for which the patient population is small.

If one or more of the above factors is not present, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to market and sell our approved medicines profitably, which would harm our business, financial condition, operating results and prospects.

If we are unable to adequately grow, maintain and scale our marketing and sales capabilities or enter into or maintain rights pursuant to agreements with third parties to market and sell our approved medicines, we may not be able to generate viable revenues.

To successfully commercialize our approved medicines, we must grow, maintain and appropriately scale our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We have established our own commercial capabilities in the U.S. to commercialize our approved medicines. We are also in the process of further establishing our capabilities related to Livmarli in certain major European markets and Canada and have entered into a limited number of partner and distributor agreements in other select geographies. We plan to continue to evaluate opportunities to partner with pharmaceutical companies that have established sales and marketing capabilities to commercialize our approved medicines and our product candidates, if approved, outside of these geographies. Our projections of the commercial and sales needs to target these markets may not be accurate. If we are materially off from our projections, our business and operating results would be harmed.

Growing and maintaining our own sales force to market Livmarli and Cholbam is expensive and time-consuming. Moreover, we may not be able to successfully or adequately develop this capability for our product candidates in development. We compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our approved medicines, and any agreements with such third parties may not be on terms that are favorable to us. To the extent we do rely on third parties to commercialize our approved medicines and our other product candidates, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized our product candidates ourselves. In addition, we have entered into a limited number of partner and distributor agreements. Any loss, commercial failure, or termination of rights pursuant to these agreements could delay or hinder our commercialization efforts.

In the event we are unable to successfully grow and maintain our marketing and sales force or collaborate with necessary third-party marketing and sales organizations, we would not be able to commercialize our approved medicines and our business, results of operations, financial condition, and prospects would be materially adversely affected.

Our commercial success may be severely hindered if we are unable to obtain and/or maintain adequate coverage and reimbursement for our approved medicines and any future product candidates, if approved.

The availability of coverage and adequate reimbursement from private third-party payors such as pharmacy benefit managers and commercial insurers, and governmental healthcare programs, such as Medicaid in the U.S. and equivalent programs in foreign countries, is critical to the commercial success of our approved medicines in the U.S. and in international markets. Coverage may be adversely affected by a number of factors, including, but not limited to:

- increasing and intense pressure from political, social, competitive and other sources to reduce drug unit costs, access drugs from other countries to achieve better pricing or limit changes in list price;
- changes in federal, state or foreign government regulations or private third-party payors' reimbursement policies;
- reimbursement decisions and price negotiations with foreign government payors;
- consolidation and increasing assertiveness of commercial payors seeking net price reduction via drug rebates and other forms of discounts linked to the placement of our approved medicines on their formularies; and
- the imposition of restrictions on access or coverage of particular drugs or pricing.

A trend in the healthcare industry is cost containment. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs by, among other methods, limiting or preventing (for example via prior authorization, prior therapy or step edit requirements) coverage for particular medications, requiring drug companies to provide them with varying levels of discounts from list prices and/or challenging the value of list prices charged for medical products. Similarly, the containment of healthcare costs has become a priority for federal and state governments around the world. Coverage decisions may depend upon the size of a patient population, perceptions of clinical efficacy and economic standards that may disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Coverage and reimbursement for drug products can differ significantly across payors. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our approved medicines to each third-party payor separately, with no assurance that coverage will be obtained or maintained. Additionally, coverage policies and third-party reimbursement rates may change at any time. For example, rebate payments may increase, or prices be adjusted, under value-based purchasing arrangements based on evidence-based measures or outcomes-based measures for a patient or beneficiary based on use of our drug. Thus, even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In many foreign countries, including Member States of the EU, the pricing of prescription drugs is subject to governmental control and the proposed pricing for a drug must be approved before it may be lawfully marketed. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product and varies between countries. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels. For instance, governmental authorities in the EU Member States and third-party payors could base pricing and reimbursement terms on what they perceive to be comparable products, even if approved for different indications. In addition, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. These pricing and reimbursement decisions may impact the pricing and reimbursement of our approved medicines in such jurisdictions. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations often continue after coverage and reimbursement have been obtained. Reference pricing or pricing comparisons to our competitors used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in December 2021, Regulation No 2021/2282 on Health Technology Assessment, (“HTA”), amending Directive 2011/24/EU (“HTA Regulation”), was adopted in the EU. The Regulation will apply beginning January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those product candidates in the EU could be negatively affected.

Historically, products launched in the EU and other foreign countries do not follow the price structures of the U.S. and prices can be significantly lower and the time to obtain pricing and reimbursement approvals is significantly longer. If pricing is set at unsatisfactory levels or if reimbursement of our approved medicines and any future product candidates, if approved, is unavailable or limited in scope or amount, our revenues from sales by us or our partners and the potential profitability of our approved medicines or any future product candidates, if approved, in those countries would be negatively affected.

Our approved medicines or any one of our product candidates, if approved, may fail to achieve the market acceptance among physicians, patients and others in the medical community necessary for commercial success.

The commercial success of our approved medicines or any one of our product candidates, if approved, depends significantly on the market acceptance among physicians, patients, tertiary care centers, transplant centers and others in the medical community. The degree and rate of market acceptance depends on a number of factors, including, among other things:

- patient demand;
- the availability of adequate reimbursement from private third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the cost of treatment in relation to alternative treatments and patients willingness to pay for our approved medicines, including relative to discretionary items;
- our ability to successfully compete with available off-label therapies, future approved therapies, and therapies in development and available for use through expanded access programs;
- acceptance by physicians, patients, tertiary care centers, transplant centers and others in the medical community that our approved medicines are safe and effective treatments;
- physician and patient willingness to adopt a new therapy over other available therapies;
- limitations, warnings or adverse drug reactions contained in the labeling or product inserts approved by the FDA, European Commission or comparable foreign regulatory authorities, and patients' and physicians' assessment of these limitations and warnings;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of the indications our approved medicines are approved for (or, if applicable, deemed medically necessary for);
- patients and caregivers properly using our approved medicines as instructed;
- the prevalence and severity of side effects from the use or potential misuse of our approved medicines;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies, and patient satisfaction with the overall treatment experience;
- the ability of specialty pharmacies we contract with to process prescriptions and dispense our approved medicines and the processes required to place orders with those pharmacies;
- the ability of our patient services hub to provide adequate support for patients and physicians to prescribe and access our approved medicines;
- the timing of market introduction of any of our approved medicines as well as competitive products;
- the effectiveness of our sales, marketing and distribution efforts and those of the third parties with whom we contract;
- adverse publicity about our approved medicines or favorable publicity about competitive products;
- potential product liability claims;
- our ability to manage our growth and operations to effectively support our commercialization activities; and
- patient satisfaction leading to a high percentage of patients deriving clinical benefit and staying on our approved medicines chronically.

If any of our approved medicines fail to achieve the market acceptance among physicians, patients, tertiary care centers, transplant centers or others in the medical community necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Our approved medicines and our product candidates may cause undesirable side effects or have other properties that could limit their commercial profile, expose us to product liability claims, delay or prevent regulatory approval of our product candidates or additional indications, or result in significant negative consequences following any additional marketing approval, any of which may adversely impact our business, financial condition, operating results and prospects.

As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events ("AEs") associated with our product candidates' use. Results of our clinical trials and expanded access program could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, European Commission or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In clinical trials of Livmarli, the most commonly reported AEs were diarrhea, abdominal pain and vomiting, and were mostly mild to moderate in severity and transient in nature. Additionally, AEs reported in greater than 5% of patients included fat-soluble vitamin deficiency, nausea, liver transaminase increases, gastrointestinal bleeding and bone fracture. The frequency of observed AEs has not increased over time. In clinical trials of volixibat, the most common AEs reported were mild to moderate GI events observed in the volixibat groups. The most common adverse events for Cholbam (≥1%) are diarrhea, reflux esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy. Related adverse events seen in one patient each from the RESTORE clinical trial assessing Chenodal in patients with CTX, included fatigue, gait disturbance, diarrhea, liver transaminase increase, bilirubin increase, ataxia, tremors, decreased appetite and psychiatric disorder.

Additionally, in respect of our approved medicines or if one or more of our product candidates receives marketing approval, and we or others (including regulatory approval authorities) later identify undesirable side effects caused by our approved medicines or such product candidates or other products with the same or related active ingredients, a number of potentially significant negative consequences could result, including, among other things:

- regulatory authorities may withdraw approvals of such product, including the FDA, European Commission or comparable foreign regulatory authorities withdrawing approval for the affected medicine;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require a recall or we or our potential partners may voluntarily recall such product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients at significant cost or instate a Risk Evaluation and Mitigation Strategies ("REMS") or Risk Management Plan ("RMP");
- regulatory authorities may require the addition of warnings, such as black box or other warnings, or contraindications in the product labeling that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- our ability to promote our approved medicines may be limited and we could be required to change administration of, or modify, such product in some other way;
- regulatory authorities may require us to modify, suspend or terminate our clinical trials, conduct additional clinical trials or engage in costly post-marketing testing and surveillance to monitor the safety or efficacy of such product;
- undesirable side effects may limit physicians' or patients' willingness to initiate or continue therapy with such product;
- sales may decrease significantly;

- we could be sued and held liable for harm caused to patients; and
- our corporate brand and reputation or the reputation of our approved medicines may suffer.

Such events could prevent us from achieving or maintaining market acceptance of our approved medicines, and could significantly harm our business, results of operations and prospects.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in, or are subject to, the Medicaid Drug Rebate Program, as administered by Centers for Medicare & Medicaid Services ("CMS"), and other federal and state government pricing programs in the U.S., and we may participate, or be asked to participate, in additional government pricing programs or supplemental rebates in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer's price ("AMP"), for single source and innovator multiple source drugs, effective January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition. In addition, the U.S. Department of Health and Human Services ("HHS") Office of Inspector General and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP, and best price, for compliance with reporting requirements under the Medicaid Drug Rebate Program. Additionally, several states have a practice of asking, or are increasing activity in requesting supplemental rebates, for covered products. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and best price data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the civil False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

We may face product liability exposure, and if claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability suits for our approved medicines and product candidates. Our approved medicines and our product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, failure to follow instructions, misuse or abuse associated with our approved medicines or our product candidates could result in injury to a patient or even death. In addition, a liability claim may be brought against us even if our approved medicines or our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by, among others, consumers, their family members, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our approved medicines or product candidates. If we are the target of product liability claims, we will incur substantial legal costs, potential liabilities and could incur reputational harm if we do not successfully defend ourselves.

In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- the inability to commercialize our approved medicines or product candidates, if approved;
- decreased demand for our approved medicines or product candidates;
- termination of clinical trial sites or entire trial programs;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- impairment of our business reputation and negative media attention;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources and employees from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; and
- loss of revenue.

Large judgments have been awarded in class action and individual lawsuits based on drugs that had anticipated or unanticipated side effects. Although we have obtained product liability insurance coverage, our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

If we are found to have improperly promoted off-label uses of our approved medicines, or unapproved uses of our product candidates, if approved, or if we are found to be the cause of physician misuse or off-label use of our approved medicines or our product candidates, if approved, we may become subject to prohibitions on the sale or marketing of such products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA, European Commission, competent authorities of individual EU Member States, and comparable foreign regulatory authorities strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA, European Commission, Health Canada or comparable foreign regulatory authorities as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. For example, although Livmarli may appeal to individuals who have not been diagnosed with cholestatic pruritus associated with ALGS or suffer from other forms of cholestatic pruritus, we are only able to promote Livmarli in the U.S. for cholestatic pruritus associated with ALGS in patients three months of age and older and in the EU for the treatment of cholestatic pruritus in patients with ALGS two months of age and older. If we are found to have promoted off-label uses of our approved medicines or product candidates, we may receive warning or untitled letters and become subject to significant criminal and civil liability, which would materially harm our business. Further, both federal and state governments have levied large civil and criminal fines against companies for alleged improper off-label promotion and have enjoined several companies from engaging in off-label promotion and to undertake corrective remedies.

If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. In some instances, the FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of off-label uses, we could be subject to FDA regulatory or enforcement actions as well as by other federal, state or foreign enforcement authorities that might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. For example, if such off-label promotion results in the submission of a reimbursement claim to a governmental healthcare program, we could be found liable under the U.S. False Claims Act. In cases where off-label promotion has resulted in violations of other statutes, the U.S. Department of Justice ("DOJ") has also required companies to enter into deferred prosecution agreements or corporate integrity agreements.

Our approved medicines and our product candidates are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

Any regulatory approvals that we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-market studies or clinical trials, and surveillance to monitor safety and effectiveness. The FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Similarly, the European Commission may require a RMP in order to collect additional information on a medicine's safety profile which may include plans for pharmacovigilance activities and measures to minimize risks. In addition, if the FDA, European Commission or comparable foreign regulatory authorities approve a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, post-marketing obligations, storage, advertising, promotion, import, export and recordkeeping for the approved product will be subject to extensive and ongoing regulatory requirements. For example, we are subject to ongoing FDA and European Commission obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and recordkeeping for Livmarli, which requirements include submissions of safety and other post-marketing information and reports and registration, as well as continued compliance with cGMP requirements and with the FDA's and equivalent foreign good clinical practice ("GCP"). We are also subject to post-marketing obligations for Cholbam including the conduct and submission of registry studies.

In addition, Livmarli was the subject of a marketing authorization granted by the European Commission under exceptional circumstances in accordance with Article 14.8 of Regulation (EC) No 726/2004 relating to the authorization and supervision of medicinal products for human and veterinary use and establishing a EMA. This type of authorization is reviewed annually to reassess the risk-benefit balance of the medicinal product. The purpose of any specific procedures/obligations imposed as part of the marketing authorization granted in exceptional circumstances is to contribute to the provision of information on the safe and effective use of the product. Grant of a marketing authorization in exceptional circumstances is for a renewable period of one year and will normally not lead to the completion of a full dossier/approval.

We are subject to various FDA and EU post-marketing requirements across our approved medicines, including the conduct and submission of non-clinical, clinical and registry studies and the FDA's and EU's prohibition against marketing medicines in uses that are not approved. These and similar requirements could be imposed by the FDA, European Commission or comparable foreign regulatory authorities for any approved product.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA, the competent authorities of the individual EU Member States, or comparable foreign regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, such events may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled letters, warning letters or holds on clinical trials;

- refusal by the FDA or European Commission to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of a product; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above or any similar event or penalty may inhibit our ability to commercialize our approved medicines or our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's, European Commission's and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval for our product candidates or restrict marketing of any then-approved product. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We may pursue approval in the U.S. or certain countries in Europe using accelerated, exceptional circumstances or conditional approval pathways, which typically require commitments to complete additional clinical trials. The additional clinical trials may not confirm the treatment effect, which may result in the loss of marketing authorization under accelerated approval, exceptional circumstances or conditional approval.

Our business depends, in part, on the success of our product candidates, each of which requires significant clinical testing before we can seek regulatory approval and potentially launch commercial sales.

Our business and future success depends, in part, on our ability to obtain regulatory approval for, and then successfully commercialize our product candidates. Our product candidates will require clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Further, we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, European Commission or comparable foreign regulatory authorities, and we may never receive such regulatory approvals for our product candidates.

Our clinical trials may not be successful and may not be completed on time or at all, and the FDA, EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials. For example, in certain of our ongoing clinical trials, the primary efficacy endpoint is a patient-reported outcome or a caregiver-reported outcome measuring the decrease in severity of pruritus. The FDA, EMA or comparable foreign regulatory authorities may not accept such patient-reported outcomes or caregiver-reported outcomes as validated. If modifications are needed for our study design to support the submission of an application for marketing approval, incorporating such modifications may be costly and could lead to delays in obtaining approval from the FDA, European Commission or comparable foreign regulatory authorities, which may significantly, adversely and materially affect our ability to successfully commercialize our product candidates. Further, even if we make changes to the study design to address these considerations, the FDA, European Commission or comparable foreign regulatory authorities may not approve our product candidates.

Even if such regulatory authorities agree with the design and implementation of our clinical trials, such regulatory authorities may change their requirements in the future. In addition, even if the clinical trials are successfully completed, the FDA, EMA or comparable foreign regulatory authorities may not interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. For example, in April 2023, we submitted a variation application and data from our MARCH Phase 3 clinical trial for PFIC to the EMA seeking to extend the label for Livmarli to include the treatment of PFIC in patients two months of age or older. However, the EMA may require additional Phase 3 trials in order to expand the label or may reject expansion altogether.

To the extent that the results of our clinical trials are not satisfactory to the FDA, EMA or comparable foreign regulatory authorities for support of a marketing application, approval for our product candidates may be significantly delayed or prevented, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval for our product candidates.

While Chenodal is standard of care for CTX, it is not approved for that indication and we cannot promote or market it until it is approved for CTX which may be delayed or denied, which could adversely affect Chenodal revenues.

Chenodal is approved for radiolucent stones in the gallbladder yet is used primarily as standard of care for CTX. While healthcare professionals have broad prescribing authority for patients under their care and the FDA has provided a letter acknowledging Chenodal as a medical necessity for CTX, prescriptions for this indication are not strictly on label. As such, any change in this view from the FDA could result in an adverse effect to the ability to sell Chenodal in this indication. Unless and until Chenodal is approved for CTX, we cannot market or promote Chenodal for CTX, which limits its growth potential.

We recently announced topline results of a Phase 3 clinical trial to evaluate the effects of Chenodal in patients with CTX, known as the RESTORE clinical trial. While RESTORE is intended to support an NDA submission for marketing authorization of Chenodal for CTX in the U.S., the FDA may not agree with our interpretation of the results and may ask for additional data to be submitted or may deny an approval for CTX. The FDA may also not agree with the completeness of our planned NDA submission and may ask for additional non-clinical, manufacturing or supportive clinical data. We have orphan designation for Chenodal for CTX which has the potential to allow seven years of orphan exclusivity upon approval. If we do not receive approval for CTX, we will not have the benefit of this orphan exclusivity. Furthermore, even with approval, we may not receive the benefit of the orphan designation or such designation may not prevent a generic launch for the treatment of radiolucent gallstones. Any such delay or denial of approval and orphan exclusivity for the treatment of CTX could lead to an adverse impact to, our business, financial condition and results of operations.

We have encountered and may continue to encounter delays and difficulties enrolling patients in our clinical trials, and as a result, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment, a significant factor in the timing of clinical trials, is generally affected by many factors including, but not limited to, the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and 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 that may be approved for the indications we are investigating.

Further, each indication for which we are evaluating Livmarli and volixibat is a rare cholestatic liver disease with limited patient populations from which to draw participants in clinical trials. We will be required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of Livmarli and volixibat. Potential patients may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our trials. In addition, patients may ultimately decide not to enroll in a particular clinical trial for reasons outside of our control. We are also conducting clinical trials in countries that have not yet had Livmarli or volixibat trials conducted and we have not yet worked with such foreign regulatory authorities. As a result, we could face patient recruitment issues in certain countries where such foreign regulatory authorities are not familiar with Livmarli or volixibat. Additionally, other pharmaceutical companies targeting these same cholestatic liver diseases are recruiting clinical trial patients from these patient populations, and have expanded access programs available, which have delayed enrollment in our clinical trials. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays. As a result, we may need to delay the completion of such trials beyond our expected timelines or abandon one or more clinical trials altogether.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of a product candidate, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that a product candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. For example, in December 2023, we announced that our Phase 2b EMBARK clinical trial evaluating Livmarli in patients with BA did not meet its primary or key secondary endpoints. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. In the case of our product candidates, we are seeking to develop treatments for rare diseases for which there is limited clinical experience, and our planned clinical trials use novel end points and measurement methodologies, which add complexity to the conduct of and analysis of data from our clinical trials and may delay or prevent regulatory approval.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow clinical trial protocols, or if our clinical trials are otherwise disrupted, the integrity of data from our clinical trials may be compromised or not accepted by the FDA, EMA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. Additional safety data generated from our expanded access program and post-marketing studies could be different from, including less favorable than, the data generated and discussed with regulatory authorities to date. Our clinical trials may not be successful, and any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in other indications.

Any delays in the commencement or completion, or termination or suspension, of our clinical trials could result in increased costs for us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA, EMA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls, and our proposed clinical trial protocol, as part of an IND application or similar regulatory filing. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials or agreement to commence our clinical trials;
- the FDA’s, EU Member State competent authorities’, or comparable foreign regulatory authorities’ failure to accept our proposed manufacturing processes and suppliers and/or requirement to provide additional information regarding our manufacturing processes before providing marketing authorization;
- any failure or delay in reaching an agreement with 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 clinical trial sites;
- obtaining approval from one or more institutional review boards (“IRBs”) or ethics committees;
- IRBs or ethics committees refusing to approve, suspending or terminating the clinical trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the clinical trial;
- changes to clinical trial protocol;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- sites deviating from clinical trial protocol or dropping out of a clinical trial;

- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related AEs;
- occurrence of serious adverse events (“SAEs”) in clinical trials of the same class of agents conducted by other companies;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA, EU Member State competent authorities or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process, suppliers or formulation that may be necessary or desired;
- the impact of geopolitical and macroeconomic developments on our ongoing and planned clinical trials; and
- 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, EMA, competent authorities of individual EU Member States or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, suspension or termination.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, European Commission or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the U.S., the EU and EU Member State competent authorities in the EU and by comparable foreign regulatory authorities in other markets. In the U.S., the EU and many foreign countries, we are not permitted to market our product candidates until we receive regulatory approval from the FDA, European Commission or comparable foreign regulatory authorities. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the U.S. or internationally, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the non-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, European Commission or comparable foreign regulatory authorities. The FDA, EMA or comparable regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program. For example, we submitted an application for marketing authorization variation to the EMA in April 2023, based on positive data from our MARCH Phase 3 clinical trial of Livmarli in patients with PFIC. However, the EMA may not agree with our interpretation of the results and the European Commission may not grant approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or the validation of our caregiver and patient reported outcome instruments;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA, EMA or comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the U.S., the EU or the applicable foreign jurisdiction;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to satisfy the FDA, EMA or comparable foreign regulatory authorities to support the submission of an NDA or other

comparable submissions in the EU or other foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;

- approval or orphan status may be blocked or rejected by the FDA or the European Commission;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, European Commission or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of the above events could prevent us from achieving market approval of our product candidates and could substantially increase the costs of commercializing our product candidates. The demand for our product candidates could also be negatively impacted by any adverse effects of a competitor's product or treatment.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, European Commission or comparable foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical trials and receive approval of an NDA or equivalent EU or foreign marketing application for our product candidates, the FDA, European Commission or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS in the U.S. or RMP in the EU, which may be required to ensure safe use of the drug after approval. The FDA, European Commission or comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA, European Commission or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. We are expecting a decision on the marketing authorization variation application in the EU in 2024, which may not occur on time or at all or be favorable. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

If we fail to develop and commercialize additional product candidates, we may be unable to grow our business. Further, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We plan to acquire rights to develop and commercialize product candidates in addition to our current approved medicines and our current product candidates. If we decide to pursue the development and commercialization of any additional product candidates, we may be required to invest significant resources to acquire or in-license the rights to such product candidates or to conduct drug discovery activities. We do not currently have the necessary drug discovery personnel or expertise adequate to discover and develop an additional product candidate on our own. Any other product candidates will require additional, time-consuming development efforts, and significant financial resources, prior to commercial sale, including preclinical studies, extensive clinical trials and approval by the FDA, European Commission or comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. Because we have limited financial and personnel resources, we focus on specific product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. We may focus our efforts and resources on product candidates that ultimately prove to be unsuccessful.

In addition, we may not be able to acquire, discover or develop any additional product candidates, and any additional product candidates we may develop may not be approved, manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. Research programs to identify new product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. If we are unable to develop or commercialize any other product candidates, our business and prospects will suffer.

Risks Related to Our Business and Industry

We have incurred net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval and become commercially viable. While we have three medicines approved for commercial sale, we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses since our inception in May 2018. For the years ended December 31, 2023, 2022 and 2021, we reported a net loss of $163.4 million, $135.7 million and $84.0 million, respectively. As of December 31, 2023, we had an accumulated deficit of $556.2 million.

We expect to continue to incur net losses for the foreseeable future as we look to acquire products and product candidates, continue our clinical development of, and seek regulatory approvals for, our product candidates and as we continue commercializing our approved medicines in the U.S. and in certain countries in Europe. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. For example, we have generated limited product revenues from our approved medicines and our approved medicines may not be successfully commercialized. Our prior net losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses, or when, if at all, we will be able to achieve profitability.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by conditions in the U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments, including potential future disruptions in access to bank deposits or lending commitments due to bank failures and military conflicts, such as the ongoing conflicts between Ukraine and Russia and in Israel and the surrounding areas as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate. For example, inflation rates have increased recently to levels not seen in years in many countries, including in the U.S., and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to high inflation, the U.S. Federal Reserve and other central banks have raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining global economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Additionally, financial markets around the world experienced volatility due to bank failures and ongoing military conflicts such as between Ukraine and Russia and in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain. For example, in connection with the military conflict between Russia and Ukraine, the U.S., United Kingdom and EU, along with others, imposed significant sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia and related sanctions, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia-Ukraine conflict and related sanctions has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Similarly, the ongoing military conflict in Israel and the surrounding areas, as well as related responses and counter-responses by various global actors, has led to additional uncertainty in financial markets, including with respect to global shipping and the resulting effects on the cost of goods. Further, a weak or declining economy could strain our suppliers and manufacturers, possibly resulting in additional supply disruption for the production of any of our approved medicines. As a result, our business and results of operations may be adversely affected by ongoing and future conflicts and any related sanctions. We have operations, as well as current and potential new suppliers and manufacturers, throughout Europe. If economic conditions in Europe and other key markets for our business remain uncertain or deteriorate further, we could experience adverse effects on our business, financial condition or results of operations.

If the market opportunities for our product candidates are smaller than we believe they are, our future revenue may be adversely affected, and our business may suffer.

If the size of the market opportunities in each of our target indications or for any assets or product candidates that we may acquire, such as the Bile Acid Medicines, is smaller than we anticipate, we may not be able to achieve profitability and growth. We focus the clinical development and commercialization of our approved medicines on rare diseases with relatively small patient populations. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. In addition, our estimates of the patient populations for our target indications have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Lastly, the potentially addressable patient population for any of our potential indications may even be further reduced if gene therapy products become more widely accepted and approved.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates is also subject to approval.

Regulatory authorities in jurisdictions outside of the U.S. and the EU have requirements for approval for product candidates with which we must comply prior to marketing in those jurisdictions, and the regulatory approval process outside the U.S. and EU generally includes all of the risks associated with obtaining FDA and European Commission approval. Consequently, approval by the FDA does not ensure approval by the European Commission, approval by the European Commission does not assure approval by the FDA, and approval of either or both of the FDA and European Commission does not assure approval by regulatory authorities in other countries or jurisdictions. Further, marketing approvals in countries outside the U.S., including in the EU, do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of any of our approved medicines or product candidates, if approved, will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

Disruptions at the FDA, EMA and other regulatory authorities caused by funding shortages or global health concerns could negatively impact our business.

The ability of the FDA, the competent authorities of EU Member States and other regulatory authorities to review and approve proposed clinical trials or new product candidates can be affected by a variety of factors, including, but not limited to, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect these regulatory agencies' ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, European Commission, EMA and other regulatory authorities may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, including as a result of the U.S. Congress failing to timely raise the U.S. debt ceiling, or if global health concerns continue to prevent the FDA, EMA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, European Commission or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the U.S., certain European countries, and some other 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 and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, Germany introduced changes to its laws governing reimbursement of medicinal products that impact, among others, orphan designation medicinal products. Previously, orphan designation drugs were presumed to provide an additional benefit upon obtaining a marketing authorization and, therefore, subject to a "limited assessment" by the German authority competent for reimbursement (G-BA) as long as the sales of the orphan designation medicinal product remained under the threshold of € 50 million in 12 months. Above this threshold, an orphan designation medicinal product would be subject to a full assessment by the G-BA regarding its benefits compared to an appropriate comparator therapy, just like any other medicinal product. This threshold will be lowered to € 30 million in the future, and if we exceed this threshold, we will need to undergo a full assessment in accordance with the German laws governing reimbursement, which may impact the reimbursement of our approved medicines. Other countries may adopt similar or new approaches that may impact the reimbursement of our product(s), increase our operating costs and impact profitability. Additionally, if adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity for our product candidates in the EU.

There have also 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 example, in March 2010, the Patient Protection and Affordable Care Act ("Affordable Care Act") was enacted in the U.S. 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 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; creates 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 CMS 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, U.S. federal tax legislation enacted in 2017, informally titled The Tax Cuts and Jobs Act ("Tax Act"), included a provision which 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. However, it is possible that the Affordable Care Act will be subject to additional judicial or Congressional challenges in the future.

In addition, 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how any additional health care reform measures of the current administration will impact the Affordable Care Act and our business.

Further, the IRA will, among other things, (i) allow HHS to negotiate the price of certain drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law and (ii) impose rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018 and the Consolidated Appropriations Act of 2023, will remain in effect until 2032 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, 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, President Biden signed the American Rescue Plan Act of 2021 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, effective January 1, 2024.

Further, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent 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 products.

In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology 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.

At the state level, individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product 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. 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 which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our approved medicines and our other product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that the Affordable Care Act, the IRA and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our approved medicines and our product candidates, if approved.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We already have and plan to seek further regulatory approval for our product candidates internationally and, accordingly, we are subject to additional risks related to operating in foreign countries if and when we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, including differing reimbursement, pricing and insurance regimes;
- the potential for regulatory approvals in other countries to result in re-examination of previously approved regulatory submissions in other countries;
- the potential for so-called parallel importing, which is what happens when a local seller, either with government approval or faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets, including as a result of high interest rates and ongoing military conflicts, as well as any related political or economic responses and counter-responses or otherwise by various global actors;

- compliance with tax, employment, immigration and labor laws for employees living or traveling internationally;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities internationally; and
- business interruptions resulting from geo-political actions, including war and terrorism.

In addition, some countries, such as Brazil, Israel and Chile, require that clinical trial participants receive the product at no cost even after the clinical trial has ended. We would not be able to recover any profit for these patients and depending on the number of patients, duration of the treatment and numerous other factors, such regulations could harm our business, prospects, financial condition and results of operations significantly. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies with products that may directly or indirectly compete with ours, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, generic pharmaceutical companies and universities and other research institutions who are active in rare disease. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than our product candidates, which may negatively affect our commercial opportunities. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

We are aware of two other companies pursuing clinical development of therapies that reduce sBA levels via the IBAT pathway. GlaxoSmithKline plc and Ipsen have IBATis in clinical development for cholestatic liver diseases.

We are aware Ipsen has received approval for odevixibat for the treatment of pruritus in patients with PFIC, and pruritus in patients with ALGS 12 months and older, in the U.S., and for the treatment of PFIC in certain European countries. Ipsen has been granted orphan designation for PFIC in certain European countries, and if Livmarli is deemed similar, it could prevent the approval of Livmarli in PFIC or result in a refusal by the European Commission to maintain orphan designation for Livmarli for PFIC in the EEA. We are aware that Ipsen has submitted a marketing application to the EMA seeking approval for odevixibat for the treatment of cholestatic pruritus in patients with ALGS. Ipsen is also conducting a study of odevixibat in BA and plans to pursue other cholestatic liver diseases. Other off-label medications are also used in ALGS and PFIC for cholestatic pruritus such as Ursodeoxycholic acid (“UDCA”), cholestyramine and other bile salt resins, rifampin, naltrexone and other agents, such as selective serotonin reuptake inhibitors. Despite the lack of FDA approval, these older, generic agents are perceived as part of the standard of care for treating ALGS and PFIC patients suffering from cholestatic pruritus.

Further, we may compete with companies that are developing gene therapy for the treatment of PFIC. Additionally, surgical interventions, such as partial external biliary diversion and nasobiliary drainage, and extracorporeal liver support, such as Molecular Adsorbent Recirculation System, are also employed in an attempt to lower bile acid levels, manage pruritus and improve measures of liver function.

In adult settings of cholestasis, similar to pediatric settings, cholestyramine, UDCA, rifampin and naltrexone are commonly used agents. We are aware that Intercept Pharmaceuticals, Inc.'s Ocaliva is approved as a second-line treatment for PBC. We are aware of several agents in clinical development for the treatment of PBC including Intercept's Ocaliva and bezafibrate, Cymabay's seladelpar, Ipsen's elafibranor, Zydus Therapeutics Inc.'s saroglitazar magnesium, Escient Pharmaceuticals Inc.'s EP547, NGM Biopharmaceuticals, Inc.'s NGM282, Calliditas Therapeutics AB's setanaxib, COUR Pharmaceuticals' CNP-104, Ascletis Pharma's ASC42, Umecrine Cognition's golexanolone, and GlaxoSmithKline's linerixibat, another IBATi.

We are not aware of FDA or European Commission approved therapeutics for the treatment of PSC. We are aware of several agents in clinical development for the treatment of PSC, including Cymabay's seladelpar, DURECT Corporation's DUR928, HighTide Biopharmaceutical Inc.'s HTD1801, Immunic Therapeutics' IMU-838, Intercept's Ocaliva, or obeticholic acid, Ipsen's elafibranor and IPN60250, NGM Biopharmaceuticals Inc.'s NGM282, Escient Pharmaceuticals's EP547, Chemomab Therapeutics Ltd.'s CM-101, and Pliant Therapeutics' bexotegrast.

Symptomatic treatment with antipruritics, such as cholestyramine, typically provides only modest relief. Bristol Myers Squibb Company has discontinued its brand name cholestyramine, but generic versions of the drug are marketed by Upsher-Smith Laboratories, Inc., Par Pharmaceutical Companies, Inc., Sandoz Inc., the generic pharmaceuticals division of Novartis AG and others. UDCA, also known as ursodiol, is marketed by a number of generic pharmaceutical companies such as Mylan Inc., Actavis Inc., Lannett Company, Inc. and Par Pharmaceutical Companies, Inc.

There are other approved chenodeoxycholic acid products available outside of the U.S. Both Dr. Falk Pharma GmbH and Leadiant Biosciences, Inc. have FDA Orphan Drug Designations granted for the treatment of CTX (granted in 2004 and 2007, respectively); however neither company, based on publicly available information, has initiated any prospective clinical studies in CTX.

There are currently no FDA-approved treatments in the U.S. that compete with Cholbam. There are other approved cholic acid products available outside of the U.S. and Laboratoires CTRS has received approval from the EMA for a version of cholic acid.

Under the Hatch-Waxman Amendments of the Federal Food, Drug, and Cosmetic Act, a pharmaceutical manufacturer may file an ANDA seeking approval of a generic copy of an approved innovator product or an NDA under Section 505(b)(2) that relies on the FDA's prior findings of safety and effectiveness in approving the innovator product. A Section 505(b)(2) NDA may be for a new or improved version of the original innovator product. Certain of our approved medicines, including Chenodal and Cholbam, are subject to immediate competition from compounded and generic entrants, as the ANDA and NDA for these drug products have no remaining or current patent or non-patent exclusivity.

In December 2019, the CREATES Act was enacted, which provides a legislatively defined private right of action under which generic companies can bring suit against companies who refuse access to product for the bioequivalence testing needed to support approval of a generic product. It is our policy, which is in compliance with the CREATES Act, to evaluate requests for samples of our branded products, and to provide samples in response to bona fide requests from qualified third parties, including generic manufacturers, subject to specified conditions. We have provided samples to certain generic manufacturers.

Even though we have obtained orphan drug designation for Livmarli in PFIC and ALGS , and Chenodal in CTX, we may not be able to obtain or maintain the benefits associated with orphan drug status, including market exclusivity.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population of greater than 200,000 individuals in the U.S., but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S.

In the EU, the European Commission, on the basis of the opinion of the EMA Committee for Orphan Medicinal Products, grants orphan drug designation for medicines to be developed for the diagnosis, prevention or treatment of diseases that are life-threatening or chronically debilitating, for which either no satisfactory method of diagnosis, prevention, or treatment exists, or if such method exists, the medicine is of significant benefit to those affected by such condition. To benefit from such designation, either the prevalence of such condition must not be more than five in 10,000 people across the EU or, if more prevalent, it must be unlikely that the marketing of the medicine would generate sufficient returns to justify the investment needed for its development. In September 2013, the FDA granted orphan drug status to Livmarli for the treatment of patients with PFIC and ALGS in the U.S. We also received orphan drug designation for Livmarli for PFIC and ALGS in the EU. The FDA granted orphan drug designation for Chenodal for the treatment of CTX in 2010. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for the same drug (or, in the case of the European Commission, a similar drug) for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in the EU, which may be extended by six months and two years, respectively, in the case of product candidates that have complied with the respective regulatory agency's agreed upon pediatric investigation plan. The exclusivity period in the EU can be reduced to six years if at the end of the fifth year a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or European Commission determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition before the expiration of the seven-year exclusivity period including the same active ingredient, if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, the European Commission may approve another drug for the same indication as Livmarli despite its orphan exclusivity on the basis that it is not a similar medicinal product or if it is considered safer, more effective, or otherwise clinically superior. Conversely, the European Commission may deny marketing approval for a product candidate if it determines such product candidate is structurally similar to an approved product for the same indication. Specifically, Ipsen has been granted orphan designation for PFIC in the EU and if Livmarli is deemed similar, it could prevent the approval of Livmarli for PFIC, or result in a refusal by the European Commission to maintain orphan designation for Livmarli for PFIC in the EEA. In addition, if an orphan designated product receives marketing approval for an indication broader than or different from what is designated, such product may not be entitled to orphan exclusivity. Even though the FDA has granted orphan drug designation to Livmarli for the treatment of PFIC, ALGS and BA and Chenodal for the treatment of CTX, if we receive approval for Livmarli or Chenodal for modified or different indications, our current orphan designations may not provide us with exclusivity.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process in the U.S. or the EU. Also, regulatory approval for any product candidate may be withdrawn, and other product candidates may obtain approval before us and receive orphan drug exclusivity, which could block us from entering the market.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition before the expiration of the orphan drug exclusivity period.

We have formed and may continue to form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have formed and may continue to form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our approved medicines, our product candidates and any future product candidates that we may develop. We also intend to establish commercial partnerships outside of North America and in major European markets.

Any of our existing relationships or any future relationships we enter into may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for volixibat because it may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view volixibat as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Following a strategic transaction or license, we may not achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved medicines would impair our ability to grow our business.

Although a substantial amount of our efforts are focused on the clinical development, potential regulatory approval and commercialization of our approved medicines and product candidates, a key element of our long-term strategy is to in-license, acquire, develop, market and commercialize a portfolio of products to treat patients with liver disease. Because we do not have the necessary internal research and development capabilities, unless we build such capabilities internally, we will be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising biopharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved medicines. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional approved medicines or product candidates on terms that we find acceptable, or at all. Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA, the European Commission and other similar regulatory authorities. All product candidates are prone to risks of failure during biopharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, any approved medicines that we acquire may not have the market potential we believe, be manufactured or sold profitably, or achieve market acceptance.

We may fail to realize all of the anticipated benefits of the Bile Acid Portfolio Acquisition or those benefits may take longer to realize than expected.

We believe that there are significant benefits that may be realized from the Bile Acid Portfolio Acquisition. The full benefits of the Bile Acid Portfolio Acquisition, including the anticipated financial contribution of newly acquired assets, may not be realized as expected, may be diminished due to competition or may not be achieved within the anticipated time frame, or at all. For example, the Phase 3 RESTORE clinical trial may not result in an approval. Failure to achieve the anticipated benefits of the Bile Acid Portfolio Acquisition could adversely affect our results of operations or cash flows, divert needed resources away from our current approved medicines and product candidates, decrease or delay any accretive effect of the Bile Acid Portfolio Acquisition and negatively impact the price of our common stock.

In addition, we will be required to devote significant attention to complete the post-closing integration of the acquired assets and rely on Travere for certain transition services while our transition services agreement with them remains in effect. We may not be able to integrate the acquired assets successfully. We have hired additional employees as part of the transaction and may not successfully integrate or deploy them for commercialization of the acquired Bile Acid Medicines. We plan to transfer and enter new contracts for a number of vendors that support the manufacture and distribution of the acquired assets. If we fail to successfully integrate the acquired assets, our results of operations could be adversely affected. The integration process will continue to require significant time and resources, require significant attention from management and may disrupt the ordinary functioning of our business, and we may not be able to manage the process successfully, which could harm our business.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations.

We conduct many of our operations at our facility in Foster City, California. This region serves as the headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock awards that vest over time. The value to employees of stock awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. In addition, in response to competition, high inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have offer letters with our key employees, these offer letters provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics are more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2023, we had 264 full time employees. As our development and commercialization plans and strategies develop, we expect to need additional development, managerial, operational, financial, sales, marketing and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our commercialization efforts while focusing on other areas of our business;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our approved medicines and our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our approved medicines, any then-approved product and product candidates depends, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. To date, we have used the services of outside vendors to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance our business. We may not be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our approved medicines, any then-approved product and product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our approved medicines and product candidates. Our ability to obtain clinical supplies of these products could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our employees, independent contractors, principal investigators, CROs, consultants, strategic partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA, EU, individual EU Member States or comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to the FDA, EMA, the competent authorities of individual EU Member States or comparable foreign regulatory authorities; (2) manufacturing standards; (3) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (4) laws that require the true, complete and accurate reporting of our financial information or data. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. If we obtain regulatory approval for any of our product candidates and begin commercializing those products in the U.S. or other foreign jurisdictions, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our relationships with customers, physicians and third-party payors may be subject, directly or indirectly, to federal, state and equivalent foreign healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees,

independent contractors, consultants, commercial partners or vendors violate these laws, we could face substantial penalties.

These laws may impact, among other things, our clinical research program, as well as sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. 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 may be alleged to be intended to induce prescribing, purchases or recommendations, include the provision of in-kind services, genetic testing services, or products or any payments of more than fair market value, and may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act and the civil monetary penalties statute;

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs;

- the Health Insurance Portability and Accountability Act ("HIPAA"), which created new federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities and their respective business associates that perform services for them as well as their covered subcontractors that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information; and

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; 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; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws, such as the EU's and the United Kingdom's General Data Protection Regulations (respectively, the "EU GDPR" and "UK GDPR", together, the "GDPR") governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, we may be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. We have adopted a code of conduct and healthcare compliance policies, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Our business is subject to complex, stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy and data protection. Our actual or perceived failure to comply with such obligations could result in regulatory investigations or actions, litigations (including class claims) and mass arbitration demands, fines and penalties, disruptions of and changes to our business practices, monetary penalties, reputational harm, loss of revenue or profits, and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data.

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In the U.S., federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g. wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM") and Telephone Consumer Protection Act ("TCPA") imposes specific requirements on communications with customers. In particular, the TCPA imposes various consumer consent requirements and other restrictions relating to marketing to individuals using technology such as telephones, mobile devices, and text messages. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to $1,500 per violation imposed through private litigation or by state authorities.

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, at the state level, the California Consumer Privacy Act , as amended by the California Privacy Rights Act of 2020 ("CPRA"), (collectively, "CCPA"), applies to personal data of consumers, business representatives and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines for violations (up to $7,500 per intentional violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data in the context of clinical trials, these developments further complicate compliance efforts and increase legal risks and compliance costs for us and our third-party partners.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR (together "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), Canada's Personal Information Protection and Electronic Document Act ("PIPEDA") and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data, and violators of these laws may face significant penalties.

For example, the GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, mandatory data breach notifications in certain circumstances, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of personal data. In addition, the definition of "personal data" under the GDPR is broad and captures "pseudonymized" or key-coded data that is commonly processed in a clinical trial-related context.

We are subject to the GDPR because of our data processing activities that involve the personal data of individuals residing in the EEA and UK, such as in connection with our clinical trials in Europe, and early access program in multiple EU countries, and because of any potential processing of personal data carried out in the context of the activities of our relevant European subsidiaries. In addition, we maintain an office in Switzerland, which subjects us to privacy and data protection laws and regulations similar to the GDPR under the Swiss Federal Act on Data Protection, or the FADP. The FADP applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The FADP has been revised and adopted by the Swiss Parliament. Companies have been required to comply with the revised version of the FADP and its revised ordinances since September 1, 2023, which may result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance.

Furthermore, the EU GDPR provides that EEA Member States may introduce specific requirements related to the processing of "special categories of personal data", including the personal data related to health and genetic information, which we may process in connection with clinical trials or otherwise; as well as personal data related to criminal offences or convictions where allowed under local law and confirmed by potential employee in employment situations. Under the GDPR, companies that do not comply may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR or 17.5 million pounds sterling under the UK GDPR, or in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Additionally, in Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations.

In the ordinary course of business, we may transfer personal data from Europe (including from our European subsidiaries) and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the U.S. and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and/or cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions, to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including limitations of our ability to conduct clinical trial activities in Europe and/or elsewhere, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer personal data and work with partners, vendors and other third parties, and/or injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside Europe for allegedly violating the EU GDPR's cross-border data transfer limitations. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring personal data to the U.S. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants and activist groups.

In addition, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Additionally, some of our customer contracts require us to host personal data locally. We also publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we endeavor to comply with our data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture.

Our, or the third parties' upon which we rely, actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in adverse consequences, including regulatory fines and bans on processing personal information, government enforcement actions (e.g. investigations, fines, penalties, audits, inspections, and similar), litigation (including class action claims), mass arbitration demands, and other liabilities, claims for damages by affected individuals, orders to destroy or not use personal information, imprisonment of company officials, additional reporting requirements and/or oversight, interruptions or stoppages in our business operations (including, as relevant, clinical trials), and damage to our reputation. Any of these consequences could have a material adverse effect on our business, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our approved medicines; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any collaboration arrangements that we have or may enter into in the future may not be successful or may result in product diversion, which could adversely affect our ability to develop and commercialize our approved medicines and any then-approved product.

Any existing or future collaborations that we enter into may not be successful. The success of our collaboration arrangements depends and will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may conduct their own clinical trials which may not be compliant, may not be successful or may generate contradictory results;
- collaborators may not pursue development and commercialization of our approved medicines and any then-approved product or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- a collaborator or series of collaborators may improperly or unknowingly sell product directly (or indirectly to a potential customer) into the "gray market" whereby our branded products are diverted from authorized sales channels into the hands of dealers, brokers or the open market, and may result in unauthorized sale of our product in a specific country or region;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;

- collaborators may own or co-own intellectual property covering our approved medicines and any then-approved product that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to Our Reliance on Third Parties

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. For example, we entered into an assignment and license agreement with Shire pursuant to which we were assigned exclusive global rights to license intellectual property and know-how related to Livmarli and volixibat, rights to license know-how related to Livmarli from Pfizer, certain patents and know-how related to volixibat from Sanofi and certain patents and know-how related to Livmarli and volixibat from Satiogen, which we subsequently acquired in May 2022. We also acquired licensed rights to commercialize Cholbam and Chenodal from certain parties via the Bile Acid Portfolio Acquisition. We are required to use commercially reasonable efforts or diligent efforts to commercialize products based on the licensed rights and to pay certain royalties based off our net sales. We may not meet these requirements, which could result in a loss or termination of any rights under such agreements. Any termination of these licenses will result in the loss of significant rights and will restrict our ability to commercialize our product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below under "Risks Related to Our Intellectual Property." If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We currently rely on, and intend to continue relying on, third-party CROs in connection with our clinical trials. We control or will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, the competent authorities of the individual EU Member States, or comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, the competent authorities of the individual EU Member States, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, such regulatory authorities may not determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and non-clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur when CROs are switched or added, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our CROs, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, prospects, financial condition and results of operations.

We rely completely on third parties to manufacture and distribute our clinical and commercial drug supplies, including certain sole-source suppliers and manufacturers. These third parties may fail to obtain and maintain regulatory approval for their facilities, fail to provide us with sufficient quantities of drug substance, drug product, or labeled finished product in a timely fashion, or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture or distribute our clinical and commercial drug supplies. Instead, we rely on contracted third parties.

We do not currently have any long-term agreements or commitment with a manufacturer to produce raw materials, active pharmaceutical ingredients ("APIs") and the finished products of our product candidates or the associated packaging. We will need to continue to identify and qualify a third-party manufacturer prior to commercialization of our product candidates, and we intend to enter into agreements for commercial production with third-party suppliers. For our approved medicines, we are reliant on third parties to successfully manufacture drug substance components and the finished drug product in accordance with regulatory requirements and in sufficient quantities for commercialization. We are also reliant on third parties for the manufacture of packaging, labeling and oral dosing dispensers for our approved medicines. As our approved medicines are intended to treat rare diseases, we will only require a low-volume of raw materials and APIs, and in some cases with single-source suppliers and manufacturers. Our reliance on third-party suppliers and manufacturers, including single-source suppliers, could harm our ability to develop our product candidates or to commercialize our currently approved medicines and any product candidates that are approved in the future.

Any of our existing or future suppliers or manufacturers may, among other things:

- fail to supply us with our approved medicines and product candidates on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities, equipment or deliveries, labor disputes or otherwise, including "acts of God";
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our clinical and commercial needs;
- be unable to meet our production demands, including due to issues related to their reliance on sole-source suppliers and manufacturers;
- become unavailable through business interruption or financial insolvency; or
- be unable or unwilling to supply or manufacture for us, or to renew current supply or manufacturing agreements when such agreements expire on a timely basis, on acceptable terms or at all.

In the event of any of the foregoing or in the event such third parties fail to meet our needs, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA, the competent authorities of the individual EU Member States or comparable foreign regulatory authorities. Any need to find and qualify new suppliers or manufacturers could adversely impact our ability to commercialize our approved medicines or our product candidates, if approved. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMP for production of both drug substances and finished products. Facilities used by our contract suppliers and manufacturers to produce the drug substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities including the competent authorities of the individual EU Member States. A number of our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA, the competent authorities of the individual EU Member States, and other equivalent foreign authorities, through their facilities inspection program and review of submitted technical information. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's, the competent authorities of the individual EU Member States, and other equivalent foreign authorities' strict regulatory requirements, they will not be able to secure or maintain FDA approval for the manufacturing facilities and our ability to secure supplies of our approved medicines or our product candidates will be negatively affected.

In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the safety of our approved medicines is compromised due to a failure to adhere to applicable laws or for other reasons, the manufacturing facilities may need to be closed for an extended period of time and we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our approved medicines.

We and our third-party suppliers and manufacturers are vulnerable to geopolitical and macroeconomic developments, such as potential future bank failures, the ongoing conflicts between Ukraine and Russia and in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, future pandemics, high inflation rates and the responses by central banking authorities to control such inflation, which could negatively impact the availability or cost of materials and the third parties on which we rely. Similarly, the manufacturing facilities of a majority of our suppliers are located outside of the U.S. This may give rise to difficulties in importing our product into the U.S. or other countries as a result of, among other things, regulatory agency approval requirements, taxes, tariffs, local import requirements such as import duties or inspections, incomplete or inaccurate import documentation, defective packaging or negative impacts on global shipping due to geopolitical and macroeconomic developments. If such events result in any interruption in the supply of a drug substance or other material or in the manufacture of our approved medicines, such interruption could have a material adverse effect on our business, financial condition, operating results and prospects.

We rely on a single specialty pharmacy and a single distributor for all of our sales of our approved medicines in the U.S. and use a single distributor in certain countries in Europe. If either the specialty pharmacy or the distributor becomes subject to bankruptcy or is acquired by a company that wants to terminate the relationship with us, and we are required to transition to a new specialty pharmacy or distributor, such transition may result in an inability for us to collect outstanding receivables, a decline in our revenue, results of operations and cash flows. Further, we are in the process of switching or adding contract manufacturing organizations for Livmarli, which is cost-intensive and time-consuming. We are also in the process of transferring contractual and technical responsibilities for manufacturing activities related to Cholbam and Chenodal. The success of these transfers is necessary for potential future commercial demand.

Risks Related to Our Financial Position and Capital Requirements

We may need substantial additional financing to continue our commercialization efforts for our approved medicines, develop our product candidates and implement our operating plans. If we fail to obtain additional financing when needed, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development and seek regulatory approval of our product candidates.

We will require significant additional amounts in order to continue our marketing and sales efforts for our approved medicines, prepare for commercialization for our product candidates, and, if approved, to launch and commercialize our product candidates.

Based on our current and anticipated level of operations, we believe our existing cash and cash equivalents will be sufficient to fund current operations through at least the next 12 months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

Additional funding may not be available on acceptable terms, or at all. As a result of adverse geopolitical and macroeconomic developments, such as potential future disruptions in access to bank deposits or lending commitments due to bank failures, the ongoing conflicts between Ukraine and Russia and in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our approved medicines and product candidates or other research and development initiatives. We also could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. For example, in April 2023, we issued and sold the Notes due 2029 for a $316.3 million aggregate principal amount. Further, in August 2023, in connection with, and immediately prior to, the closing of the Bile Acid Portfolio Acquisition, we completed a private placement of our common stock, pursuant to which we issued 8,000,000 shares of our common stock. Additionally, in November 2023, we entered into a Sales Agreement (the “2023 Sales Agreement”) with Leerink Partners LLC and Cantor Fitzgerald & Co., pursuant to which we may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $200.0 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders as such. For example, if we elect to settle our conversion obligation under the Notes in shares of our common stock or a combination of cash and shares of our common stock, the issuance of such common stock may dilute the ownership interests of our stockholders and sales in the public market could adversely affect prevailing market prices. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our approved medicines and product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us. If our cash flows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital.

We may be unable to raise the funds necessary to repurchase the Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and any future indebtedness may limit our ability to repurchase the Notes or pay cash upon their conversion.

Holders of the Notes may, subject to a limited exception described in certain provisions in the Notes and the related Indenture (the "Indenture") between the Company and U.S. Bank Trust Company, National Association, as trustee, require us to repurchase the Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes or pay any cash amounts due upon conversion. In addition, applicable law, regulatory authorities and agreements governing any future indebtedness may restrict our ability to repurchase the Notes or pay any cash amounts due upon conversion. Our failure to repurchase the Notes or to pay any cash amounts due upon conversion when required will constitute a default under the Indenture. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing any future indebtedness, which may result in that any future indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under any future indebtedness and the Notes.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2023, we had federal and California and other state net operating loss ("NOL") carryforwards of approximately $166.9 million, $30.0 million and $59.7 million, respectively. The federal NOL carryforwards do not expire, and the California and other state NOL carryforwards will begin to expire in 2038 and 2032, respectively, unless previously utilized. Our ability to utilize our NOL carryforwards and certain other tax attributes may be limited. As of December 31, 2023, we also had federal and state research and development credit carryforwards totaling $36.5 million and $4.8 million, respectively. The federal research and development credit carryforwards will begin to expire in 2039, unless previously utilized. The state research and development credits do not expire.

Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), federal NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. Our NOL carryforwards and other applicable tax attributes are subject to review and possible adjustment by the U.S. Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points (by value), as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. It is possible that we have experienced one or more such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. We may therefore be limited in the portion of NOL carryforwards and other applicable tax attributes that we can use in the future to offset future taxable income. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under our indebtedness.

As of December 31, 2023, we had $316.3 million aggregate principal amount of indebtedness under the Notes.

We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Notes, and our cash needs may increase in the future.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results, and conversion of our outstanding Notes may result in the dilution of existing stockholders, create downward pressure on the price of our common stock, and restrict our ability to take advantage of future opportunities.

The conditional conversion feature of the Notes entitles holders of the Notes to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity.

The Notes may be converted into cash and shares of our common stock (subject to our right or obligation to pay cash in lieu of all or a portion of such shares). If shares of our common stock are issued to the holders of the Notes upon conversion, there will be dilution to our stockholders' equity and the market price of our shares may decrease due to the additional selling pressure in the market. Any downward pressure on the price of our common stock caused by the sale or potential sale of shares issuable upon conversion of the Notes could also encourage short sales by third parties, creating additional selling pressure on our stock. The existence of the Notes and the obligations that we incurred by issuing them may restrict our ability to take advantage of certain future opportunities, such as engaging in future debt or equity financing activities.

The accounting method for the Notes could adversely affect our reported financial condition and results.

In August 2020, the Financial Accounting Standards Board published an Accounting Standards Update, which we refer to as ASU 2020-06, which simplifies certain of the accounting standards that apply to convertible notes. In accordance with ASU 2020-06, the Notes are reflected as a liability on our balance sheets, with the initial carrying amount equal to the principal amount of the Notes, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the Notes. As a result of this amortization, the interest expense that we expect to recognize for the Notes for accounting purposes will be greater than the cash interest payments we will pay on the Notes, which will result in lower reported income.

In addition, the shares underlying the Notes are reflected in our diluted earnings per share using the "if converted" method, in accordance with ASU 2020-06. Under that method, diluted earnings per share would generally be calculated assuming that all the Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share.

In the future, we may, in our sole discretion, irrevocably elect to settle the conversion value of the Notes in cash up to the principal amount being converted. Following such an irrevocable election, if the conversion value of the Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share by assuming that all of the Notes were converted at the beginning of the reporting period and that we issued shares of our common stock to settle the excess, unless the result would be anti-dilutive.

Furthermore, if any of the conditions to the convertibility of the Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their Notes and could materially reduce our reported working capital.

Risks Related to Our Intellectual Property

We do not currently have patent protection or regulatory exclusivity for certain of our approved medicines or rely on regulatory exclusivity. If we are unable to obtain and maintain sufficient intellectual property protection for our approved medicines and our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our approved medicines and our other product candidates, if approved, may be adversely affected.

Our commercial success will depend in part on obtaining and maintaining a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We do not have, and do not expect to obtain, patent protection for Chenodal or Cholbam. Any unauthorized disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in many jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other jurisdictions may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our approved medicines or product candidates, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, import, and sell our approved medicines or our product candidates;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;

- any successful opposition or other post-grant proceeding to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;
- because patent applications in the U.S. and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our approved medicines or our product candidates, proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- jurisdictions other than the U.S. may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our approved medicines, our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our approved medicines and our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our approved medicines and any then-approved medicine;
- we cannot ensure that we will be able to successfully commercialize our approved medicines and any then-approved product on a substantial scale, if approved, before the relevant patents that we own or license expire; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or other patent office proceedings before the USPTO or non-U.S. patent offices.

We cannot be certain that the claims in our issued patents and pending patent applications covering our approved medicines or our product candidates will be considered patentable by the USPTO, courts in the U.S., or by patent offices and courts in foreign jurisdictions. Furthermore, the laws of some foreign jurisdictions do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our approved medicines or our product candidates in the U.S. or in foreign jurisdictions. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition or other post-grant proceeding to our patents could deprive us of exclusive rights necessary for the successful commercialization of our approved medicines or our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for approved medicines or our product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our approved medicines or our product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our approved medicines or our product candidates.

Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our approved medicines or our product candidates under patent protection would be reduced. In addition, patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. A patent term extension of up to five years based on regulatory delay may be available in the U.S. under the Hatch-Waxman Act. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Further, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, an approved method for using it or a method for manufacturing it may be extended. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

For U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the "first to file" provisions, were enacted on March 16, 2013. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our approved medicines and our product candidates and drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, such as third parties involved in the manufacture of our approved medicines and our product candidates and third parties involved in our clinical trials to enter into confidentiality agreements. We cannot be certain that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

We currently rely on method-of-use and formulation patents to protect Livmarli and composition-of-matter and method-of-use patents to protect volixibat.

We currently have rights to patents and patent applications in the U.S., Europe and other jurisdictions covering methods of treating certain cholestatic liver diseases using certain IBATis, including maralixibat (the active pharmaceutical ingredient of Livmarli) and volixibat. Patent applications may never issue as patents. We do not have patents or patent applications covering maralixibat as a composition-of-matter. Therefore, the primary patent-based intellectual property protection for our Livmarli program are granted method-of-use patents and any patents that may grant on currently pending method-of-use and formulation patent applications.

Composition-of-matter patents on active pharmaceutical ingredients are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Method-of-use patents protect the use of a product for the specified method. Method-of-use patents do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indication(s), physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Obtaining and maintaining our 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 process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes 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 abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect Livmarli and our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U.S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. may, at any time, enact changes to U.S. patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weakened the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. Other jurisdictions may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. Further, the U.S. and other governments may, at any time, enact changes to laws and regulations that create new avenues for challenging the invalidity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting and defending patents on Livmarli and our product candidates in all jurisdictions throughout the world would be prohibitively expensive. In addition, the laws of some foreign jurisdictions do not protect intellectual property rights in the same manner and to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions outside the U.S. 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 of such patent protection is not as strong as that in the U.S. These products may compete with Livmarli and any then-approved product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The requirements for patentability may differ in certain jurisdictions. For example, unlike other jurisdictions, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the U.S., there is no link between regulatory approval for a drug and its patent status. In addition to India, certain jurisdictions in Europe and developing jurisdictions, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those jurisdictions, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, due to the Russia-Ukraine conflict, the U.S. and other foreign governments have implemented various economic sanctions and trade and activity restrictions involving Russia and Belarus. It is possible that additional sanctions and restrictions will be imposed by the United States or other jurisdictions as the Russia-Ukraine conflict continues, and such actions may include limiting or preventing filing, prosecution, and/or maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Finally, Europe’s Unified Patent Court may in particular present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. On June 1, 2023, the EU unitary patent system was launched, providing a single pan-European Unitary Patent and a new European Unified Patent Court (“UPC”), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents that have not been opted out of the UPC, and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU unitary patent system, we will have the right to opt our patents out of the UPC over the first seven years of the court’s existence, but doing so may preclude us from realizing the benefits of the new unified court.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted intellectual property rights that are important to our business. For example, certain trade secrets related to maralixibat are licensed from Pfizer, and patents, patent applications and trade secrets related to volixibat are licensed from Sanofi. Our existing license agreements as related to maralixibat and volixibat impose various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under a license agreement, or we are subject to a bankruptcy, the license agreement may be terminated, in which event we would not be able to develop, commercialize or market our approved medicines or other product candidates, as the case may be.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our approved medicines and our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing Livmarli or our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have intellectual property rights, through licenses from third parties related to our approved medicines and our product candidates. For example, we have license agreements with Shire and Satiogen for both maralixibat and volixibat. We have our license agreement with Shire, Satiogen and Pfizer for our intellectual property rights covering maralixibat. Further, we have our license agreement with Sanofi for our intellectual property rights covering volixibat. Because our programs may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, Livmarli or our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for Livmarli or our product candidates. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our approved medicines or our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to commercialize our approved medicines and any then-approved product, and our business, financial condition and prospects for growth could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including inter partes review, post-grant proceedings, interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are marketing our approved medicines and developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our approved medicines and our product candidates may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Any of our approved medicines or our current or future product candidates may infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by our approved medicines or one of our current or future product candidates. Nevertheless, we are not aware of any issued patents that will prevent us from marketing our approved medicines or our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our approved medicines or our product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our approved medicines, our product candidates or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our approved medicines or one or more of our product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our approved medicines or our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney’s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our approved medicines and any then-approved product or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do either. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management’s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our approved medicines or our product candidates.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our approved medicines, our product candidates or the use thereof;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims;
- patent applications are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our approved medicines and any then-approved product. Further, we may incorrectly determine that our technologies, our approved medicines and any then-approved product, or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our approved medicines or our product candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our approved medicines, our product candidates and future approved medicines or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are marketing our approved medicines and developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our approved medicines and our product candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other jurisdictions have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our approved medicines and our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our approved medicines and our product candidates, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in jurisdictions where the laws may not protect those rights as fully as in the U.S. Further, because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or made a misleading statement during prosecution, i.e. committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we or our licensors hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product or product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights 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, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and inventions agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our approved medicines and any then-approved product that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets may over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets 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. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our approved medicines and any then-approved product and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We have and may continue to license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we have proposed to use with our product or product candidates in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark.

The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark or regulatory laws, not infringe the existing rights of third parties and be acceptable to the relevant administrative body. Furthermore, in many jurisdictions, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may also determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights denying our claim. In this case, we could ultimately be forced to cease use of such trademarks. Similar requirements exist in most jurisdictions worldwide.

Risks Related to Ownership of Our Common Stock

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. For example, the closing price of our common stock since January 1, 2023 to March 14, 2024 has ranged from a low of $19.19 to a high of $34.93. In addition to the factors discussed in this “Risk Factors” section, these factors include, among others:

- the degree of physician and patient adoption of our approved medicines and use of our approved medicines necessary for commercial success;
- our failure to grow and maintain our own sales force to market our approved medicines;
- our ability to market and sell our approved medicines, where approved;
- any delay in our regulatory filings for Livmarli, Chenodal or volixibat and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- our ability to scale our distribution capabilities;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- our failure to commercialize our product candidates;
- the commencement, enrollment or results of our ongoing clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- changes in laws or regulations applicable to our approved medicines and our product candidates, including but not limited to clinical trial requirements for approvals;
- changes in the structure of health care payment systems;
- the failure to obtain coverage and adequate reimbursement of our approved medicines and our product candidates, if approved;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our inability to maintain or establish collaborations if needed;

- our ability to in-license, acquire, develop and market additional product candidates or approved medicines;
- management transitions and additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our approved medicines or our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth, if any, of the markets for our approved medicines with approved indications;
- our ability to successfully enter new markets or develop additional product candidates;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- geopolitical and macroeconomic developments, including the ongoing military conflicts, economic slowdowns, recessions, inflation, bank failures, high interest rates and tightening of credit markets; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and Nasdaq-listed and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares representing a significant percentage of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company, including costs resulting from our no longer qualifying as an emerging growth company and a smaller reporting company and becoming a large accelerated filer. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including through our automatic shelf registration statement on Form S-3 filed with the SEC (the “2022 Shelf Registration”). For example, in November 2023, we entered into the 2023 Sales Agreement, pursuant to which we may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $200.0 million through the sales agents. The remaining capacity under the 2023 Sales Agreement was $200.0 million as of December 31, 2023. Further, in connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, we completed a private placement of our common stock, pursuant to which we issued 8,000,000 shares of our common stock, and we filed a registration statement registering 7,937,448 of these shares for resale. If these additional shares of common stock are resold, or if it is perceived that they will be resold, in the public market, the trading price of our common stock could decline. Subject to the limitations on our ability to sell common stock described above, if we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, including noteholders who have received shares of our common stock upon conversion of their notes, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2019 Equity Incentive Plan (“2019 Plan”), our management is authorized to grant equity incentive awards to our employees, directors and consultants. We also maintain a 2019 Employee Stock Purchase Plan (“ESPP”) pursuant to which our management is authorized to grant options to purchase shares of our common stock to our employees. In addition, pursuant to our 2020 Inducement Plan, our board of directors, or a committee thereof, is authorized to grant inducement awards to new hires as a material inducement to their employment with us.

Additionally, the number of shares of our common stock reserved for issuance under our 2019 Plan is subject to an automatic increase on January 1 of each year through and including January 1, 2029, by 5.0% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The number of shares of our common stock reserved for issuance under our ESPP is subject to an automatic increase on January 1 of each year through and including January 1, 2029, by the lesser of (i) 1.0% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, and (ii) 1,500,000 shares of common stock. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. Shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the "Securities Act"). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Our business could be negatively affected as a result of actions by activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL"), which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

In addition, certain provisions in the Notes and the related Indenture could make a third party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change under our Indenture, then noteholders will have the right to require us to repurchase their Notes for cash. In addition, if a takeover constitutes a make-whole fundamental change under our Indenture, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. will be the exclusive forums 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 amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions 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 and may discourage these types of lawsuits. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

If our information technology systems, or those used by our CMOs, CROs or other contractors, consultants or third parties upon which we rely, or your data are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigation, actions, litigation, fines and penalties, disruptions of our business operations, reputation harm, loss or revenue or profits, and other adverse consequences.

In the course of our business, we and the third parties upon which we rely, process proprietary, confidential and sensitive information, including personal data (such as health-related data), intellectual property and trade secrets (collectively, sensitive information).

The sensitive information processed and stored in our technology systems, and those of our research collaborators, CROs, contractors, consultants and other third parties on which we depend to operate our business, may be vulnerable to cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities. These threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of threats, including but not limited to errors or malfeasance by our personnel or the personnel of the third parties, malware (including as a result of advanced persistent threat intrusions), malicious code (such as viruses and worms), software vulnerabilities, hacking, denial of service attacks, credential stuffing, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), ransomware, supply-chain attacks, server malfunctions, software or hardware failure, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence (AI) and other similar threats. Threat actors may continue to develop and use more sophisticated tools and techniques (including AI) that are specifically designed to circumvent security controls, evade detection, and obfuscate forensic evidence, making it more difficult for us to identify, investigate and recover from incidents. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work remains common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee communications, and other functions. Likewise, we rely on third-party research institution collaborators, contract manufacturing organizations (CMOs), CROs, other contractors and consultants for many aspects of our business, including research and development activities and manufacturing of our approved medicines and our product candidates, and similar events relating to their computer systems or data could also have a material adverse effect on our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. For example, we have been made aware of a cyberattack against one of the largest prescription processors in the country as of February 23, 2024 that may impact claims processing for certain of our approved medicines. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented information security measures designed to protect against security incidents, we cannot assure you that our security measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our approved medicines and services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If such an event were to occur, or we (or a third party upon whom we rely) are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss, and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. More specifically, for example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Security incidents and any unauthorized access or disclosure of our sensitive information could also compromise our intellectual property and patent portfolio, expose sensitive business information, expose the personal data of our employees, require us to incur significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and cybersecurity practices, that such coverage will continue to be available to us on commercially reasonable terms, or at all, or that such coverage will pay future claims. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the U.S., to sell our approved medicines and any then-approved product internationally once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We qualify for the reduced reporting requirements applicable to smaller reporting companies, which may make our common stock less attractive to investors.

We will no longer qualify as a "smaller reporting company" as defined in the Exchange Act beginning with our Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2024. We may take advantage of certain of the scaled disclosures available to smaller reporting companies in this Annual Report and in the information incorporated by reference into this Annual Report, including in our definitive proxy statement for our 2024 Annual Meeting of Stockholders. Investors may find our common stock less attractive because we may rely on these exemptions. 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 our stock price may be more volatile.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which could adversely impact our investors' confidence in our financial reports and our stock price could be adversely affected.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Each fiscal year, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial professional fees and internal costs related to our accounting and finance functions and that we expend significant management efforts.

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2023, management identified material weaknesses in the design of controls and level of evidence retained over the existence and valuation of inventory, including the controls over existence of inventory located at third parties and the net realizable value assessment of on-hand inventory and future purchases under firm commitments, and over the precision of management review controls and the sufficiency of control evidence related to prospective financial information used to determine the fair value of acquired developed technology. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Although we are taking steps to improve our internal control over financial reporting and remediate these material weaknesses, the measures we have taken to date may not be sufficient to avoid potential future material weaknesses. Additionally, a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we identify new material weaknesses in our internal control over financial reporting, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to maintain proper and effective internal controls, or if our independent registered public accounting firm is unable to express an opinion that our internal control over financial reporting is effective in future periods, we may not be able to produce timely and accurate financial statements and investors may lose confidence in the accuracy and completeness of our financial reports. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or comparable foreign regulatory authorities.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period. As of June 30, 2023, the market value of our common stock held by non-affiliates exceeded $700.0 million. Consequently, we are a large accelerated filer and no longer an emerging growth company. As a result, we will be subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company and expect to incur additional legal and financial compliance costs as a result. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss and may require us to reduce costs in other areas of our business or increase the prices of our approved medicines and any then-approved product or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials and approved medications ("Information Systems and Data").

Our information security team, supported by our legal and compliance departments, help identify, assess and manage our cybersecurity threats and risks. Our information security team identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, depending on the context, including, for example manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, conducting scans of certain environments, evaluating our and our industry's risk profile, evaluating threats reported to us, coordinating with law enforcement about certain threats, conducting internal audits and threat assessments, and conducting vulnerability assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, incident detection and response procedures; disaster recovery/business continuity plans; risk assessments; implementation of security standards; encryption of certain data; network security, access, and physical controls for certain systems; management, tracking and disposal of certain assets; systems monitoring; employee training; penetration tests by third-party service providers; tabletop exercises; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the information security team works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business and our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional service firms such as legal counsel, threat intelligence providers, cybersecurity consultants and software providers, and other third-party service providers including for identity management solutions.

We use third-party service providers to perform a variety of functions throughout our business application providers, hosting companies, contract research organizations (CROs), contract manufacturing organizations (CMOs), supply chain resources, and other business-related SaaS platforms. We have a vendor management program to manage cybersecurity risks associated with our use of certain of these providers. The program includes conducting risk assessments of certain vendors, reviewing certain vendors' security assessments, and reviewing reports of certain of our vendors' security. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*Our business is subject to complex, stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy and data protection. Our actual or perceived failure to comply with such obligations could result in regulatory investigations or actions, litigations (including class claims) and mass arbitration demands, fines and penalties, disruptions of and changes to our business practices, monetary penalties, reputational harm, loss of revenue or profits, and other adverse business consequences.*"; and "*If our information technology systems, or those used by our CMOs, CROs or other contractors, consultants or third parties upon which we rely, or your data are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigation, actions, litigation, fines and penalties, disruptions of our business operations, reputation harm, loss or revenue or profits, and other adverse consequences.*"

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing our cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Senior Director of Information Technology/Information Security, internal legal counsel, Chief Compliance Officer ("CCO"), and Chief Financial Officer ("CFO"). Our Senior Director of Information Technology/Information Security has over ten years of experience in information technology and security, and previously held positions such as Associate Director of Informational Technology and Operations, Senior Manager of Informational Technology, and similar roles at other companies.

Our Senior Director of Information Technology/Information Security is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, helping prepare for cybersecurity incidents, approving cybersecurity processes, reviewing security assessments and other security-related reports, and communicating key priorities to relevant personnel. Our CFO is responsible for approving budgets as related to cybersecurity.

Our incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the Senior Director of Information Technology/Information Security, Data Protection Officer, and the Vice President, Legal. These individuals work with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee of the board of directors receives annual reports from our Senior Director of Information Technology/Information Security concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee of the board of directors also receives and has access to various presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

We lease 11,154 square feet of space for our headquarters in Foster City, California under an agreement (the "First Agreement") that expires in March 2025; however, we have entered into a separate agreement (the "Second Agreement") in January 2024 in which we will lease 36,318 square feet of space for our new headquarters in Foster City, California. The Second Agreement expires in approximately August 2029, subject to the occurrence of the Commencement Date, which term is defined in the Second Agreement. In connection with the Second Agreement, we have entered into an amendment to the First Agreement that will accelerate the termination date of the First Agreement to be shortly after the Commencement Date. We anticipate the Commencement Date to occur in approximately May 2024, and the First Agreement to terminate shortly after.

We also lease approximately 3,200 square feet of space for an office in Basel, Switzerland under an agreement that expires in June 2028. Additionally, we lease approximately 3,500 square feet of office space in Zug, Switzerland that expires in January 2025. We believe that our facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if needed.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "MIRM" since July 18, 2019. Prior to that date, there was no public market for our common stock.

Holders of Common Stock

As of March 8, 2024 there were 47,003,329 shares of our common stock outstanding held by approximately 21 holders of record. The actual number of stockholders is greater than this number because certain stockholders who are beneficial owners hold our common stock in "street" name with brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Stock Performance Graph

Not applicable.

Recent Sales of Unregistered Securities

Not applicable.

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.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included in Item 8 “Financial Statements and Supplementary Data” and included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements based upon our current beliefs, estimates, plans and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those contained in these forward-looking statements as a result of various factors, including those set forth under “Risk Factors” or in other parts of this Annual Report.

Overview

We are a biopharmaceutical company focused on the identification, acquisition, development and commercialization of novel therapies for debilitating rare and orphan diseases. We have three approved medicines: Livmarli, Cholbam, and Chenodal.

Livmarli is a novel, orally administered, minimally-absorbed IBATi that is approved for the treatment of cholestatic pruritus in patients with ALGS in the United States and various other countries around the world and for cholestatic pruritus in patients with PFIC in the United States. We market and commercialize Livmarli in the United States and certain countries in Europe through our specialized and focused commercial team. We have also entered into license and distribution agreements with several rare disease companies for the commercialization of Livmarli in additional countries. We are also developing Livmarli for PFIC outside of the United States. We submitted a marketing authorization variation to the EMA in April 2023, for which we expect an approval decision in the first half of 2024, based on positive data from our MARCH Phase 3 clinical trial of Livmarli in patients with PFIC.

On August 31, 2023, we completed the acquisition of assets of Travere that are primarily related to the development, manufacture (including synthesis, formulation, finishing or packaging) and commercialization of the Bile Acid Medicines pursuant to an asset purchase agreement dated July 16, 2023. The FDA approved Cholbam in March 2015 as the first FDA-approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects and for adjunctive treatment of patients with peroxisomal disorders, including PBD-ZSD and SLOS. Chenodal is approved for the treatment of radiolucent stones in the gallbladder and has received medical necessity recognition by the FDA for the treatment of CTX. We commercialize Chenodal and Cholbam in the United States through our specialized and focused commercial team. We have also assumed several license and distribution agreements with several rare disease companies for the commercialization of Chenodal and Cholbam in additional countries. In October 2023, we reported positive topline data from our RESTORE clinical trial evaluating Chenodal in patients with CTX. We plan to submit a new drug application for Chenodal for the treatment of CTX to the FDA in the first half of 2024.

We are also advancing our product candidate, volixibat, a novel, oral, minimally-absorbed agent designed to inhibit IBAT, for the treatment of adult patients with cholestatic liver diseases. We are developing volixibat in the setting of PSC and PBC. Volixibat has been studied in over 400 adults for up to 48 weeks. Clinical trials of volixibat have shown significant activity on IBAT and bile acid markers such as 7αC4, fecal bile acids and cholesterol, demonstrating potent biological activity. We expect to conduct an interim analysis of our VISTAS Phase 2b clinical trial in PSC and report interim data from our VANTAGE Phase 2b clinical trial in PBC, both in the first half of 2024.

We were incorporated in May 2018 and commenced operations in November 2018. To date, we have focused primarily on acquiring and in-licensing our product candidates, organizing and staffing our company, business planning, raising capital, advancing our product candidates through clinical development, preparing for commercialization of our product candidates, commercializing Livmarli, and conducting business development activities relating to, among other things, portfolio expansion through collaborations and acquisitions.

We have not generated operating income to date. We expect to incur significant operating losses for the foreseeable future. Since inception, we have funded our operations primarily through debt, equity, revenue interest financings and cash from our product sales, net and collaboration revenue.

Financial Overview

Our net loss was $163.4 million and $135.7 million for the years ended December 31, 2023 and 2022, respectively. Our net loss for the year ended December 30, 2023 includes a $49.1 million loss related to the extinguishment of the liabilities related to the RIPA. As of 2023, we had an accumulated deficit of $556.2 million compared to $392.8 million as of December 31, 2022. As of December 31, 2023, we had cash and cash equivalents of $286.3 million, compared to cash, cash equivalents, restricted cash and investments of $251.7 million as of December 31, 2022.

We anticipate we will continue to generate losses for the foreseeable future as we continue commercial activities for our approved medicines, conduct our ongoing and planned clinical trials, seek regulatory approvals for our product candidates and make potential milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates. We expect total product sales of our approved medicines will continue to increase on an annual basis, though we expect quarterly fluctuations. We have entered into collaboration arrangements with other companies whereby we are entitled to receive upfront and license fees, research and development funding, development and sales-based milestones, and tiered royalties based on sales of commercialized products. In select countries, we have entered into distribution agreements for the sale of Livmarli and such distributors may have fluctuating purchase levels of Livmarli. As a result, our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

We expect to satisfy future cash needs through existing capital balances, revenue from our approved medicines and through a combination of equity offerings, including the private placement described above, debt financings or other capital sources, collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate the development of one or more of our product candidates or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Geopolitical and Macroeconomic Developments

Due to the ongoing military conflicts between Ukraine and Russia and in Israel and the surrounding areas, the U.S. and global financial markets experienced volatility, which has led to disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. In connection with the military conflict between Russia and Ukraine, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia and related sanctions, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations may be adversely affected by the ongoing military conflicts and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

Although we did not see a significant financial impact to our business operations as a result of recent geopolitical and macroeconomic developments, such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures and the ongoing military conflicts for the year ended December 31, 2023, there may be potential impacts to our business in the future that are highly uncertain and difficult to predict such as disruptions or restrictions in our supply chain, disruption or restrictions on our employees' ability to travel, disruptions to or delays in ongoing non-clinical trials, clinical trials, third-party manufacturing supply and other operations, inability for patients to see their healthcare providers and access our product and product candidates, or adverse geopolitical and macroeconomic concerns, interruptions or delays in the operations of the FDA or other regulatory authorities, continued increases in inflation and interest rates, bank failures, changes in availability and cost of credit and our ability to raise capital and conduct business development activities. The ultimate impact of these geopolitical and macroeconomic developments, as well as any lasting effects on our revenue and the way we conduct our business, is highly uncertain and subject to continued change, and we recognize that they may continue to present unique challenges for us.

We believe that our existing cash and cash equivalents and existing sources of and access to financing are adequate to satisfy our needs for operating capital, working capital, capital expenditures, and debt service in the 12 months from the issuance of the consolidated financial statements included in this Annual Report. However, should adverse geopolitical and macroeconomic events and any associated recession or depression continue for a prolonged period, our results of operations, financial condition, liquidity and cash flows could be materially impacted as a result of a lower likelihood of effectively and efficiently developing new product candidates and successfully commercializing our approved medicines.

Asset Purchase Agreement with Travere Therapeutics, Inc.

On August 31, 2023, we completed the Bile Acid Portfolio Acquisition. We paid $210.4 million upon closing of the transaction, and up to an additional $235.0 million is payable upon the achievement of certain milestones based on specified amounts of annual net sales of the Bile Acid Medicines.

We concurrently entered into a transitional services agreement with Travere, pursuant to which Travere is obligated to perform certain services for a period of time, not anticipated to last beyond 12 months post-close, with respect to our use and operation of the assets purchased.

In connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, we completed the private placement of 8,000,000 shares of our common stock at a price per share of $26.25, resulting in net proceeds of approximately $202.2 million.

Satiogen Acquisition

In May 2022, we completed the acquisition of Satiogen for total consideration of $24.2 million. At the closing of the acquisition, Satiogen's assets consisted of cash and intangible assets related to developed technology. Through the transaction, we obtained all Satiogen-owned intellectual property relating to Livmarli and volixibat. The transaction resulted in a reduction of total licensing royalty obligations for Livmarli and volixibat.

The total potential consideration for the acquisition consisted of 841,792 shares of common stock and approximately $2.6 million in cash, excluding $0.2 million of stock option exercise prices deemed to have been paid immediately prior to the acquisition, in respect of an equivalent amount of cash on the books of Satiogen acquired by us at closing.

Assignment and License Agreement with Shire (Takeda)

In November 2018, we entered into the Shire License Agreement with Shire, which was subsequently acquired by Takeda, in which we were granted an exclusive, royalty bearing worldwide license to develop and commercialize our two product candidates, Livmarli and volixibat. As part of the Shire License Agreement, we were assigned license agreements held by Shire with Satiogen, Pfizer, and Sanofi (collectively, "Assigned License Agreements").

Under the Shire License Agreement and Assigned License Agreements, to date, we have paid aggregate development regulatory and sales milestones of $71.0 million related to our Livmarli and volixibat programs.

Components of Results of Operations

Revenue

Product Sales, Net

We have three approved medicines: Livmarli, Cholbam and Chenodal. We expect total product sales of our approved medicines will continue to increase on an annual basis, though we expect quarterly fluctuations.

Our U.S. revenue from product sales, net further depends on our prescription mix of commercial payors, Medicaid and free medicines under our patient assistance program. We expect our prescription mix and resulting gross to net adjustment in the U.S. to remain consistent; however, we cannot reliably estimate it given our limited experience in the market. Our rest of world revenue from product sales, net primarily depends on our contractual obligations with our distributors and results of pricing negotiations with governmental authorities in certain European countries where we launch Livmarli and expect to launch our other product candidates, if approved. In addition, in certain countries, governments place large periodic orders. The timing of these orders can be inconsistent and can create quarter-to-quarter variation in revenue.

License Revenue

Under the exclusive licensing agreements with CANbridge and GC Biopharma, we have recognized as revenue the upfront nonrefundable payments related to the licenses granted upon satisfaction of certain performance obligations. Pursuant to the agreements, we are eligible to receive future milestone payments. These milestone payments are fully constrained and will be recognized in revenue in the period when it is probable that a significant reversal of cumulative revenue recognized for the contract would not occur. We are also eligible to receive royalty payments related to the agreements, which will be recognized as the underlying product sales occur.

Our license revenue is dependent upon our licensees' achievement of future milestones, which are not within our control, and we are unable to reliably estimate the timing of such revenues.

Cost of Sales

Cost of sales consist of raw materials, third-party manufacturing costs, personnel, facility and other costs of manufacturing commercial products, transportation and freight, amortization of finite-lived intangible assets, amortization of capitalized intangibles and royalty payments payable on net sales of our approved medicines under licensing agreements. Cost of sales may also include period costs related to certain manufacturing services and charges for inventory valuation reserves.

As of the date of our acquisition of the Bile Acid Medicines from Travere, inventory acquired was valued at its fair value. As a result, our cost of sales exceeds the historical cost to manufacture the inventory and has a negative impact on our gross margin. We expect to sell the acquired inventory within the next two years from the balance sheet date. In addition, in connection with the acquisition, we have firm commitments for the purchase of minimum order quantities for active pharmaceutical ingredients. We periodically evaluate these firm commitments to determine if these commitments are in excess of our needs. If any net loss is determined, we record a charge to cost of sales in the period identified.

Prior to the regulatory approval of Livmarli, the manufacturing and related costs were expensed as research and development as any future economic benefit was not considered probable; accordingly, these costs were not capitalized and as a result gross margins resulting from product sales were initially higher until inventories that we had expensed prior to receiving approval were depleted. As of December 31, 2023, such inventories were substantially depleted.

Operating Expenses

Research and Development Expenses

Research and development expenses primarily relate to clinical development and manufacturing activities of our product candidates. Our research and development expenses include, among other things:

- salaries and related expenses for employee personnel, including benefits, travel and expenses related to stock-based compensation granted to personnel in development functions;
- external expenses paid to clinical trial sites, contract research organizations and consultants that conduct our clinical trials;
- expenses related to drug formulation development and the production of clinical trial supplies, including fees paid to contract manufacturers;

- licensing milestone payments related to development or regulatory events;
- research and development funding for collaboration arrangements;
- expenses related to non-clinical studies;
- expenses related to compliance with drug development regulatory requirements; and
- other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of equipment, and other supplies.

We expense research and development costs as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed. Upfront payments, research and development funding and milestone payments made to third parties in connection with licenses and research and development collaborations are expensed as incurred.

Our research and development expense may increase in the future as we continue to develop our current product candidates and look to acquire and develop additional product candidates.

Selling, General and Administrative Expense

Sales and marketing expense, which is a component of selling, general and administrative expense, primarily consisted of employee-related expenses for our sales group, brand marketing, patient support groups and pre-commercialization expenses related to our product candidates. General and administrative expense, which is a component of selling, general and administrative expense, primarily consists of corporate support and other administrative expenses, including employee-related expenses.

We anticipate that our selling, general and administrative expenses will increase in the future to support our continued commercialization efforts of our approved medicines in the United States and internationally as well as increased costs of operating as a global commercial stage biopharmaceutical public company. These increases will likely include increased costs related to hiring of additional personnel and fees to outside consultants to support further marketing, legal, tax, planning and accounting activities.

Loss from termination of revenue interest purchase agreement

Loss from termination of RIPA is related to the repurchase and termination of the RIPA in the second quarter of 2023. The repurchase payment included a premium over the remaining revenue interest liability and resulted in the recognition of a loss from termination of RIPA in our consolidated statements of operations and comprehensive loss.

Interest Income

Interest income consists of interest earned on our cash equivalents and investments.

Interest Expense

We incur interest expense on our convertible notes and on the RIPA. Interest on our convertible notes consists of a 4% per annum fixed rate of interest and amortization of debt discount and amortization costs. Interest on the RIPA consisted primarily of costs associated with our liability and non-cash interest costs associated with the amortization of the related debt discount and deferred issuance costs. Prior to extinguishment of the RIPA in the second quarter of 2023, we imputed interest expense associated with this liability using the effective interest rate method which is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement.

Other Expense, Net

Other expense, net consists of gain or loss from remeasurement of the liabilities associated with the common stock issued in connection with the acquisition of Satiogen after the satisfaction of certain purchase price adjustments and indemnification obligations that may arise during the 12 month period following the asset acquisition date (“Indemnification Holdback”) and the liability associated with the common stock to be issued in connection with the acquisition of Satiogen as contingent consideration upon achievement of a certain milestone (“Contingent Milestone”) both of which were recorded in connection with our acquisition of Satiogen, unrealized and realized currency gains and losses on net assets and liabilities denominated in foreign currency.

Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with U.S. generally accepted accounting principles (“GAAP”) and our discussion and analysis of our financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported, including the amount of assets, liabilities, expenses and the disclosure of contingent assets and liabilities. Note 2, “Summary of Significant Accounting Policies,” of the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. Management bases its estimates on historical experience, known trends and events, and on various other assumptions it 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. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Intangible Assets, Net

Intangible assets, net are measured at their fair values as of the acquisition date or, in the case of commercial milestone payments, the date they become due. Intangible assets are generally amortized on a straight-line basis over their estimated useful lives. We base the useful lives and related amortization expense on the period of time we estimate the assets will generate net product sales or otherwise be used. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

We evaluate our intangible assets with finite lives for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, we reduce the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period.

We make significant judgments in relation to the valuation of intangible assets resulting from asset acquisitions, particularly in the forecasts of future operating results that are used in the discounted cash flow valuation models. It is possible that plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges.

Product Sales, Net

Revenues from direct product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, including amounts from payors and other third parties on behalf of our customers. For revenues from partner markets, we record net product sales based on the estimated variable consideration to be received when the product is sold. The transaction price, which may include fixed or variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the product sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenue recognized will not occur in a future period. We recognize our best estimate of the consideration that we expect to receive when control of the inventory is transferred to our customer and revenue is recognized. Estimates are reviewed and updated quarterly as additional information becomes known. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Government Rebates

We are obligated to pay rebates for mandated discounts under the Medicaid Drug Rebate Program. Our rebate calculations may require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. We update estimates and assumptions on a quarterly basis and record any necessary adjustments to revenue in the period identified. Estimated rebates are recorded as a reduction of revenue in the period the related sale is recognized. To date, actual government rebates have not differed materially from our estimates.

Revenue Interest Liability, Net

We imputed interest expense associated with this liability using the effective interest rate method. The effective interest rate was calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The effective interest rate on the liability varied during the term of the agreement depending on a number of factors, including the level of actual and forecasted product sales, net. We evaluated the interest rate quarterly based on actual product sales, net and on product sales, net forecasts utilizing the prospective method. In April 2023, we repurchased all future Revenue Interests and as a result, the RIPA was terminated in accordance with its terms.

At December 31, 2022, the revenue interest liability was calculated using our estimated global forecasted net sales of Livmarli at the time and was impacted by a debt discount comprising the estimated value of a bifurcated derivative liability and issuance costs incurred.

Cost of Product Sales

Prior to receiving approval from the FDA or other foreign regulatory authorities for a new medicine or new formulation, we expense all costs incurred related to the manufacture of such medicines as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and our lack of history for regulatory approval of drug candidates. Subsequent to receiving FDA or other foreign regulatory authority approval, when commercialization is considered probable and the future economic benefit is expected to be realized, we begin capitalizing inventory costs as incurred.

Cost of product sales consist of raw materials, manufacturing costs, transportation and freight, amortization of capitalized intangible assets, royalties and indirect overhead costs associated with the manufacturing and distribution of the Company’s approved products. Cost of product sales may also include period costs related to certain manufacturing services and inventory adjustment charges.

We analyze our inventory levels quarterly for obsolescence and, if required, adjust inventory to its net realizable value for quantities in excess of expected demand. The analysis uses quantitative forecast and historical demand considerations in combination with shelf life and stop sell dates in our estimates to evaluate inventory that may not be sellable. The resulting adjustments are recognized as Cost of Sales.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We accrue and expense clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the life of the individual study and patient enrollment rates in accordance with agreements established with clinical research organizations, clinical trial sites and other vendors associated with the clinical trials. We determine the estimates by reviewing contracts, vendor agreements and purchase orders and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

We make estimates of accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Uncertain Tax Positions

We are subject to income taxes in the United States and certain foreign jurisdictions. The evaluation of uncertain tax positions involves significant judgment in the interpretation and application of GAAP and complex tax laws. Although management believes our reserves are reasonable, no assurance can be given that the final tax outcome of these matters will not be different from that which is reflected in our reserves. Reserves are adjusted considering changing facts and circumstances, such as the closing of a tax examination or the refinement of an estimate. Resolution of these uncertainties in a manner inconsistent with management's expectations could have a material impact on our financial condition and operating results.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included elsewhere in this Annual Report.

Results of Operations for the Years Ended December 31, 2023 and 2022

In this section, we discuss the results of our operations for the year ended December 31, 2023, compared to the year ended December 31, 2022. For a discussion of the year ended December 31, 2022 compared to the year ended December 31, 2021, please refer to our Annual Report on Form 10-K filed with the SEC on March 8, 2023.

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Revenue:			
Product sales, net	$ 178,874	$ 75,062	$ 103,812
License revenue	7,500	2,000	5,500
Total revenue	186,374	77,062	109,312
Operating expenses:			
Cost of sales	47,039	12,374	34,665
Research and development	102,609	106,842	(4,233)
Selling, general and administrative	145,880	89,066	56,814
Total operating expenses	295,528	208,282	87,246
Loss from operations	(109,154)	(131,220)	22,066
Other income (expense):			
Interest income	13,735	3,857	9,878
Interest expense	(15,105)	(15,979)	874
Change in fair value of derivative liability	—	906	(906)
Loss from termination of revenue interest purchase agreement	(49,076)	—	(49,076)
Other (expense) income, net	(2,824)	365	(3,189)
Net loss before provision for income taxes	(162,424)	(142,071)	(20,353)
Provision for (benefit from) income taxes	991	(6,406)	7,397
Net Loss	$ (163,415)	$ (135,665)	$ (27,750)

Product Sales, Net

Product sales, net was $178.9 million for the year ended December 31, 2023, compared to $75.1 million for the year ended December 31, 2022. The increase in product sales, net was a result of our continued commercialization of Livmarli in the United States, in certain countries in Europe and other international sales through partner market supply orders and sales of Bile Acid Medicines for a partial year following the completion of the Bile Acid Portfolio Acquisition.

The following table disaggregates total Product sales, net:

	Year Ended December 31,		
	2023	2022	Change
Product sales, net:			
Livmarli	$ 141,795	$ 75,062	$ 66,733
Bile Acid Medicines	37,079	—	37,079
Total product sales, net	$ 178,874	$ 75,062	$ 103,812

License Revenue

License revenue was $7.5 million for the year ended December 31, 2023 due to the achievement of regulatory milestones by CANbridge and GC Biopharma associated with our license agreements, compared to $2.0 million for the year ended December 31, 2022, due to the achievement of a regulatory milestone by CANbridge associated with our license agreement.

Cost of Sales

Cost of sales was $47.0 million for the year ended December 31, 2023, compared to $12.4 million for the year ended December 31, 2022. The increase in cost of sales was primarily a result of increased royalties payable of $9.8 million on net sales of Livmarli and the Bile Acid Medicines under licensing agreements, $7.5 million of amortization of acquired intangibles primarily associated with our acquisition of the Bile Acid Medicines in August 2023 and Satiogen in May 2022, a $5.2 million charge related to net losses associated with excess inventory from certain firm minimum purchase commitments in connection with our acquired Bile Acid Medicines, $3.9 million of increased costs associated with reserves for excess and obsolete inventory, increased product cost of sales of approximately $4.0 million primarily related to the Bile Acid Medicines and $4.0 million of increased commercial product development and supply chain costs.

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses relating to our product candidates in development for the periods indicated (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022	Change
Product-specific costs:			
Livmarli	$ 29,438	$ 40,228	$ (10,790)
Volixibat	20,286	21,159	(873)
Non product-specific costs:			
Personnel	28,569	25,298	3,271
Stock-based compensation	10,892	10,051	841
Other	13,424	10,106	3,318
Total research and development expenses	$ 102,609	$ 106,842	$ (4,233)

Research and development expenses were $102.6 million for the year ended December 31, 2023, a decrease of $4.2 million compared to the year ended December 31, 2022. The decrease was primarily due to:

- for Livmarli programs, a decrease of $10.8 million, primarily due to decreases of $5.4 million in manufacturing development expenses, $3.1 million in clinical trial expenses primarily related to the MARCH Phase 3 clinical trial which was completed during 2022 and $2.4 million in non-clinical and general research and development expenses; and
- for volixibat programs, a decrease of $0.9 million, primarily due to a $3.3 million decrease in clinical expenses associated with the discontinuation of the intrahepatic cholestasis of pregnancy clinical trial and lower clinical manufacturing expenses of $1.8 million, partially offset by an increase of $4.1 million of clinical trial expenses for PSC and PBC.

The decreases were partially offset by increases due to:

- for personnel related expenses, an increase of $3.3 million, related to an increase in employee headcount to support our development pipeline; and
- for other expense, an increase of $3.3 million, primarily due to other general research and development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $145.9 million for the year ended December 31, 2023, an increase of $56.8 million compared to the year ended December 31, 2022. The increase was primarily due to an increase of $26.6 million in personnel and other compensation related expenses, including an increase of $7.2 million in stock-based compensation, reflecting an increase in the number of our selling, marketing and administrative employees to support commercial activities for our approved medicines, and costs associated with the acquisition of the Bile Acid Portfolio and international expansion. The increase was also due to $17.0 million in expenses primarily related to legal, public relations, accounting and international expansion activities, $9.6 million in advertising, promotion and medical affairs associated with commercial activities of our approved medicines and $3.5 million in other general administrative expenses.

Loss from termination of revenue interest purchase agreement

Loss from termination of RIPA was $49.1 million for the year ended December 31, 2023, compared to zero for the year ended December 31, 2022. The loss was related to the premium paid to repurchase the revenue interests pursuant to the RIPA.

Interest Income

Interest income was $13.7 million for the year ended December 31, 2023, an increase of $9.9 million compared to the year ended December 31, 2022. The increase was primarily due to higher interest earned on our cash equivalents and investment balances largely due to higher money market and treasury yields and higher cash equivalent balance throughout the year ended December 31, 2023.

Interest Expense

Interest expense was $15.1 million for the year ended December 31, 2023, a decrease of $0.9 million compared to the year ended December 31, 2022. For the year ended December 31, 2023, interest expense consisted of $10.0 million related to our convertible notes and $5.1 million related to the RIPA prior to extinguishment. For the year ended December 31, 2022, interest expense of $16.0 million was related to the RIPA.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability for the year ended December 31, 2022 was a gain of $0.9 million and was related to the remeasurement of the derivative liability at December 31, 2022. The gain reflects a decrease in value of the put option associated with the RIPA attributable to the decay in time value of the put option. There was no change in the estimated fair value of the derivative liability in 2023 prior to extinguishment of the RIPA.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $2.8 million, net for the year ended December 31, 2023, compared to an income of $0.4 million, net for the year ended December 31, 2022. For the year ended December 31, 2023, the expense was primarily attributable to $1.8 million in unrealized currency losses on net assets and liabilities denominated in foreign currency, $0.7 million of expense associated with the remeasurement of the Contingent Milestone liability and the Indemnification Holdback liability prior to issuance of the underlying common stock as well as $0.4 million of realized currency loss. For the year ended December 31, 2022, the income was primarily related to the remeasurement of the Contingent Milestone liability and the Indemnification Holdback liability of $0.9 million and $0.3 million of unrealized currency gains on net assets and liabilities denominated in foreign currency, partially offset by $0.8 million of realized currency losses.

Provision For (Benefit From) Income Taxes

Provision for income taxes was $1.0 million for the year ended December 31, 2023 compared to a benefit from income taxes of $6.4 million for the year ended December 31, 2022. The change was related to the deferred tax liability recognized as a result of intangible assets acquired as part of the Satiogen acquisition and corresponding reduction in our valuation allowance against our net deferred tax assets during the year ended December 31, 2022.

Liquidity and Capital Resources

Overview

Since inception, we have funded our operations primarily through debt, equity, a revenue interest financing and, to a lesser extent, cash from our product sales and license and collaboration revenue. We had $286.3 million of cash and cash equivalents as of December 31, 2023, compared to cash, cash equivalents, restricted cash equivalents and investments of $251.7 million as of December 31, 2022. Since inception, we have incurred operating losses and negative cash flows from operations. As of December 31, 2023, we had an accumulated deficit of $556.2 million, compared to $392.8 million as of December 31, 2022.

On August 31, 2023, we completed the Bile Acid Portfolio Acquisition for an aggregate purchase price of up to $445.0 million in cash, with $210.4 million paid at the Closing and up to $235.0 million upon achievement of certain milestones based on specified amounts of annual net sales (tiered from $125.0 million to $500.0 million) of the Bile Acid Medicines. In connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, we completed the private placement of 8,000,000 shares of our common stock at a price per share of $26.25, resulting in net proceeds of approximately $202.2 million which we used to finance the upfront payment at the closing of the Bile Acid Portfolio Acquisition.

On April 17, 2023, we completed an offering of $316.3 million aggregate principal of the Notes, which includes the exercise of the initial purchasers' option in full. The offering resulted in net proceeds of $305.3 million after deducting the initial purchasers' discounts and commissions and offering expenses. The terms of the convertible Notes are further described in Note 10 to our consolidated financial statements. We used a portion of the net proceeds to repurchase the revenue interests from the Purchasers at a call price of $192.7 million. Upon repurchase of the revenue interests from the Purchasers, the RIPA, in accordance with its terms, was terminated with no further payments due to the Purchasers and the $100.0 million of our previously restricted cash equivalents was no longer restricted from use.

In September 2022, we filed an automatic statement on Form S-3 with the SEC (the "2022 Shelf Registration"), which became effective upon filing, pursuant to which we registered for sale from time to time in one or more offerings an unlimited amount of any combination of our common stock, preferred stock, debt securities and warrants, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. This automatic shelf registration statement will remain in effect for up to three years from the date it became effective. As of December 31, 2023, we have not issued any securities pursuant to the 2022 Shelf Registration. We may lose well-known seasoned issuer status in the future upon the occurrence of certain events prescribed by the Securities Act or the rules and regulations of the SEC occurring after we file this Quarterly Report if, at the time of those certain events, the worldwide market value of our voting and non-voting common equity held by our non-affiliates does not equal $700.0 million or more, calculated as of a date within 60 days prior to such events. If that were to occur and we were no longer considered a well-known seasoned issuer, we anticipate needing to amend our automatic shelf registration statement on Form S-3 prior to the occurrence of such events in order to sell securities under that Form S-3 on an ongoing basis.

On November 2, 2023, we entered into a Sales Agreement (the "2023 Sales Agreement") with Leerink and Cantor Fitzgerald & Co. (the "Sales Agents"), pursuant to which we may, from time to time, sell up to an aggregate amount of $200.0 million of our common stock through the Sales Agents in an "at-the-market" offering (the "ATM Offering") pursuant to the 2022 Shelf Registration. We are not required to sell shares under the 2023 Sales Agreement. Sales of our common stock, if any, under the 2023 Sales Agreement may be made in any transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act. We will pay a given designated Sales Agent a commission of up to 3.0% of the aggregate gross proceeds of any shares of common stock sold through it pursuant to the 2023 Sales Agreement. No sales may be made under the 2023 Sales Agreement until a prospectus supplement relating to the ATM Offering is filed with the Securities and Exchange Commission.

In August 2020, the SEC declared effective the 2020 Shelf Registration covering the sale of up to $300.0 million of our securities. Also, in August 2020, we entered into the 2020 Sales Agreement with Leerink pursuant to which we could issue and sell, in an at the market offering, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the 2020 Shelf Registration through Leerink acting as the sales agent and/or principal. During the year ended December 31, 2023 we issued and sold 658,206 shares of common stock pursuant to the 2020 Sales Agreement resulting in aggregate gross proceeds to us of $15.0 million. For the year ended December 31, 2023, the net proceeds to us after deducting sales commissions to Leerink and other issuance expenses were approximately $14.5 million. As of December 31, 2023, we have issued and sold an aggregate of 2,125,090 shares of common stock pursuant to the 2020 Sales Agreement, resulting in aggregate gross proceeds to us of $43.7 million. The 2020 Shelf Registration expired in August 2023, and no further sales may be made under the 2020 Sales Agreement.

In August 2022, we completed an underwritten public offering of our common stock pursuant to the 2020 Shelf Registration. We sold 3,478,261 shares of common stock at a price to the public of $23.00 per share. In addition, we granted the underwriters an option, exercisable for 30 days, to purchase up to 521,739 additional shares of our common stock at the public offering price, less the underwriting discounts, commissions and offering expenses, which the underwriters exercised in full. The underwritten public offering, including the underwriters' exercise of their option, resulted in net proceeds to us of $86.1 million after deducting underwriting discounts, commissions and offering expenses.

Based on our current and anticipated level of operations and cash generated from sales of our approved medicines, we believe our existing cash and cash equivalents will be sufficient to fund our planned operations through at least the next 12 months from the filing of this Annual Report and beyond. Our cash and cash equivalents include readily available checking and money market funds. We maintain established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue research efforts and the development of our product candidates, continue commercialization activities for our approved medicines and potentially expand into additional markets, hire additional staff, including clinical, scientific, operational, financial and management personnel and pay potential development and commercial and sales based milestones.

Our primary use of cash is to fund operating expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Although Livmarli has been approved for the treatment of cholestatic pruritus in patients with ALGS in patients three months of age and older and cholestatic pruritus in patients with PFIC five years of age and older in the U.S. and for the treatment of cholestatic pruritus in ALGS patients two months of age and older in Europe, and we expect product revenues to increase as we continue commercial activities, Livmarli may not achieve commercial success. Certain of our approved medicines, including the Bile Acid Medicines, are subject to immediate competition from compounded and generic entrants, as the ANDA and NDA for these drug products have no remaining or current patent or non-patent exclusivity. In addition, Chenodal is approved for radiolucent stones in the gallbladder yet is used primarily as standard of care for CTX. The FDA has provided a letter acknowledging Chenodal as a medical necessity for CTX, but prescriptions for this indication are not on label. As such, any change in this view from the FDA could adversely affect our ability to sell Chenodal in this indication. Unless and until Chenodal is approved for CTX, we cannot market or promote Chenodal for CTX which limits its growth potential.

Our principal source of liquidity is product revenue from sales of approved medicines, and, to a lesser extent, from our collaboration agreements. Until such time, if ever, as we can generate sufficient product revenue from sales of our approved medicines, our current product candidates or any future product candidates, if approved, to fund operations, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. Our primary cash needs are for day-to-day operations and to fund our working capital requirements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. As a result of adverse geopolitical and macroeconomic developments, such as the ongoing military conflicts between Ukraine and Russia and in Israel and the surrounding areas, and related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, bank failures, the global credit and financial markets have experienced volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

In addition to ongoing capital needs to fund our ongoing operations, our material cash requirements include the following contractual and other obligations.

On April 17, 2023, we completed an offering of $316.3 million aggregate principal of the Notes, which includes the exercise of the initial purchasers' option in full. The offering resulted in net proceeds of $305.3 million after deducting the initial purchasers' discounts and commissions and offering expenses. The Notes are our senior, unsecured obligations and accrue interest at a rate of 4.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year. Our first interest payment was due on November 1, 2023. The Notes will mature on May 1, 2029, unless earlier converted, redeemed or repurchased by us. The terms of these Notes are further described in Note 10 to our consolidated financial statements.

We used a portion of the net proceeds from the Notes to repurchase the revenue interests from the Purchasers at a call price of $192.7 million. Upon repurchase of the revenue interests from the Purchasers, the RIPA, in accordance with its terms, was terminated with no further payments due to the Purchasers.

Under the Shire License Agreement and Asset Purchase Agreement with Travere, as well as our other license and acquisition agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. The amount and timing of milestone obligations are unknown or uncertain as we are unable to estimate the timing or likelihood of achieving the milestone events. Additionally, the amount of royalty payments are based upon future product sales, which we are unable to predict with certainty. These potential obligations are further described in Note 7 to our consolidated financial statements.

We additionally have contractual obligations for our operating leases for our corporate headquarters. These obligations are further described in Note 9 to our consolidated financial statements.

We are party to certain license and collaboration agreements, which contain a number of contractual obligations. Those contractual obligations may entitle us to receive, or may obligate us to make, certain payments. The amount and timing of those payments are unknown or uncertain as we are unable to estimate the timing or likelihood of the events that will obligate those payments.

We enter into contracts in the normal course of business with clinical research organizations and clinical sites for the conduct of clinical trials, non-clinical research studies, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

We enter into commercial inventory supply agreements that obligate us to firm commitments for the purchase of minimum order quantities, which may be material to our financial statements.

Cash Flows

The following table provides a summary of the net cash flow activity for the periods indicated (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (70,944)	$ (120,136)
Net cash (used in) provided by investing activities	(107,200)	7,700
Net cash provided by financing activities	336,600	109,087
Effect of exchange rate on cash, cash equivalents and restricted cash equivalents	(133)	12
Net increase (decrease) in cash, cash equivalents and restricted cash equivalents	$ 158,323	$ (3,337)

Net Cash Used in Operating Activities

Net cash used in operating activities was $70.9 million for the year ended December 31, 2023, reflecting our net loss of $163.4 million, partially offset by non-cash adjustments of $115.1 million. Non-cash adjustments consisted primarily of a loss from termination of RIPA of $49.1 million, $35.0 million of stock-based compensation, $11.4 million of depreciation and amortization of our intangible assets and fixed assets and non-cash lease expense, a $9.3 million charge associated with excess and obsolete inventory and losses on firm purchase commitments, $5.1 million of effective interest expense in connection with the RIPA, $3.4 million related to the cost of sale of inventory acquired in the Bile Acid Portolio Acquisition, $0.7 million expense related to the change in fair value of contingent liabilities associated with an acquisition, $1.8 million of unrealized foreign exchange losses and $1.1 million amortization of debt discount and offering costs, partially offset by $1.7 million net accretion of discounts on our investments. Additionally, cash used in operating activities reflected changes in net operating assets of $22.6 million, consisting primarily of a $44.0 million increase in accounts receivable due to the increase in the sales of Livmarli and the acquisition of the Bile Acid Medicines, a $30.8 million increase in accounts payable, accrued expenses and other liabilities resulting primarily from a $19.4 million increase in accrued sales deductions, a $4.3 million increase in accrued royalties payable both due to our increased net product sales, a $6.3 million increase in accrued compensation and related benefits and a $2.1 million increase in accrued interest expense related to the Notes issued in April 2023, a $4.4 million increase in inventory related to Livmarli and a $3.6 million increase in prepaid and other current assets due to timing of payment for deposits for professional services, software license and regulatory fees.

Net cash used in operating activities was $120.1 million for the year ended December 31, 2022, reflecting our net loss of $135.7 million partially offset by non-cash items of $36.6 million. Non-cash items consisted primarily of $27.0 million of stock-based compensation, $16.0 million of effective interest expense in connection with the RIPA, $3.7 million of depreciation and amortization of our intangible assets and fixed assets and non-cash lease expense, $6.6 million related to deferred tax liability recognized as a result of intangible assets acquired as part of the Satiogen acquisition, $1.7 million accretion of discounts on our investments, $0.9 million gain related to the change in fair value of Indemnification Holdback and Contingent Milestone liabilities and $0.9 million gain related to the change in fair value of the derivative liability. Additionally, cash used in operating activities reflected changes in net operating assets of $21.0 million, consisting primarily of a $20.7 million increase in accounts receivable related to sales of Livmarli, a $3.4 million increase in inventory, a $3.7 million increase in prepaid expenses and other current assets, a $0.1 million increase in other long term assets, and a $0.7 million decrease in operating lease liability, partially offset by a $7.6 million increase in accounts payable, accrued expenses and other liabilities.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $107.2 million for the year ended December 31, 2023, primarily due to $212.8 million paid in connection with our acquisition of the Bile Acid Medicines from Travere, $27.3 million used in purchases of investments and $20.0 million used in the acquisition of intangible assets associated with our license payments for Livmarli regulatory and commercial milestones, partially offset by proceeds of $153.0 million from maturities of investments.

Net cash provided by investing activities was $7.7 million for the year ended December 31, 2022, primarily due to proceeds of $140.3 million from maturities of investments, partially offset by $132.3 million used in purchases of investments and $0.3 million used in purchases of property and equipment.

<u>Net Cash Provided by Financing Activities</u>

Net cash provided by financing activities was $336.6 million for the year ended December 31, 2023, due to net proceeds of $305.3 million from the issuance of convertible notes, net proceeds of $202.2 million from the issuance and sale of common stock in a private placement offering, $14.5 million net proceeds from the issuance and sale of common stock under the 2020 Sales Agreement with Leerink, pursuant to which we issued and sold an aggregate of 658,206 shares of common stock at a weighted-average price of $22.79 per share, and proceeds of $10.5 million from employee equity award exercises, partially offset by $195.6 million in revenue interest payments and payments to repurchase the revenue interests under the RIPA.

Net cash provided by financing activities was $109.1 million for the year ended December 31, 2022, due to net proceeds of $86.1 million from completion of an underwritten public offering of 4,000,000 shares of common stock at a price of $23.00 per share, net proceeds of $21.3 million from the issuance and sale of common stock under the Sales Agreement with SVB Securities, pursuant to which we issued and sold an aggregate of 1,160,915 shares of common stock at a weighted-average price of $19.01 per share, and proceeds of $7.3 million from employee equity award exercises, partially offset by $5.6 million of revenue interest payments made under the RIPA.

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

Interest Rate Risk

Our cash and cash equivalents as of December 31, 2023 consist of readily available checking and money market funds. The primary objective of our investment activities is to preserve our capital to fund operations. We may invest in highly liquid and high-quality government and debt securities. As a result, our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. As of the date of this report, we do not hold investments that expose us to interest rate risk. Should interest rates decrease on money market funds, it will result in lower interest income in future periods. In addition, we maintain significant amounts of cash and cash equivalents at one financial institution that is in excess of federally insured limits.

We have outstanding $316.3 million aggregate principal of the Notes. The interest rate on these Notes is fixed and therefore they do not expose us to risk related to increases in interest rates. As of December 31, 2023, the approximate fair value of our Notes was $387.3 million.

Foreign Currency Rate Risk

Our operations include activities in the U.S. and to a lesser extent Switzerland and certain other countries in Europe. As a result, our financial results may be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we sell our products. Our operating results are exposed to changes in foreign currency exchange rates between the U.S. Dollar (USD) and various foreign currencies, primarily the Euro. When the USD strengthens against these currencies, the relative value of the sales and operating expenses made in the respective foreign currency decreases. Conversely, when the USD weakens against these currencies, the relative value of such sales and operating expenses increases.

Based on our overall foreign currency denominated exposures as of December 31, 2023, we believe that a near-term 10% fluctuation of the USD exchange rate could result in a potential change in the fair value of our net assets and liabilities denominated in foreign currency by approximately $5.8 million. We expect to continue to enter into transactions based in foreign currencies that could be impacted by changes in exchange rates.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Mirum Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Mirum Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, Mirum Pharmaceuticals, Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified material weaknesses in the design of controls and level of evidence retained over the existence and valuation of inventory, including the controls over existence of inventory located at third parties and the net realizable value assessment of on-hand inventory and future purchases under firm commitments, and over the precision of management review controls and the sufficiency of control evidence related to prospective financial information used to determine the fair value of acquired developed technology.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls relating to the Bile Acid Portfolio, which is included in the 2023 consolidated financial statements of the Company and constituted approximately 6% of total assets (excluding intangible assets) as of December 31, 2023, and 20% of total revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of the Bile Acid Portfolio.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes. The material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated March 15, 2024, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California
March 15, 2024

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Mirum Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Mirum Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 15, 2024 expressed an adverse opinion thereon.

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 audits. We are a public accounting firm registered with the 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 audits 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. Our audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

	Acquisition of the Bile Acid Portfolio
Description of the Matter	As described in Note 7 to the consolidated financial statements, during the year ended December 31, 2023, the Company completed its acquisition of the Bile Acid Portfolio for total consideration of $212.8 million, which was accounted for as an asset acquisition. Auditing the Company's accounting for its acquisition of the Bile Acid Portfolio was complex due to the significant estimation uncertainty in determining the fair value of the developed technology intangible assets and consideration transferred, including contingent consideration, with such intangible assets valued and recorded at $198.5 million. The Company used a discounted cash flow model to measure the estimated fair value of the developed technology intangible assets, the most significant assumptions of which included the projections of future revenue and the discount rate . The Company used the fair value of the contingent consideration in determining whether the acquisition of the Bile Acid Portfolio should be accounted for as an asset acquisition. The Company estimated the fair

	value of the contingent consideration using a Monte Carlo simulation model, which includes the amount and timing of revenue projections subsequent to the acquisition date as a significant assumption. The significant estimation uncertainty was primarily due to the judgmental nature of the inputs to the valuation models used by the Company and the sensitivity of the estimated fair value to the underlying significant assumptions. Each of the significant assumptions are forward-looking and could be affected by future economic and market conditions.
How We Addressed the Matter in Our Audit	To test the estimated fair values of the developed technology intangible assets and the contingent consideration, our substantive audit procedures included, among others, evaluating the Company's application of acquisition accounting, involvement of our valuation specialists to assist us in the evaluation of the valuation methodologies used by the Company and procedures to test the significant assumptions used in the valuation, including the completeness and accuracy of the underlying data. We performed a sensitivity analysis of the projections of future revenue and the discount rate to evaluate the change in the estimated fair value resulting from changes in the assumptions. We also compared the revenue forecast assumptions to historical results of the acquired assets and to other guideline companies within the same industry and had our valuation specialists perform corroborative calculations.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Mateo, California
March 15, 2024

Mirum Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 286,326	$ 28,003
Short-term investments	—	123,716
Accounts receivable	67,968	23,994
Inventory	22,312	5,565
Prepaid expenses and other current assets	10,935	8,947
Total current assets	387,541	190,225
Restricted cash equivalents	—	100,000
Property and equipment, net	706	914
Operating lease right-of-use assets	1,284	1,431
Intangible assets, net	252,925	58,954
Other assets	4,165	1,382
Total assets	$ 646,621	$ 352,906
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,416	$ 8,690
Accrued expenses	78,544	54,018
Operating lease liabilities	1,104	931
Derivative liability	—	1,090
Total current liabilities	87,064	64,729
Revenue interest liability, net	—	140,351
Operating lease liabilities, noncurrent	617	1,257
Convertible notes payable, net	306,421	—
Other liabilities	3,849	4,532
Total liabilities	397,951	210,869
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, and no shares issued and outstanding as of December 31, 2023 and 2022;	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 46,723,143 and 36,956,345 shares issued and outstanding as of December 31, 2023 and 2022	5	4
Additional paid-in capital	803,260	535,074
Accumulated deficit	(556,239)	(392,824)
Accumulated other comprehensive income (loss)	1,644	(217)
Total stockholders' equity	248,670	142,037
Total liabilities and stockholders' equity	$ 646,621	$ 352,906

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

Mirum Pharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31, 2023	2022	2021
Revenue:			
Product sales, net	$ 178,874	$ 75,062	$ 3,138
License revenue	7,500	2,000	16,000
Total revenue	186,374	77,062	19,138
Operating expenses:			
Cost of sales	47,039	12,374	1,903
Research and development	102,609	106,842	131,428
Selling, general and administrative	145,880	89,066	59,220
Total operating expenses	295,528	208,282	192,551
Loss from operations	(109,154)	(131,220)	(173,413)
Other income (expense):			
Interest income	13,735	3,857	366
Interest expense	(15,105)	(15,979)	(17,590)
Change in fair value of derivative liability	—	906	(732)
Loss from termination of revenue interest purchase agreement	(49,076)	—	—
Gain from sale of priority review voucher, net	—	—	108,000
Other (expense) income, net	(2,824)	365	(582)
Net loss before provision for income taxes	(162,424)	(142,071)	(83,951)
Provision for (benefit from) income taxes	991	(6,406)	37
Net loss	$ (163,415)	$ (135,665)	$ (83,988)
Net loss per share:			
Basic	$ (4.00)	$ (4.01)	$ (2.77)
Diluted	$ (4.00)	$ (4.02)	$ (2.77)
Weighted-average shares outstanding:			
Basic	40,885,124	33,839,072	30,321,722
Diluted	40,885,124	33,982,493	30,321,722

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

Mirum Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31, 2023	2022	2021
Net loss	$ (163,415)	$ (135,665)	$ (83,988)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale investments	230	(194)	(117)
Cumulative translation adjustments	1,631	12	(1)
Comprehensive loss	$ (161,554)	$ (135,847)	$ (84,106)

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

Mirum Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	29,776,544	$ 3	$ 345,180	$ (173,171)	$ 83	$ 172,095
Issuance of common stock in connection with equity incentive plans	207,595	—	844	—	—	844
Issuance of common stock in connection with public offering, net of issuance costs of $476	375,654	—	7,038	—	—	7,038
Restricted common stock vested in the period	133,592	—	—	—	—	—
Issuance of common stock in connection with Employee Stock Purchase Plan	89,211	—	1,254	—	—	1,254
Stock-based compensation	—	—	23,087	—	—	23,087
Net loss	—	—	—	(83,988)	—	(83,988)
Other comprehensive loss	—	—	—	—	(118)	(118)
Balance as of December 31, 2021	30,582,596	$ 3	$ 377,403	$ (257,159)	$ (35)	$ 120,212
Issuance of common stock in connection with asset acquisition	609,305	—	15,585	—	—	15,585
Issuance of common stock in connection with equity incentive plans	357,934	—	5,438	—	—	5,438
Issuance of common stock in at-the-market offerings, net of issuance costs of $785	1,160,915	—	21,289	—	—	21,289
Issuance of common stock in connection with public offering, net of issuance costs $5,922	4,000,000	1	86,077	—	—	86,078
Restricted common stock vested in the period	122,464	—	—	—	—	—
Issuance of common stock in connection with Employee Stock Purchase Plan	123,131	—	1,834	—	—	1,834
Stock-based compensation	—	—	27,448	—	—	27,448
Net loss	—	—	—	(135,665)	—	(135,665)
Other comprehensive loss	—	—	—	—	(182)	(182)
Balance as of December 31, 2022	36,956,345	$ 4	$ 535,074	$ (392,824)	$ (217)	$ 142,037
Issuance of common stock in private placement, net of issuance costs of $7,796	8,000,000	1	202,203	—	—	202,204
Issuance of common stock in at-the-market offerings, net of issuance costs of $518	658,206	—	14,480	—	—	14,480
Issuance of common stock in connection with asset acquisition	231,624	—	5,188	—	—	5,188
Issuance of common stock in connection with equity award plans	760,226	—	8,279	—	—	8,279
Issuance of common stock in connection with employee stock purchase plan	116,742		2,191			2,191
Stock-based compensation	—	—	35,845	—	—	35,845
Net loss	—	—	—	(163,415)	—	(163,415)
Other comprehensive income	—	—	—	—	1,861	1,861
Balance as of December 31, 2023	46,723,143	$ 5	$ 803,260	$ (556,239)	$ 1,644	$ 248,670

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

Mirum Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2023	2022	2021
Operating activities			
Net loss	$ (163,415)	$ (135,665)	$ (83,988)
Reconciliation of net loss to net cash used in operating activities:			
Stock-based compensation	35,023	27,007	23,087
Depreciation and amortization	10,829	3,238	595
Non-cash lease expense	620	443	380
Net accretion of discounts on investments	(1,725)	(1,703)	(137)
Non-cash interest expense related to the revenue interest liability	5,060	15,979	17,590
Amortization of debt discount and offering costs	1,117	—	—
Change in fair value of derivative liability	—	(906)	732
Change in fair value of contingent liabilities associated with acquisition	671	(899)	—
Inventory reserves and firm purchase commitment losses	9,257	—	—
Loss from termination of revenue interest purchase agreement	49,076	—	—
Costs recognized on sale of acquired inventory	3,419	—	—
Unrealized foreign exchange loss	1,764	—	—
Deferred income taxes associated with an acquisition	—	(6,580)	—
Gain on sale of priority review voucher, net	—	—	(108,000)
Change in operating assets and liabilities:			
Accounts receivable	(43,974)	(20,727)	—
Prepaid and other current assets	(3,600)	(3,676)	(4,009)
Inventory	(4,393)	(3,448)	(495)
Other assets	(511)	(127)	(519)
Accounts payable, accrued expenses and other liabilities	30,778	7,639	22,655
Operating lease liabilities	(940)	(711)	(649)
Net cash used in operating activities	(70,944)	(120,136)	(132,758)
Investing activities			
Purchase of investments	(27,329)	(132,322)	(198,029)
Proceeds from maturities of investments	153,000	140,300	155,600
Proceeds from paydown of investments	—	—	2,000
Purchase of property and equipment	(109)	(278)	(24)
Cash paid for acquisition	(212,762)	—	—
Payments made for additions to intangible assets	(20,000)	—	(19,000)
Proceeds from sale of priority review voucher, net	—	—	108,000
Net cash (used in) provided by investing activities	(107,200)	7,700	48,547
Financing activities			
Proceeds from issuance of common stock in private placement, net of issuance costs	202,204	—	—
Proceeds from issuance of common stock in at-the-market offerings, net of issuance costs	14,480	21,289	—
Proceeds from issuance of common stock in public offerings, net of issuance costs	—	86,078	6,914
Proceeds from the issuance of convertible notes, net	305,304	—	—
Proceeds from issuance of common stock pursuant to equity plans	10,470	7,272	2,098
Payments of deferred offering costs	(281)	—	—
Payments on revenue interest liability	(195,577)	(5,552)	(121)
Proceeds from revenue interest liability, net of issuance costs	—	—	64,575
Net cash provided by financing activities	336,600	109,087	73,466
Effect of exchange rate on cash, cash equivalents and restricted cash equivalents	(133)	12	(1)
Net increase (decrease) in cash, cash equivalents and restricted cash equivalents	158,323	(3,337)	(10,746)
Cash, cash equivalents and restricted cash equivalents at beginning of period	128,003	131,340	142,086
Cash, cash equivalents and restricted cash equivalents at end of period	$ 286,326	$ 128,003	$ 131,340
Supplemental disclosure of cash flow information:			
Operating cash flows paid for operating lease	$ 1,079	$ 911	$ 864
Cash paid for income taxes	$ 125	$ —	$ —
Cash paid for interest	$ 6,817	$ —	$ —
Non-cash operating, investing and financing activities:			
Inventory purchases included in accrued liabilities	$ 6,076	$ 163	$ 1,018
Right-of-use assets obtained in exchange for lease liability	$ 473	$ 285	$ —
Stock-based compensation capitalized into inventory	$ 822	$ 441	$ 71
Issuance of common stock in connection with settlement of Contingent Milestone and Indemnification Holdback liabilities	$ 5,188	$ —	$ —
Issuance of common stock in exchange for acquired intangible assets	$ —	$ 15,585	$ —
Accrued milestone payments classified as intangible assets, net	$ —	$ 15,000	$ —
Deferred tax liability incurred from acquired intangible	$ —	$ 6,580	$ —
Contingent milestone liability for common stock issuance for acquired intangible assets	$ —	$ 4,600	$ —
Indemnification Holdback liability for common stock issuance in exchange for acquired intangible assets	$ —	$ 831	$ —

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

Mirum Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of Business

Mirum Pharmaceuticals, Inc. (the "Company") was incorporated in the State of Delaware on May 2, 2018, and is headquartered in Foster City, California. The Company is a biopharmaceutical company focused on the identification, acquisition, development and commercialization of novel therapies for debilitating rare and orphan diseases.

The Company has three approved medicines: LIVMARLI® (maralixibat) oral solution ("Livmarli"), Cholbam® (cholic acid) capsules, and Chenodal® (chenodiol) tablets ("Chenodal"). Livmarli is approved for the treatment of cholestatic pruritus in patients with Alagille syndrome ("ALGS") three months of age and older and cholestatic pruritus in patients with primary familial intrahepatic cholestasis ("PFIC") five years of age and older in the United States, and for the treatment of cholestatic pruritus in patients with ALGS two months of age and older in Europe.

On July 16, 2023, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Travere Therapeutics, Inc., a Delaware corporation ("Travere"), pursuant to which, upon the closing in August 2023, the Company acquired Travere's bile acid product portfolio, including Chenodal and Cholbam (also known as Kolbam, and together with Chenodal, the "Bile Acid Medicines"), two therapies addressing rare diseases in high-need settings (such acquisition, the "Bile Acid Portfolio Acquisition") (Note 7). Cholbam is FDA-approved for the treatment of bile acid synthesis disorders due to single enzyme deficiencies and adjunctive treatment of peroxisomal disorders in patients who show signs or symptoms or liver disease. Chenodal is approved for the treatment of radiolucent stones in the gallbladder and has received medical necessity recognition by the FDA for the treatment of cerebrotendinous xanthomatosis ("CTX").

The Company's development pipeline consists of the clinical-stage product candidate volixibat and life-cycle extension opportunities for Livmarli. The Company commenced significant operations in November 2018.

The Company views its operations and manages its business as one operating segment. The Company determined its operating segment on the same basis that it uses to evaluate its performance internally.

Liquidity

The Company has a limited operating history, has incurred significant operating losses since its inception, and the revenue and income potential of the Company's business and market are unproven. As of December 31, 2023, the Company had an accumulated deficit of $556.2 million and cash and cash equivalents of $286.3 million. The Company believes that its cash and cash equivalents of $286.3 million as of December 31, 2023 provide sufficient capital resources to continue its operations for at least twelve months from the issuance date of the accompanying consolidated financial statements. The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities.

In April 2023, the Company completed a convertible notes offering, as further described in Note 10, with net proceeds of $305.3 million, after deducting the initial purchasers' discounts and commissions and offering expenses. From the net proceeds, $192.7 million was used to repurchase all future revenue interests (the "Revenue Interests") in connection with the Company's Revenue Interest Purchase Agreement ("RIPA") (Note 6). Upon repurchase and the termination of the RIPA, in accordance with its terms, the previously restricted cash equivalents of $100.0 million were no longer restricted from use.

In August 2023, the Company completed the Bile Acid Portfolio Acquisition contemplated by the Purchase Agreement and acquired substantially all of the assets of Travere that are primarily related to the development, manufacture and commercialization of the Bile Acid Medicines. Under the terms of the Purchase Agreement, the

Company paid an upfront purchase price of $210.4 million in cash to Travere and may pay additional amounts of up to $235.0 million upon the achievement of certain milestones based on specified amounts of net annual sales of the Bile Acid Medicines. In connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, the Company completed the private placement of 8,000,000 shares of the Company's common stock at a price per share of $26.25, resulting in net proceeds of approximately $202.2 million.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The Company translates the financial statements of its foreign subsidiaries using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the financial statements and accompanying notes. These estimates and assumptions are based upon historical experience, knowledge of current events and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results could differ materially from those estimates.

The Company’s consolidated financial statements as of and for the year ended December 31, 2023 reflect the Company’s estimates of the impact of the geopolitical and macroeconomic environment, including the impact of inflation, bank failures, high interest rates and foreign exchange rate fluctuations. The duration and the scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact the Company’s business, results of operations and financial condition, is uncertain. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company’s assets or liabilities as of the date of this filing.

Cash, Cash Equivalents and Restricted Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash without penalty and with original maturities of three months or less at the date of purchase to be cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

Restricted cash equivalents as of December 31, 2022 consisted of deposits placed in a segregated bank account as required under the terms of the Company’s RIPA, as amended in September 2021, with Mulholland SA LLC, an affiliate of Oberland Capital LLC (“Oberland”), as agent for the purchasers party thereto (the “Purchasers”), and the Purchasers in connection with the sale of the Priority Review Voucher in December 2021. Upon repurchase and the termination of the RIPA in April 2023, in accordance with its terms, the previously restricted cash equivalents of $100.0 million were no longer restricted from use.

The following table provides a reconciliation of cash, cash equivalents and restricted cash equivalents reported within the consolidated balance sheets that together reflect the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 286,326	$ 28,003
Restricted cash equivalents	—	100,000
Total cash, cash equivalents, and restricted cash equivalents	$ 286,326	$ 128,003

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, accounts receivable and investments. The Company limits the amount of credit exposure by investing cash that is not required for immediate operating needs in money market funds, government obligations and/or commercial paper with short maturities. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. To date, the Company has not experienced any losses associated with this credit risk and continues to believe that this exposure is not significant.

The Company relies on a specialty pharmacy and a single distributor for all of the Company's sales of Livmarli in the United States as well as a single distributor for sales outside the United States. The Company relies on a specialty pharmacy for all the Company's sales of Chenodal and Cholbam in the United States.

The Company sources materials and services through several vendors. Certain materials are sourced from a single vendor. The loss of certain vendors could result in a temporary disruption of the Company's commercialization efforts.

As of December 31, 2023, the Company did not have any customers that individually accounted for more than 10% of accounts receivable. As of December 31, 2022, the Company had one customer that accounted for approximately 23% of accounts receivable. For the years ended December 31, 2023, 2022 and 2021, the Company did not have revenue attributable to any one customer in excess of 10% of sales.

Investments

The Company classifies all investments in securities as available-for-sale. Management determines the appropriate classification of its investments in securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the balance sheet date, are classified as a current asset.

Investments are recorded at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized, with the exception of any declines in fair value below the cost basis that are a result of a credit loss, which, if any, are reported in other income (expense), net in the current period through an allowance for credit losses. Each reporting period, the Company evaluates whether declines in fair values of its available-for-sale securities below their cost basis are a result of credit loss or other factors and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, the creditworthiness of the security issuers, as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis and are also included in other income (expense). To date, the Company has not identified any declines in fair value of its investments related to credit loss.

Fair Value of Financial Instruments

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. The following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1: Observable inputs (unadjusted) such as quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly for similar assets or liabilities; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Accounts Receivable

The Company has accounts receivable amounts due from product sales. The Company also has accounts receivable amounts due from license agreements for milestones achieved, but not yet paid. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company estimates the allowance for credit losses using the current expected credit loss model. Under this model, the allowance for credit losses reflects the Company's estimate of lifetime expected credit losses. The Company evaluates the collectability of the cash flows based on the risk of loss over the contractual life, even when that risk is remote, based on judgments about the creditworthiness of its customers, historical experience and other relevant information that is available to the Company. There was no allowance for credit losses as of December 31, 2023. There was no bad debt expense for the years ended December 31, 2023, 2022 and 2021.

Inventory

Inventory is valued at the lower of cost or net realizable value, with cost determined on a first-in, first-out (FIFO) basis. The Company periodically reviews the composition of inventory to identify excess, obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the decline in value is recognized through a charge to cost of sales. Furthermore, the Company periodically reviews its firm commitments for the purchase of minimum order quantities. If the minimum order quantities exceed the Company's future demand, a net loss is accrued in cost of sales for such future inventory purchases. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

Accruals for firm purchase commitments amounted to $5.2 million as of December 31, 2023, of which $3.8 million was included in other liabilities on the consolidated balance sheets.

Prior to the initial regulatory approval for Livmarli, the Company expensed costs relating to raw materials and production of inventory as research and development expense in the accompanying consolidated statements of operations, in the period incurred. The Company has substantially depleted such inventories as of December 31, 2023.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, ranging from three to five years. Leasehold improvements are amortized over the shorter of their useful lives or the related lease term. As of December 31, 2023, property and equipment consisted primarily of leasehold improvements of $1.3 million and furniture and equipment of $0.9 million. As of December 31, 2022, property and equipment consisted primarily of leasehold improvements of $1.3 million and furniture and equipment of $0.6 million. Accumulated depreciation as of December 31, 2023 and 2022 was $1.5 million and $1.0 million, respectively. Depreciation expense was $0.3 million for each of the years ended December 31, 2023, 2022 and 2021.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment loss is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the projected discounted future cash flows arising from these assets. There were no impairments of long-lived assets for any of the periods presented.

Intangible Assets, Net

The Company accounts for asset acquisitions that do not meet the definition of a business using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the asset (or assets) acquired on the basis of its (or their) relative fair value(s) on the measurement date. No goodwill is recognized in an asset acquisition.

Intangible assets are measured at their fair values as of the acquisition date or, in the case of commercial milestone payments, the date they become due. The evaluation of intangible assets includes assessing the amortization period for which the asset is expected to contribute to the future cash flows of the Company. Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis when the Company is unable to reliably estimate the pattern of cash flow. The Company tests its finite lived intangible assets for impairment annually or if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. If it is determined that the asset is impaired, the carrying value is written down to its estimated fair value, with the related impairment charge recognized in the consolidated statements of operations in the period in which the impairment occurs. The Company has not recorded any impairments to its intangible assets for any of the periods presented.

The components of the Company's intangible assets were as follows (in thousands, except for weighted-average remaining amortization period):

	December 31, 2023			
	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Amortization Period (Years)
Commercial milestones	$ 39,000	$ (3,318)	$ 35,682	16.2
Developed technology	226,620	(10,239)	216,381	11.7
Assembled workforce	970	(108)	862	2.7
Total intangible assets	$ 266,590	$ (13,665)	$ 252,925	12.3

	December 31, 2022			
	Gross Carrying Value	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Amortization Period (Years)
Commercial milestones	$ 34,000	$ (1,333)	$ 32,667	17.1
Developed technology	28,107	(1,820)	26,287	8.4
Total intangible assets	$ 62,107	$ (3,153)	$ 58,954	11.9

Amortization expense was $10.5 million, $2.9 million and $0.3 million for the years ended December 31, 2023, 2022 and 2021, respectively, and was included in cost of sales on the accompanying consolidated statements of operations.

The following table summarizes the estimated future amortization expense associated with the Company's intangible assets as of December 31, 2023 (in thousands):

	Amount
2024	$ 21,545
2025	21,545
2026	21,436
2027	21,221
2028	21,221
Thereafter	145,957
	$ 252,925

Leases

The Company determines if a contractual arrangement is or contains a lease at inception. Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating leases are included in ROU assets, current operating lease liabilities, and long-term operating lease liabilities on the accompanying consolidated balance sheets. Operating lease ROU assets and lease liabilities are initially recognized based on the present value of the future minimum lease payments over the lease term at commencement date calculated using the Company's incremental borrowing rate applicable to the leased asset, unless the implicit rate is readily determinable. Operating lease ROU assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The Company determines the lease term as the noncancelable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets. The Company's leases do not contain any residual value guarantees. Lease expense for minimum lease payments is recognized as rent expense on a straight-line basis over the lease term. Variable lease payments include lease operating expenses.

Accrued Research and Development Expenses

The Company accrues and expenses clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the life of the individual study and patient enrollment rates in accordance with agreements established with clinical research organizations and clinical trial sites. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

The Company makes estimates of accrued expenses as of each balance sheet date based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The Company has not experienced any material differences between accrued costs and actual costs incurred for the periods presented. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Convertible Notes

The Company evaluates all conversion, repurchase and redemption features contained in a debt instrument to determine if there are any embedded features that require bifurcation as a derivative. The Company accounts for its convertible notes (refer to Note 10) as a long-term liability equal to the proceeds received from issuance, including any embedded conversion features, net of the unamortized debt discount and offering costs in the accompanying consolidated balance sheets. The debt issuance and offering costs are amortized over the contractual term of the convertible notes, using the effective interest method, as interest expense in the accompanying consolidated statements of operations.

Revenue Interest Liability, Net

The revenue interest liability, net, associated with the RIPA that the Company entered into in December 2020, as amended in September 2021, with Oberland as agent for Purchasers, and the Purchasers, was presented net of issuance costs and a debt discount on the consolidated balance sheet as of December 31, 2022. The Company imputed interest expense associated with this liability using the effective interest rate method. The effective interest rate was calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on the liability varied during the term of the agreement depending on a number of factors, including the level of actual and forecasted product sales, net. The Company evaluated the interest rate quarterly based on actual product sales, net and forecast product sales, net, utilizing the prospective method. In April 2023, the Company repurchased all future Revenue Interests and as a result, the RIPA was terminated in accordance with its terms (refer to Note 6).

Derivative Liability

The RIPA contained certain features that met the definition of being an embedded derivative requiring bifurcation as a separate compound financial instrument apart from the RIPA. The derivative liability was initially measured at fair value on issuance and was subject to remeasurement at each reporting period with changes in fair value recognized as other income (expense) in the accompanying consolidated statements of operations as the change in fair value of derivative liability. In April 2023, the derivative liability was extinguished in connection with the termination of the RIPA (refer to Note 6).

Revenue Recognition

The Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services.

Product Sales, Net

The Company recognizes product sales, net when the customer obtains control of our product, which occurs at a point in time, typically upon delivery of the Company's product to the customer.

Revenues from product sales are recorded at the net sales price, or the transaction price, which may include fixed or variable consideration for discounts, government rebates, co-pay assistance, returns and other allowances that are offered within contracts with a customer relating to the sale of the Company's approved medicines. Estimates of variable consideration are calculated based on the actual product sales each reporting period and the nature of the variable consideration related to those sales. Overall, these estimates reflect the Company's best estimate of the amount of consideration to which the Company expects to be entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in product sales, net only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimates are reviewed and updated quarterly as additional information becomes known. Actual amounts of consideration ultimately received may differ materially from estimates. If actual results in the future vary from estimates, the Company will adjust these estimates, which would affect product sales, net and earnings in the period such variances are adjusted. Significant categories of sales discounts and allowances are as follows:

Government Rebates: The Company records rebates payable under Medicaid and other government programs as a reduction of revenue at the time product revenues are generated. The Company's rebate calculations may require estimates, including estimates of customer mix, to determine which sales will be subject to rebates and the amount of such rebates. The Company updates its estimates and assumptions on a quarterly basis and records any necessary adjustments to revenue in the period identified. The liability for unpaid rebates is included in accrued expenses on the accompanying consolidated balance sheets. To date, actual government rebates have not differed materially from the Company's estimates.

Other Incentives: Other incentives include a branded co-pay assistance program for eligible patients with commercial insurance in the United States. The branded co-pay assistance program assists commercially insured patients who have coverage for the Company's approved medicines and is intended to reduce each participating patient's portion of the financial responsibility of the purchase price up to a specified dollar amount of assistance. The calculation of the accrual for co-pay assistance is based upon an identification of claims and the cost per claims associated with product that has been recognized as revenue. The Company records amounts paid under the brand specific co-pay assistance program for each patient as a reduction of revenue from product sales. To date, actual other incentives have not differed materially from the Company's estimates.

Product Returns: The Company records revenue for product sales, net of estimated product returns. Customers have limited return rights related only to the product's damage or defect identified upon delivery of the product. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period the related product revenue is recognized. To date, actual returns have not differed materially from the Company's estimates.

The following table presents Total revenues and disaggregates Product sales, net by approved medicine (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Product sales, net:			
Livmarli	$ 141,795	$ 75,062	$ 3,138
Bile Acid Medicines	37,079	—	—
Total product sales, net	178,874	75,062	3,138
License revenue	7,500	2,000	16,000
Total revenues	$ 186,374	$ 77,062	$ 19,138

The following table sets forth Product sales, net by geographic area based on the ship-to location (in thousands):

	Year Ended December 31,		
	2023	2022	2021
United States	$ 146,699	$ 67,920	$ 2,913
Rest of world	32,175	7,142	225
Total product sales, net	$ 178,874	$ 75,062	$ 3,138

License and Collaboration Arrangements

The Company enters into collaborative arrangements with partners and analyzes the collaboration arrangements to assess whether they are within the scope of *Collaborative Arrangements (Topic 808)* ("Topic 808") and determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. The accounting for some of the activities under collaboration arrangements may be subject to *Revenue from Contracts with Customers (Topic 606)* ("Topic 606") for distinct units of account that are reflective of a vendor-customer relationship. For other elements of collaboration arrangements, such as reimbursements of certain development costs, the Company generally records reimbursements received as a reduction of research and development expenses.

In determining the appropriate amount of revenue to be recognized under Topic 606 as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the contracts with customers; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) determination and measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The terms of the Company's license and collaborative research and development agreements include upfront license fees, research, development and other funding or reimbursements, milestone and other contingent payments for the achievement of defined collaboration objectives and certain development, regulatory and sales-based events, as well as royalties on sales of commercialized products. Arrangements that include upfront payments may require deferral of revenue recognition to a future period until the Company satisfies performance obligations under these arrangements.

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting in Topic 606. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the applicable performance obligation is satisfied.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues attributed to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price as variable consideration using the most likely amount method or expected value method, depending on the nature of the contingency and the variable payments. If it is probable that a significant reversal of cumulative revenue recognized for the contract would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not generally considered probable of being achieved until those approvals are received. Given the high degree of uncertainty around the occurrence of these events, the Company generally determines the milestone and other contingent amounts to be fully constrained until the uncertainty associated with these payments is resolved. At the end of each reporting period, the Company re-evaluates the probability of achievement of any development milestones, and if necessary, adjusts its estimate of the transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, the Company recognizes revenue at the later of (i) when or as the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Accounting for these arrangements requires the Company to develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company has never sold the performance obligations in its collaborative arrangements separately; therefore, an observable stand-alone selling price does not exist. Accordingly, the Company estimates a stand-alone selling price through maximizing the use of observable inputs such as market data, project cost estimates, and targeted margins.

Cost of Product Sales

Prior to receiving approval from the U.S. Food and Drug Administration ("FDA") or other foreign regulatory authorities for a new medicine or new formulation, the Company expenses all costs incurred related to the manufacture of such medicines as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for the Company of regulatory approval of drug candidates. Subsequent to receiving FDA or other foreign regulatory authority approval, when commercialization is considered probable and the future economic benefit is expected to be realized, the Company begins capitalizing inventory costs incurred.

Cost of product sales consist of manufacturing costs, transportation and freight, amortization of capitalized intangible assets, royalties and indirect overhead costs associated with the manufacturing and distribution of the Company's approved products. Cost of product sales may also include period costs related to certain manufacturing services and inventory adjustment charges.

Research and Development Expenses

Research and development expenses consists primarily of fees paid to contract research organizations and other vendors for clinical, non-clinical and manufacturing services, salaries and employee benefits, including stock-based compensation, consultant expenses, costs related to acquiring manufacturing materials, costs related to compliance with regulatory requirements and license payments related to acquiring intellectual property rights for the Company’s product candidates. Research and development expenses are expensed as incurred.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses relate to sales and marketing, finance, human resources, legal and other administrative activities. SG&A expenses consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses, and other general and administrative costs.

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $6.3 million, $4.0 million and $9.2 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Stock-Based Compensation

The Company recognizes stock-based compensation for all stock-based awards based on the grant date fair value of the award granted to employees and nonemployees, including members of its board of directors. For stock-based awards with service conditions, the fair value of the awards is recognized on a straight-line basis over the requisite service period in which the awards are expected to vest. For stock-based awards with performance vesting conditions, stock-based compensation is recognized when it is considered probable that the performance conditions will be satisfied. At each reporting period, the Company reassesses the probability of the achievement of the performance vesting conditions. Any change in stock-based compensation resulting from an adjustment in the vesting is treated as a cumulative catch-up in the period of adjustment. For stock-based awards with market conditions, stock-based compensation is recognized over the appropriate requisite service period. The Company accounts for forfeitures as they occur.

The Company evaluates the grant date fair value of awards granted for impacts of any potential material non-public information at the time of grant.

Foreign Currency

The consolidated financial statements are presented in U.S. dollars. The functional currency for most of the Company's foreign subsidiaries is their local currency. Balance sheet accounts of international subsidiaries are translated at the current exchange rates as of the end of each accounting period. Income statement items are translated at average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of stockholders' equity.

Foreign currency transaction gains and losses are included in other income (expense), net in the consolidated statements of operations. Transaction gains and losses result primarily from fluctuations in exchange rates when intercompany receivables and payables are denominated in currencies other than the functional currency of our subsidiary that recorded the transaction. Unrealized foreign exchange losses amounted to $1.8 million for the year ended December 31, 2023, and were insignificant for the years ended December 31, 2022 and 2021. Realized foreign exchange gains and losses were insignificant for the years ended December 31, 2023, 2022 and 2021.

Income Taxes

Income taxes are recorded using the liability method, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are recorded against deferred tax assets, including net operating losses and tax credits, when it is determined it is more-likely-than-not that some or all of the tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification No. 740, *Income Taxes* ("ASC 740"). When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Interest and penalties related to unrecognized tax benefits, if any, are recorded as a component of income tax expense.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. Diluted net loss per share excludes the potential impact of the Company's common stock subject to repurchase, common stock options, restricted stock units, contingently issuable employee stock purchase plan shares and common stock issuable upon conversion of convertible notes because their effect would be anti-dilutive due to the Company's net loss.

The following table sets for the computation of basic and diluted earnings per share for the years ended December 31, 2023, 2022 and 2021(in thousands, except share and per share data):

	Year Ended December 31, 2023	2022	2021
Numerator:			
Net loss, basic	$ (163,415)	$ (135,665)	$ (83,988)
Add: Change in fair value of Holdback Indemnification liability	—	(214)	—
Add: Change in fair value of Contingent Milestone liability	—	(700)	—
Net loss, diluted	$ (163,415)	$ (136,579)	$ (83,988)
Denominator:			
Weighted-average shares of common stock outstanding, basic	40,885,124	33,839,072	30,321,722
Effect of dilutive securities:			
Weighted-average Holdback-Indemnification shares issuable	—	19,590	—
Weighted-average contingent milestone shares	—	123,831	—
Weighted-average shares of common stock outstanding, diluted	40,885,124	33,982,493	30,321,722
Net loss per share, basic	$ (4.00)	$ (4.01)	$ (2.77)
Net loss per share, diluted	$ (4.00)	$ (4.02)	$ (2.77)

The following outstanding potential dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of December 31, 2023	2022	2021
Options to purchase common stock and restricted stock units	10,909,831	8,955,557	6,940,556
Common stock issuable upon conversion of convertible notes	9,964,247	—	—
Employee stock purchase plan contingently issuable	23,054	26,305	23,116
Common stock subject to repurchase	—	—	122,464
Total	20,897,132	8,981,862	7,086,136

Recently Adopted Accounting Pronouncements

On January 1, 2023, the Company adopted Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to utilize a new impairment model that requires measurement and recognition of expected credit losses for most financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The new guidance also modifies the impairment models for purchased financial assets with credit deterioration since their origination. There was no impact on the accompanying consolidated financial statements as of the adoption date.

In March 2020, the Financial Accounting Standards Board ("FASB") issued ASU No. 2020-3, *Codification Improvements to Financial Instruments* which makes narrow-scope improvements to various financial instruments topics, including the new credit losses standard and clarifies the following areas (i) the contractual term of a net investment in a lease should be the contractual term used to measure expected credit losses; (ii) when an entity regains control of financial assets sold, an allowance for credit losses should be recorded. The Company adopted this standard on January 1, 2023. There was no impact on the accompanying consolidated financial statements as of the adoption date.

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the accompanying consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). This new guidance is designed to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. Early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). This new guidance is designed to enhance the transparency and decision usefulness of income tax disclosures. The amendments of this update are related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements.

3. Fair Value Measurements

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type are presented in the following table (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 278,116	$ —	$ —	$ 278,116
Total financial assets	$ 278,116	$ —	$ —	$ 278,116

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 124,227	$ —	$ —	$ 124,227
U.S. treasury bills	4,975	—	—	4,975
Commercial paper	—	74,386	—	74,386
U.S. government bonds	—	44,354	—	44,354
Total financial assets	$ 129,202	$ 118,740	$ —	$ 247,942
Financial liabilities:				
Contingent milestone liability	$ 3,900	$ —	$ —	$ 3,900
Derivative liability	—	—	1,090	1,090
Indemnification holdback	—	—	617	617
Total financial liabilities	$ 3,900	$ —	$ 1,707	$ 5,607

The carrying amounts of certain financial instruments such as cash and cash equivalents, restricted cash equivalents, accounts receivable, prepaid expenses, other current assets, accounts payable and accrued expenses as of December 31, 2023 and 2022 approximate their related fair values due to the short-term maturities of these instruments.

Money market funds and U.S. treasury bills are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. government bonds and commercial paper are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date.

The carrying amount of the revenue interest liability as of December 31, 2022 approximates its fair value and is based on the Company's contractual repayment obligation to the Purchasers, based on the current estimates of future revenues, over the life of the RIPA.

At the time of issuance, the Contingent Milestone liability was recognized at fair value using Level 3 inputs as no observable inputs were available at the time in the market. As of December 31, 2022, the Contingent Milestone liability is considered a Level 1 input as the significant inputs were known and observable. The derivative liability and Indemnification Holdback liability (each as defined below) as of December 31, 2022 are each considered a Level 3 input based on the three-level hierarchy.

Derivative Liability

The debt pursuant to the RIPA (refer to Note 6 "Revenue Interest Purchase Agreement" for further information) contained an embedded derivative requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" method. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative was the fair value of the derivative liability at December 31, 2022. The estimated probability and timing of underlying events triggering the exercisability of the put option contained within the RIPA, forecasted cash flows and the discount rate were significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. As of December 31, 2022, the discount rate used for valuation of the derivative liability was 15.7%. In 2023, there was no change in the fair value of the derivative liability prior to its extinguishment in connection with the termination of the RIPA in April 2023.

Indemnification Holdback and Contingent Milestone Liabilities

In May 2022, in connection with the acquisition of Satiogen (refer to Note 7 "Asset Acquisitions" for further information), the Company recorded at fair value liabilities related to the Company's common stock issuable upon satisfaction of certain purchase price adjustments and indemnification obligations that may arise during the 12 month period following the asset acquisition date ("Indemnification Holdback") and contingent consideration upon achievement of a certain milestone ("Contingent Milestone"). The fair value of the Indemnification Holdback and the Contingent Milestone was classified within Level 3 of the fair value hierarchy and was estimated based upon the value of the Company's common stock price. The fair value of the Indemnification Holdback was additionally determined based on management's estimate of the probability of indemnification obligations being incurred during the one year following the acquisition date, while the fair value of the Contingent Milestone was additionally determined based upon management's estimate of the probability of the milestone being met. The fair value of the Indemnification Holdback and Contingent Milestone was initially measured on May 20, 2022, the date on which the Company completed the acquisition of Satiogen. The Company assessed the fair value of the Indemnification Holdback and Contingent Milestone each reporting period until resolution of the related contingency, and changes in fair value were recorded in other income (expense), net in the accompanying consolidated statements of operations. As of December 31, 2022, the contingency for the Contingent Milestone was resolved and the fair value of the liability was determined based solely upon the closing price of the Company's common stock. In January 2023, the Company issued 199,993 shares of common stock in connection with the Contingent Milestone liability. In June 2023, the contingencies related to the Indemnification Holdback were resolved and the Company issued 31,631 shares of common stock.

The following table provides a summary of the changes in the estimated fair value of the Indemnification Holdback and Contingent Milestone liability within Level 3 of the fair value hierarchy (in thousands):

	Indemnification Holdback Liability	Contingent Milestone Liability
Balance at January 1, 2022	$ —	$ —
Initial recognition	831	4,600
Change in fair value	(214)	(700)
Transfer out of Level 3 fair value hierarchy	—	(3,900)
Balance at December 31, 2022	617	—
Change in fair value	279	—
Settlement of Indemnification Holdback liability	(896)	—
Balance at December 31, 2023	$ —	$ —

The Contingent Milestone and Indemnification Holdback liability is included in other liabilities on the accompanying consolidated balance sheets as of December 31, 2022. There was no outstanding balance related to the Contingent Milestone and Indemnification Holdback liability as of December 31, 2023.

4. Financial Instruments

The fair value and amortized cost of cash equivalents and available-for-sale investments by major security type are presented in the following table (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents and investments:				
Money market fund	$ 278,116	$ —	$ —	$ 278,116
Total cash equivalents and investments	$ 278,116	$ —	$ —	$ 278,116
Classified as:				
Cash equivalents				$ 278,116
Total cash equivalents and investments				$ 278,116

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents and investments:				
Money market funds	$ 124,227	$ —	$ —	$ 124,227
U.S. treasury bills	4,980	—	(5)	4,975
Commercial paper	74,386	—	—	74,386
U.S. government bonds	44,579	—	(225)	44,354
Total cash equivalents and investments	$ 248,172	$ —	$ (230)	$ 247,942
Classified as:				
Cash equivalents				$ 24,226
Cash equivalents - restricted				100,000
Short-term investments				123,716
Total cash equivalents, restricted cash equivalents and investments				$ 247,942

During the years ended December 31, 2023 and 2022, there have been no significant realized gains or losses on available-for-sale investments, no investments have been in a continuous unrealized loss position for more than 12 months, and the Company did not recognize any credit losses on these securities.

5. Balance Sheet Components

Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 2,998	$ —
Work in progress	9,873	5,351
Finished goods	9,441	214
Total inventory	$ 22,312	$ 5,565

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2023		December 31, 2022	
Accrued compensation and related benefits	$	20,939	$	14,660
Accrued sales deductions		23,650		4,284
Accrued clinical trials		7,268		8,319
Accrued professional service fees		7,941		5,372
Accrued manufacturing and non-clinical costs		9,922		3,927
Accrued royalties payable		6,716		2,456
Accrued interest		2,108		—
Accrued milestone payments		—		15,000
Total accrued expenses	$	78,544	$	54,018

6. Revenue Interest Purchase Agreement

In December 2020, the Company entered into the RIPA, as amended in September 2021, with Oberland as agent for the Purchasers, and the Purchasers to obtain financing for the commercialization and further development of Livmarli and other working capital needs. Pursuant to the RIPA, the Company has received $115.0 million consisting of an upfront payment of $50.0 million in December 2020 and $65.0 million in April 2021 associated with the acceptance for filing by the FDA of a New Drug Application for Livmarli for the treatment of cholestatic pruritus in patients with ALGS, less certain transaction expenses.

Under the RIPA, the Company was entitled to receive an additional $35.0 million upon FDA approval of Livmarli, which it elected to forgo. The Company was also entitled to receive up to approximately $50.0 million at the option of the Purchasers to finance in-licenses or other acquisitions on or prior to December 31, 2022, which the Company did not request.

As consideration for such payments, the Purchasers had the right to receive the Revenue Interests from the Company based on annual product sales, net of Livmarli, in tiered payments (the “Revenue Interest Payments”) based on whether annual product sales, net were (i) less than or equal to $350.0 million (“Tier 1”), (ii) exceeding $350.0 million and less than or equal to $1.1 billion (“Tier 2”), or (iii) exceeding $1.1 billion (“Tier 3”). The Revenue Interest Payments were initially 9.75% (at Tier 1) and 2.0% (at Tier 2 and Tier 3) of such annual net sales.

Under the RIPA, the Company had an option (the “Call Option”) to terminate the RIPA and repurchase future Revenue Interests at any time upon advance written notice. Additionally, the Purchasers had an option (the “Put Option”) to terminate the RIPA and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect or a change of control, or upon the 12^{th} anniversary of the first payment made by Purchasers. If the Put Option is exercised prior to the first anniversary of the closing date by the Purchasers (except pursuant to a change of control), the required repurchase price is 120.0% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests). In all other cases, if the Put Option or the Call Option are exercised, the required repurchase price is 175.0% of the Cumulative Purchaser Payments (minus all payments the Company has made to the Purchasers in connection with the Revenue Interests), if such option is exercised prior to the third anniversary of the closing date, and 195.0% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests) if such option is exercised thereafter.

In addition, the RIPA contained various representations and warranties, information rights, non-financial and financial covenants, indemnification obligations and other provisions that are customary for a transaction of this nature. The Purchasers’ obligations to fund the scheduled installments were subject to certain customary conditions as set forth in the RIPA.

Concurrently with the RIPA, the Company entered into a Common Stock Purchase Agreement ("CSPA") with certain affiliates of Oberland, pursuant to which the Company sold an aggregate of 509,164 shares of its common stock for an aggregate purchase price of $10.0 million. The $50.0 million upfront payment received pursuant to the RIPA and $10.0 million received pursuant to the CSPA was allocated between the resulting financial instruments on a relative fair value basis, with $49.2 million allocated to the debt under the RIPA and $10.8 million allocated to the common stock issued under the CSPA.

The Put Option under the RIPA that was exercisable by Purchasers upon certain contingent events was determined to be an embedded derivative requiring bifurcation and separately accounted for as a single compound derivative instrument. The Company recorded the initial fair value of the derivative liability of $1.3 million as a debt discount, which was amortized to interest expense over the expected term of the debt using the effective interest method.

The Company imputed interest expense associated with the revenue interest liability using the effective interest rate method. The effective interest rate was calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability was variable during the term of the agreement depending on a number of factors, including the level of forecasted product sales, net. The Company evaluated the interest rate quarterly based on each period's product sales, net forecasts utilizing the prospective method. The Company recorded interest expense related to this arrangement of $5.1 million, $16.0 million and $17.6 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The Company incurred $0.9 million of issuance costs in connection with the RIPA, which were being amortized to interest expense over the estimated term of the debt.

In April 2023, the Company exercised the Call Option and repurchased all future Revenue Interests. In connection with such repurchase, the Company made a payment of $192.7 million, or 175% of the Cumulative Purchaser Payments (minus all payments that were made to the Purchasers in connection with the Revenue Interests). As a result, the RIPA terminated in accordance with its terms.

The following table summarizes the revenue interest liability activity during the years ended December 31, 2023 and 2022 (in thousands):

	Revenue Interest Liability	Derivative Liability
Balance at January 1, 2022	$ 129,923	$ 1,996
Interest expense recognized	15,979	—
Revenue interest payments	(5,551)	—
Change in fair value	—	(906)
Revenue interest liability at December 31, 2022	140,351	1,090
Interest expense recognized	5,060	—
Revenue interest payments	(2,883)	—
Revenue interest liability settlement	(192,694)	—
Loss (gain) from termination of revenue interest purchase agreement	50,166	(1,090)
Revenue interest liability at December 31, 2023	$ —	$ —

The net loss from termination of the RIPA of $49.1 million, comprised of the $50.2 million loss related to the settlement of the revenue interest liability and the $1.1 million gain on the derecognition of the related derivative liability, was recorded in the accompanying consolidated statements of operations. As of December 31, 2023, there were no outstanding balances related to the revenue interest liability and the derivative liability.

7. Asset Acquisitions

Asset Purchase Agreement with Travere Therapeutics, Inc.

On August 31, 2023, the Company completed the Bile Acid Portfolio Acquisition.

In accordance with the terms and conditions of the Purchase Agreement, the Company purchased from Travere substantially all of the assets related to its business of development, manufacturing (including synthesis, formulation, finishing or packaging) and commercialization of the Bile Acid Medicines. The Company paid $210.4 million upon closing of the transaction, and up to an additional $235.0 million is payable upon the achievement of certain milestones based on specified amounts of annual net sales of the Bile Acid Medicines. The Company assessed the fair value of this contingent consideration in its determination of whether the acquisition of the Bile Acid Portfolio should be accounted for as an asset acquisition. The Company estimated the fair value of the contingent consideration using a Monte Carlo simulation model, which includes the amount and timing of revenue projections subsequent to the acquisition date as a significant assumption.

The Company and Travere concurrently entered into a transitional services agreement pursuant to which Travere is obligated to perform certain services for a period of time, not anticipated to last beyond 12 months post-close, with respect to the Company's use and operation of the assets purchased.

The Company accounted for the transaction as an asset acquisition as substantially all the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets, namely, the developed technology related to the Bile Acid Medicines. The developed technology asset consists of certain processes and at-market contracts related to the manufacture and commercialization of the Bile Acid Medicines, regulatory approvals, and other assets, and are considered a single asset as they are interdependently linked. The Company estimated the fair value of the developed technology asset using the discounted cash flow method. This approach incorporates significant estimates and assumptions related to the forecasted results including, but not limited to, estimates and assumptions regarding revenues, expenses, and discount rates to estimate future cash flows. The Company determined that the developed technology asset acquired was commercially viable and the cost of the acquisition was recorded as an intangible asset in the accompanying consolidated balance sheet as of December 31, 2023. The acquired assets are amortizable for tax purposes.

The Company is obligated to pay tiered royalties, based on licensing agreements acquired with the Bile Acid Medicines, with rates ranging from high single digit to mid-teens based on net sales of the Bile Acid Medicines.

The following represents the consideration paid and allocation of the purchase price for the acquisition of the Bile Acid Medicines (in thousands):

Cash consideration	$	210,378
Transaction costs		2,384
Total purchase consideration		212,762
Assets acquired:		
Inventory		12,900
Intangible assets - developed technology		198,513
Intangible assets - assembled workforce		970
Other current and noncurrent assets		379
Total assets acquired	$	212,762

The Company amortizes the acquired intangible assets straight-line over their estimated useful lives of 12.5 years for developed technology and 3 years for assembled workforce (Note 2).

Assignment and License Agreement with Shire International GmbH (Takeda)

In November 2018, the Company entered into an Assignment and License Agreement (the "Shire Agreement") with Shire International GmbH ("Shire"), which was subsequently acquired by Takeda Pharmaceutical Company Limited ("Takeda"). Under the terms of the Shire Agreement, Shire granted the Company an exclusive, royalty bearing worldwide license to develop and commercialize its two product candidates, Livmarli and volixibat. As part of the Shire Agreement, the Company was assigned license agreements held by Shire with Satiogen, Pfizer Inc. ("Pfizer") and Sanofi-Aventis Deutschland GmbH ("Sanofi"). The Company has the right to sublicense under the Shire Agreement and additionally has the right to sublicense under the Satiogen, Pfizer and Sanofi licenses subject to the terms of those license agreements.

The Company is obligated to pay Shire up to an aggregate of $109.5 million upon the achievement of certain clinical development and regulatory milestones for Livmarli in certain indications and an additional $25.0 million upon regulatory approval of Livmarli for each and every other indication. In addition, the Company is required to pay up to an aggregate of $30.0 million upon the achievement of certain clinical development and regulatory milestones for volixibat solely for the first indication sought. Upon commercialization, the Company is obligated to pay Shire product sales milestones on total licensed products up to an aggregate of $30.0 million. The Company is also obligated to pay tiered royalties with rates ranging from low double-digits to mid-teens based upon annual worldwide net sales for all licensed products; however, these royalties are reduced in part by royalties due under the Satiogen and Sanofi licenses, as discussed below, related to Livmarli and volixibat, as applicable. The Company's royalty obligations will continue on a licensed product-by-licensed product and country-by-country basis until the later to occur of the expiration of the last valid claim in a licensed patent covering the applicable licensed product in such country, expiration of any regulatory exclusivity for the licensed product in a country and ten years after the first commercial sale of a licensed product in such country. As of December 31, 2022, the Company accrued $15.0 million for a regulatory milestone associated with approval of Livmarli by the European Commission for the treatment of cholestatic pruritus in patients with ALGS two months of age and older, which was paid by the Company in January 2023. In September 2023, the Company accrued $5.0 million for a commercial milestone associated with product sales, which was paid by the Company in December 2023. No additional milestones were accrued as of December 31, 2023 as there were no potential milestones yet considered probable. There were no volixibat development and regulatory milestones achieved during the years ended December 31, 2023 and 2022.

On March 13, 2024, the Company received regulatory approval for Livmarli for the treatment of cholestatic pruritus in patients with PFIC five years of age and older by the FDA for marketing in the U.S. In connection with this approval, the Company will accrue and pay a $10.0 million regulatory milestone under this license agreement.

Satiogen License

Through the Shire Agreement, the Company was assigned a license agreement with Satiogen pursuant to which the Company obtained an exclusive, worldwide license to certain patents and know-how, with the right to sublicense to a third party subject to certain financial considerations. Pursuant to the terms of the license agreement, the Company was obligated to pay to Satiogen up to an aggregate of $10.5 million upon the achievement of certain milestones, of which $0.5 million was for initiation of certain development activities, $5.0 million for the completion of regulatory approvals and $5.0 million for commercialization activities. Additionally, the Company was required to pay a low single-digit royalty on net sales. The Company's royalty obligations continued on a licensed product-by-licensed product and country-by-country basis until the expiration of the last valid claim in a licensed patent covering the applicable licensed product in such country. Royalty obligations under the Satiogen license were creditable against the royalty obligations to Shire under the Shire Agreement. The Company has not paid milestone payments pursuant to this agreement for the periods presented.

In May 2022, the Company completed the merger and acquisition of Satiogen for total consideration of approximately $24.2 million. At acquisition, Satiogen's assets consisted of cash and intangible assets related to developed technology. The purchase consideration consisted of 609,305 shares of the Company's common stock issued upon the closing of the acquisition and cash consideration of $2.6 million, excluding $0.2 million of stock option exercise prices deemed to have been paid immediately prior to the acquisition, in respect of an equivalent amount of cash on the books of Satiogen, with up to an additional 32,494 shares of common stock that would have been issued upon the closing of the acquisition except the parties agreed to such shares being held back by the Company for 12 months from the acquisition date to satisfy certain purchase price adjustments and indemnification obligations that may arise during this period. Specifically, purchase price adjustments and indemnification obligations that arise will reduce the number of shares issuable by the Company at settlement in accordance with the terms of the definitive acquisition agreement. The purchase consideration also included issuance of up to an additional 199,993 shares of the Company's common stock, contingent upon the achievement of a certain milestone by June 30, 2025, subject to adjustment to satisfy certain purchase price adjustments and indemnification obligations that may arise. In December 2022, with the approval of Livmarli by the European Commission for the treatment of cholestatic pruritus in patients with ALGS two months of age and older, the milestone was achieved and the Company issued 199,993 shares of common stock in January 2023. Additionally, in June 2023, the contingencies related to the held back shares were resolved and the Company issued 31,631 shares of common stock. Through the transaction, the Company obtained all Satiogen licensing payments and Satiogen-owned intellectual property relating to Livmarli and volixibat. The transaction resulted in a reduction of total licensing royalty obligations for Livmarli and volixibat.

The Company accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business and substantially all the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets, namely, the Satiogen intangible assets consisted of intellectual property. The Company evaluated that the intellectual property assets acquired were deemed to be commercially viable and the cost of the acquisition was recorded as an intangible asset.

There was no gain or loss recognized from settlement of the preexisting contractual relationship with Satiogen as the pre-existing contract was determined to be at fair value on the date of acquisition. Through the date of settlement in June 2023, there were no significant expenses incurred that were approved for settlement against the Indemnification Holdback.

As the number of shares potentially issuable upon the resolution of the Indemnification Holdback and the Contingent Milestone was variable, they were recorded as liabilities at their respective fair values on the date of acquisition using the Company's common stock price. The fair value of the Indemnification Holdback was additionally determined based on management's estimate of the probability of indemnification obligations being incurred during the one year following the acquisition date, while the fair value of the Contingent Milestone was additionally determined based upon management's estimate of the probability of the milestone being met until the contingency was resolved in December 2022. The fair value of the Indemnification Holdback liability and the Contingent Milestone liability were remeasured at each reporting period until settled, with resulting changes in the fair value recorded in other income (expense) in the accompanying consolidated statements of operations.

The following represents the consideration paid and allocation of purchase price for the acquisition of Satiogen (in thousands, except per share data):

Issued common stock	$	15,585
Cash consideration		2,600
Indemnification Holdback		831
Contingent consideration settled in common stock		4,600
Transaction costs		545
Total purchase consideration		24,161
Assets acquired:		
Intangible assets - developed technology		21,561
Cash consideration		2,600
Total assets acquired	$	24,161

Pfizer License

Through the Shire Agreement, the Company was assigned a license agreement with Pfizer pursuant to which the Company obtained an exclusive, worldwide license to certain Pfizer know-how with a right to sublicense. Upon commercialization of any product utilizing the licensed product, the Company will be required to pay to Pfizer a low single-digit royalty on net sales of product sold by the Company, its affiliates or sublicensees. The Company's royalty obligations continue on a licensed product-by-licensed product basis until the eighth anniversary of the first commercial sale of such licensed product anywhere in the world.

Sanofi License

Through the Shire Agreement, the Company was assigned a license agreement with Sanofi pursuant to which the Company obtained an exclusive, worldwide license to certain patents and know-how with the right to sublicense to a third party subject to certain financial considerations. The Company is obligated to pay up to an aggregate of $36.0 million upon the achievement of certain regulatory, commercialization and product sales milestones. Additionally, upon commercialization, the Company is required to pay tiered royalties in the mid to high single-digit range based upon net sales of licensed products sold by the Company and sublicensees in a calendar year, subject to adjustments in certain circumstances. The Company's royalty obligations continue on a licensed product-by-licensed product and country-by-country basis until the later to occur of the expiration of the last valid claim in a licensed patent covering the applicable licensed product in such country and ten years after the first commercial sale of a licensed product in such country. Royalty obligations under the Sanofi license are creditable against the royalty obligations to Shire under the Shire Agreement. The Company has not paid milestone payments pursuant to this agreement for the periods presented. As of December 31, 2023, no milestones had been accrued as there were no potential milestones considered probable.

8. Collaboration and License Agreements

License and Collaboration Agreement with CANbridge

In April 2021, the Company entered into an exclusive license and collaboration agreement with CANbridge Pharmaceuticals, Inc. ("CANbridge"). Under the terms of the agreement, CANbridge has obtained the exclusive right to develop and commercialize Livmarli within the Greater China regions (China, Hong Kong, Macau and Taiwan). In connection with the agreement, the Company received an upfront payment of $11.0 million, which, upon satisfaction of the performance obligation and receipt by CANbridge of the right to use and benefit from the license in May 2021, was recorded as license revenue. Additionally, the Company is eligible to receive up to $5.0 million in research and development funding, and up to $109.0 million for the achievement of future regulatory and commercial milestones, with double-digit tiered royalties based on product net sales. The Company concluded at inception of the agreement that the transaction price should not include the variable consideration related to unachieved developmental and regulatory milestones as this consideration was considered to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue. The Company will recognize any consideration related to sales-based payments when the related sales occur, as the Company has determined that these amounts relate predominantly to the license granted and therefore will be recognized at the later of (i) when or as the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. In January 2022 and June 2023, CANbridge achieved regulatory milestones, triggering milestone payments to the Company of $2.0 million and $5.0 million, respectively, which, upon the release of the constraints, were recorded as license revenue in the accompanying consolidated statements of operations for the years ended December 31, 2023 and 2022. For the years ended December 31, 2023, 2022 and 2021, the Company recorded research and development funding of $2.3 million, $0.9 million and $1.9 million, respectively, payable by CANbridge to the Company which is reflected as a reduction of research and development expense in the accompanying consolidated statements of operations. As of December 31, 2023 and 2022, such research and development funding included in accounts receivable on the accompanying consolidated balance sheets was immaterial.

License and Collaboration Agreement with GC Biopharma

In July 2021, the Company entered into an exclusive license and collaboration agreement with GC Biopharma. Under the terms of the agreement, GC Biopharma has obtained the exclusive right to develop and commercialize Livmarli within South Korea for ALGS, PFIC, and biliary atresia ("BA"). In connection with the agreement, the Company received a $5.0 million upfront payment, which, upon satisfaction of the performance obligation and receipt by GC Biopharma of the right to use and benefit from the license, was recorded as license revenue. Additionally, the Company is entitled to certain research and development funding and up to $23.0 million for the achievement of future regulatory and commercial milestones, with double-digit tiered royalties based on product net sales. At inception of the agreement, the Company concluded that the transaction price should not include the variable consideration related to unachieved developmental and regulatory milestones as this consideration was considered to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in cumulative revenue for this contract when the uncertainty is resolved in the future. The Company will recognize any consideration related to sales-based payments (including milestones and royalties) when the related sales occur, as the Company has determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation or the occurrence of the related sales. The Company re-evaluates the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. In February 2023, GC Biopharma achieved a regulatory milestone under this agreement triggering a milestone payment to the Company of $2.5 million, which upon the release of the constraint was recognized as license revenue in the accompanying consolidated statements of operations for the year ended December 31, 2023. For the years ended December 31, 2023, 2022 and 2021, research and development funding payable by GC Biopharma to the Company, which is reflected as a reduction of research and development expense in the accompanying consolidated statements of operations, was immaterial. As of December 31, 2023 and 2022, such research and development funding recorded as a receivable in accounts receivable on the accompanying consolidated balance sheets was immaterial.

Licensing Agreement with Takeda

In September 2021, the Company entered into an exclusive licensing agreement with Takeda for the development and commercialization of Livmarli in Japan for ALGS, PFIC, and BA. Under the terms of the agreement, Takeda will be responsible for regulatory approval and commercialization of Livmarli in Japan. Takeda will also be responsible for development, including conducting clinical studies in cholestatic indications. The Company is responsible for commercial supply to Takeda. In exchange, the Company is eligible to receive a percentage of Takeda's annualized net sales, which range from high double digits declining to mid double digits over the first four years from commercial launch and thereafter remains at mid double digits. The Company fully constrained all revenues upon transfer of control of the license to Takeda, which occurred when Takeda could use and benefit from the license, and will recognize any consideration related to sales-based payments when the related sales occur, as the Company has determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation or the occurrence of the related sales.

9. Leases

In January 2019, the Company entered into an operating lease agreement for office space which consisted of approximately 5,600 square feet (the "Initial Lease"). The lease term is approximately four years with an option to extend the term for one five-year term, which at the time was not reasonably assured of exercise and therefore, not included in the lease term. The lease contained a tenant improvement allowance of $0.4 million, which has been recorded as leasehold improvements on the accompanying consolidated balance sheets with a corresponding reduction of the ROU asset at inception of the lease. Rent payments commenced in August 2019. In November 2019, the Company amended the operating lease agreement (the "Amended Agreement") to extend the term of the Initial Lease through March 2025. This extension was accounted for as a lease modification and the Company recorded an increase to the ROU asset and lease liability of $0.6 million at the time of the amendment.

Additionally, pursuant to the Amended Agreement, the Company expanded the office space by 5,555 square feet for a five-year term expiring in March 2025 (the "Expanded Space"). The Company accounted for the Expanded Space as a separate contract as there were material additional rights of use that were not included in the Initial Lease. The Amended Agreement contained a tenant improvement allowance of $0.8 million in connection with the expanded space, which has been recorded as leasehold improvements within property and equipment, net on the accompanying consolidated balance sheets with a corresponding reduction of the ROU asset at inception of the lease for the expanded space.

The ROU and corresponding lease liabilities were estimated using a weighted-average incremental borrowing rate of 8.0%.

As of December 31, 2023, the Company recorded an aggregate ROU asset of $1.3 million and an aggregate lease liability of $1.7 million in the accompanying consolidated balance sheets. The weighted-average remaining lease term is 2.1 years.

As of December 31, 2023, undiscounted future minimum payments under the Company's operating leases are as follows (in thousands):

Years Ended December 31,	**Undiscounted Rent Payments**
2024	$ 1,193
2025	366
2026	123
2027	123
2028	61
Total undiscounted lease payments	1,866
Less: imputed interest	(145)
Total lease liability	$ 1,721

Rent expense was $0.8 million for each of the years ended December 31, 2023 and 2022, and $0.7 million for the year ended December 31, 2021. Variable lease payments for each of the years ended December 31, 2023 and 2022 were $0.2 million. Variable lease payments for the year ended December 31, 2021 were immaterial.

On January 17, 2024, the Company entered into an operating lease agreement for approximately 36,300 square feet of office space (the “New Lease”). The lease term is approximately five years and the Company will be paying approximately $10.8 million in base rent during the term. The Company expects the New Lease to commence in May 2024. Concurrently with entering into the New Lease, the Company entered into an amendment of its existing Amended Agreement to accelerate the lease expiration date from March 2025 to shortly after the commencement date of the New Lease. As of the date these financial statements are issued, the Company has not finalized the accounting for the amendment of its Amended Agreement or the New Lease.

10. Convertible Notes

In April 2023, the Company issued $316.3 million aggregate principal amount of its 4.00% Convertible Senior Notes due 2029 (the "Notes") in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Notes are subject to the terms and conditions of an Indenture (the “Indenture”) between the Company and U.S. Bank Trust Company, National Association, as trustee.

The net proceeds from the issuance of the Notes were $305.3 million, after deducting the initial purchasers’ discounts and commissions and offering expenses.

The Notes are the Company’s senior, unsecured obligations and are (i) senior in right of payment to any of the Company’s indebtedness that is expressly subordinated to the Notes in right of payment; (ii) equal in right of payment to any of the Company’s indebtedness that is not so subordinated; (iii) effectively subordinated to any of the Company’s secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company’s subsidiaries.

The Notes accrue interest at a rate of 4.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year, beginning on November 1, 2023. The Notes will mature on May 1, 2029, unless earlier converted, redeemed or repurchased by the Company. Before January 2, 2029, noteholders will have the right to convert their Notes only in the following circumstances:

(i) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on June 30, 2023, if the last reported sale price per share of the Company’s common stock exceeds 130% of the conversion price for the Notes for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;

(ii) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the “measurement period”) if the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the common stock on such trading day and the conversion rate on such trading day;

(iii) upon the occurrence of certain corporate events or distributions on the common stock, as described in the Indenture; and

(iv) if the Company calls such Notes for redemption.

Additionally, noteholders will have the right to convert their Notes at any time from January 2, 2029 until the close of business on the scheduled trading day immediately before the maturity date. The Company may settle conversions by paying or delivering, as applicable, cash, shares of its common stock or a combination of cash and shares of its common stock, at the Company’s election. The initial conversion rate for the Notes is 31.5075 shares of common stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $31.74 per share of common stock. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a “Make-Whole Fundamental Change” (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Company may not redeem the Notes at its option at any time before May 5, 2026. The Notes are redeemable, in whole or in part (subject to the partial redemption limitation described below), at the Company’s option at any time, and from time to time, on or after May 5, 2026 and, in the case of a partial redemption, on or before the 50th scheduled trading day immediately before the maturity date, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. In addition, calling any Note for redemption will constitute a Make-Whole Fundamental Change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption. Pursuant to the partial redemption limitation, the Company may not elect to redeem less than all of the outstanding Notes unless at least $75.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice.

If a "Fundamental Change" (as defined in the Indenture) occurs, then, subject to a limited exception for certain cash mergers, noteholders may require the Company to repurchase their Notes at a cash repurchase price equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition of Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the Company's common stock.

The Indenture contains customary events of default with respect to the Notes and provides that upon certain events of default occurring and continuing, the Trustee may, and the Trustee at the request of holders of at least 25% in principal amount of the Notes shall, declare all principal and accrued and unpaid interest, if any, of the Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company or a significant subsidiary, all of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable.

As of December 31, 2023, the Notes consisted of the following (in thousands):

	Convertible Notes
Principal amount	$ 316,250
Unamortized debt discount and issuance costs	(9,829)
Net carrying amount	$ 306,421

The Company incurred $10.9 million of transaction costs related to the issuance of the Notes, which are being amortized to interest expense over the term of the Notes using the effective interest method. As of December 31, 2023, the remaining amortization period of the debt discount was approximately 5.3 years and the effective interest on the Notes was 4.6%. The following table sets forth interest expense recognized related to the Notes (in thousands):

	Year Ended December 31, 2023
Coupon interest expense	$ 8,925
Amortization of debt discount and issuance costs	1,120
Total interest expense on convertible notes	$ 10,045

As of December 31, 2023, the estimated fair value of the Notes was $387.3 million. The fair values were determined based on the quoted price of the convertible notes in an inactive market on the last trading day of the reporting period and has been classified as Level 2 in the fair value hierarchy.

11. Stockholders' Equity

Common Stock

In August 2020, the SEC declared effective a registration statement on Form S-3 ("2020 Shelf Registration") covering the sale of up to $300.0 million of the Company's securities. Also, in August 2020, the Company entered into a sales agreement ("2020 Sales Agreement") with SVB Securities LLC, recently acquired by Leerink Partners

LLC ("Leerink") pursuant to which the Company could elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the 2020 Shelf Registration through Leerink acting as the sales agent and/or principal. During the year ended December 31, 2023, the Company issued and sold 658,206 shares of common stock pursuant to the 2020 Sales Agreement resulting in gross proceeds to the Company of $15.0 million. The net proceeds for the year ended December 31, 2023 to the Company after deducting sales commissions to SVB Securities and other issuance expenses were approximately $14.5 million. As of December 31, 2023, the Company has issued and sold an aggregate of 2,125,090 shares of common stock pursuant to the 2020 Sales Agreement resulting in aggregate gross proceeds to the Company of $43.7 million. The 2020 Shelf Registration expired in August 2023, and no further sales may be made under the 2020 Sales Agreement.

In August 2022, the Company completed an underwritten public offering of its common stock pursuant to the 2020 Shelf Registration. The Company issued and sold 3,478,261 shares of common stock at a public offering price of $23.00 per share. In addition, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to 521,739 additional shares of its common stock at the public offering price, less the underwriting discounts, commissions and offering expenses, which the underwriters exercised in full. The underwritten public offering, including the underwriters' exercise of their option, resulted in net proceeds to the Company of $86.1 million after deducting underwriting discounts, commissions and offering expenses.

On September 9, 2022, the Company filed an automatic shelf registration statement on Form S-3 with the SEC (the "2022 Shelf Registration"), which became effective upon filing, pursuant to which the Company registered for sale from time to time in one or more offerings an unlimited amount of any combination of the Company's common stock, preferred stock, debt securities and warrants, so long as the Company continues to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. This automatic shelf registration statement will remain in effect for up to three years from the date it became effective. As of December 31, 2023, the Company had not issued any securities pursuant to the automatic shelf registration statement.

On August 31, 2023, in connection with and immediately prior to the closing of the Bile Acid Portfolio Acquisition, the Company completed the private placement of 8,000,000 shares of the Company's common stock at a price per share of $26.25, resulting in net proceeds of approximately $202.2 million.

On November 2, 2023, the Company entered into a Sales Agreement (the "2023 Sales Agreement") with Leerink and Cantor Fitzgerald & Co. (the "Sales Agents"), pursuant to which the Company may, from time to time, sell up to an aggregate amount of $200.0 million of its common stock through the Sales Agents in an "at-the-market" offering (the "ATM Offering"). The Company is not required to sell shares under the 2023 Sales Agreement. Sales of the Company's common stock, if any, under the 2023 Sales Agreement may be made in any transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act. The Company will pay a given designated Sales Agent a commission of up to 3.0% of the aggregate gross proceeds of any shares of common stock sold through such Sales Agent pursuant to the 2023 Sales Agreement. As of December 31, 2023, the Company had not issued any securities pursuant to the 2023 Sales Agreement.

Common Stock Reserved for Issuance

Common stock reserved for issuance is as follows:

	December 31,	
	2023	**2022**
Stock options, restricted stock units and performance stock units issued and outstanding	10,909,831	8,955,557
Reserved for future stock awards or option grants	2,230,264	1,596,947
Reserved for employee stock purchase plan	1,040,828	1,157,570
Common stock issuable upon conversion of convertible notes	9,964,247	—
Common stock held back in connection with asset acquisition	—	31,638
Common stock issuable as contingent consideration in connection with asset acquisition	—	199,993
	24,145,170	11,941,705

12. Stock-Based Compensation

Equity Incentive Plans

In November 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan"), which permits the granting of stock awards and incentive and nonstatutory stock options to employees, directors and consultants of the Company.

In July 2019, the Company's board of directors and stockholders approved and adopted the 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan became effective on July 17, 2019. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock or cash-based awards to individuals who are then employees, officers, directors or consultants of the Company. Shares subject to outstanding awards under the 2018 Plan as of the effective date of the 2019 Plan that are subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under the 2019 Plan. In addition, the number of shares of common stock available for issuance under the 2019 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2019 Plan, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to 5% of the outstanding number of shares of the Company's common stock on December 31st of the preceding calendar year or such lesser amount as determined by the Company's board of directors. As of December 31, 2023, 1,119,312 shares of common stock were available for issuance under the 2019 Plan.

In March 2020, the compensation committee of the Company's board of directors approved and adopted the 2020 Inducement Plan (the "2020 Inducement Plan"). Under the 2020 Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock and restricted stock units to new employees entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). At adoption, the 2020 Inducement Plan authorized 750,000 shares of the Company's common stock for future issuance. In 2023, 2021 and 2020, the Company's board of directors authorized an additional 1,500,000, 1,000,000 and 750,000 shares of the Company's common stock for future issuance, respectively. As of December 31, 2023, 1,110,952 shares of common stock were available for issuance under the 2020 Inducement Plan.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2023 (in thousands, except share and per share data):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	8,340,083	$ 13.63	7.5	$ 51,645
Granted	2,066,089	$ 25.35		
Exercised	(514,443)	$ 16.09		
Canceled and forfeited	(259,225)	$ 18.80		
Outstanding as of December 31, 2023	9,632,504	$ 15.87	6.9	$ 131,785
Vested and exercisable as of December 31, 2023	5,978,571	$ 12.12	5.9	$ 104,048

Intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the per share fair value of the common stock on the date of exercise. The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2023, 2022 and 2021 was $18.25, $12.73 and $13.39 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was $5.7 million, $3.0 million and $1.3 million, respectively. As of December 31, 2023, the total unrecognized stock-based compensation related to unvested stock option awards granted was $48.5 million, which the Company expects to recognize over a weighted-average period of approximately 2.6 years.

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the expected stock price volatility was based upon the weighting of the

Company’s historical volatility and the historical volatility of a peer group of publicly traded companies. The historical volatility data was computed using the daily closing prices for the Company’s and its peer companies’ shares during the equivalent period of the calculated expected term of the stock-based awards. Due to the lack of historical exercise history, the expected term of the Company’s stock options for employees has been determined utilizing the “simplified” method for awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following assumptions were used to estimate the fair value of stock option awards granted during the following periods:

	Year ended December 31,		
	2023	2022	2021
Expected term (in years)	5.3-6.1	5.5-6.1	5.5-6.1
Expected volatility	80.17%-85.24%	80.86%-83.20%	82.76%-94.06%
Risk-free interest rate	3.35%-4.67%	1.46%-4.10%	0.62%-1.34%
Expected dividend yield	—	—	—

Restricted Stock Units

The following table summarizes the activity under the Company’s restricted stock units for the year ended December 31, 2023:

	Number of Awards	Weighted-Average Grant Date Fair Value per Award
Unvested and outstanding as of December 31, 2022	615,474	$ 18.36
Granted	824,584	$ 25.48
Vested	(245,783)	$ 18.36
Cancelled/Forfeited	(64,783)	$ 20.82
Unvested and Outstanding as of December 31, 2023	1,129,492	$ 23.41

The fair value of restricted stock unit ("RSU") awards granted to employees and nonemployees is equal to the closing market price of the Company’s common stock on the grant date.

As of December 31, 2023, the total unrecognized stock-based compensation related to restricted stock unit awards granted was $19.6 million, which the Company expects to recognize over a weighted-average period of approximately 2.2 years.

Performance Stock Units

In January 2023, the Company granted an aggregate of 135,835 performance stock units to certain executive participants (“2023 Executive PSUs”). The 2023 Executive PSUs are subject to a performance condition of achieving certain net product sales levels related to Livmarli during the year ended December 31, 2024. If the performance condition is met, the first tranche of the award will vest on March 15, 2025 and the second tranche will vest on March 15, 2026, subject to the executive employees’ continuous service through each vesting date. The number of units to be vested in the first tranche of the 2023 Executive PSUs is calculated by multiplying two-thirds of the 2023 Executive PSUs granted by a percentage calculated based on attained Livmarli sales metrics, as certified by the Company’s Compensation Committee. The number of units to be vested in the second tranche of the 2023 Executive PSUs equals 50% of the units vested in the first tranche.

In June 2023, the Company granted an aggregate of 12,000 PSUs to certain employees ("2023 Employee PSUs"). The 2023 Employee PSUs are subject to a performance condition of achieving certain net product sales related to Livmarli in the US for the year ended December 31, 2023.

The following table summarizes the activity under the Company's performance stock units for the year ended December 31, 2023:

	Number of Awards		Weighted-Average Grant Date Fair Value per Award
Unvested and outstanding as of December 31, 2022	—	$	—
Granted	147,835	$	23.64
Unvested and outstanding as of December 31, 2023	147,835	$	23.64

As of December 31, 2023, the total unrecognized stock compensation related to performance stock units granted was $2.1 million, which the Company expects to recognize over a weighted-average period of approximately 1.5 years.

2019 Employee Stock Purchase Plan

In July 2019, the Company's board of directors and stockholders approved and adopted the 2019 Employee Stock Purchase Plan ("ESPP"). The number of shares of common stock available for issuance under the ESPP will be automatically increased on the first day of each calendar year during the first ten years of the term of the ESPP, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to the lesser of (i) 1% of the outstanding number of shares of common stock on December 31st of the preceding calendar year, (ii) 1,500,000 shares of common stock or (iii) such lesser amount as determined by the Company's board of directors. The ESPP became effective on July 17, 2019 and generally provides for six-month consecutive offering periods beginning on May 11th and November 11th of each year. During the year ended December 31, 2023, 116,742 shares were issued under the ESPP. As of December 31, 2023, the Company had 1,040,828 shares available for future issuance under the ESPP. The stock-based compensation related to the ESPP for the years ended December 31, 2023, 2022 and 2021 was $0.9 million, $0.7 million and $0.7 million, respectively.

Restricted Common Stock

In November 2018, in connection with the issuance of Series A Preferred Stock, the Company's founders agreed to modify their outstanding shares of common stock to include vesting provisions that require continued service to the Company in order to vest in those shares. As such, the 562,500 modified shares of common stock became compensatory upon such modification. During the years ended December 31, 2022 and 2021, 122,464 shares and 133,593 shares vested, respectively. All restricted common stock was fully vested as of December 31, 2022.

Compensation Expense

Total stock-based compensation is reflected in the accompanying consolidated statements of operations as follows (in thousands):

	Year Ended December 31,					
		2023		2022		2021
Selling, general and administrative	$	24,131	$	16,957	$	13,128
Research and development		10,892		10,050		9,888
Total	$	35,023	$	27,007	$	23,016

Stock-based compensation reflected in cost of goods sold for the years ended December 31, 2023, 2022 and 2021 was insignificant. Stock-based compensation of $0.8 million, $0.4 million and $0.1 million was capitalized into inventory for the years ended December 31, 2023, 2022 and 2021, respectively.

13. Gain from Sale of Priority Review Voucher

In November 2021, the Company entered into a definitive agreement to sell the PRV that it received from the FDA in connection with the approval of Livmarli for the treatment of cholestatic pruritus in patients with ALGS one year of age and older, for cash proceeds of $110.0 million. In December 2021, the Company completed its sale of the PRV and received net proceeds of $108.0 million, after deducting commission costs, which was recorded as a gain within other income (loss) in the accompanying consolidated statements of operations.

14. Income Taxes

The Company's losses before provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
U.S. loss before taxes	$ (164,953)	$ (142,661)	$ (84,217)
Foreign income before taxes	2,529	590	266
Loss before income taxes	$ (162,424)	$ (142,071)	$ (83,951)

The income tax (expense) benefit applicable to income before income taxes consists of the following:

	Year Ended December 31,		
	2023	2022	2021
Current income taxes:			
Federal	$ 37	$ —	$ —
State	67	18	—
Foreign	887	157	37
Total current	991	175	37
Deferred taxes:			
Federal	—	(5,503)	—
State	—	(1,078)	—
Total deferred	—	(6,581)	—
Income tax (benefit) expense	$ 991	$ (6,406)	$ 37

The Company acquired Satiogen in a tax-free reorganization, whereby the Company did not receive a step-up in tax basis of the acquired intangible assets, resulting in a deferred tax liability of $6.6 million. The deferred tax liability provided an additional source of taxable income to support the realization of the pre-existing deferred tax assets. As a result, a portion of the Company's valuation allowance was released and a $6.6 million tax benefit was recorded for the year ended December 31, 2022.

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2023	2022	2021
Federal statutory income tax rate	21.00 %	21.00 %	21.00 %
State tax	3.57	7.40	1.32
Permanent differences	(0.50)	(0.65)	(1.70)
Other	(0.13)	(0.93)	0.02
Executive compensation	—	(2.99)	—
Global intangible low-taxed income	(1.69)	(1.43)	—
Tax credits	1.91	4.96	7.72
Change in valuation allowance	(24.77)	(22.85)	(28.41)
Total tax benefit	(0.61) %	4.51 %	(0.05) %

The significant components of the Company's deferred taxes are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating losses	$ 40,455	$ 34,522
Capitalized research and development	38,065	23,569
Tax credit carryforwards	30,071	26,747
Interest limitation attributes	15,814	3,127
Stock-based compensation	8,419	6,726
Intangibles	4,055	4,733
Accrued expenses	3,953	3,101
Inventory	2,316	426
Lease liability	269	460
Total deferred tax assets	143,417	103,411
Deferred tax liabilities:		
Operating lease right-of-use assets	(161)	(272)
Fixed assets	(37)	(100)
Total deferred tax liabilities	(198)	(372)
Valuation allowance	(143,219)	(103,039)
Net deferred tax assets	$ —	$ —

The valuation allowance increased by $40.2 million, $32.5 million and $23.9 million for the years ended December 31, 2023, 2022 and 2021, respectively. The tax benefit of deductible temporary differences or carryforwards is recorded as a deferred tax asset to the extent that management assesses the realization is "more likely than not." Future realization of the tax benefit ultimately depends on the existence of sufficient taxable income within the period available under the tax law. At December 31, 2023 and 2022, the Company has set up valuation allowances against all federal and state net deferred tax assets, because based on all available evidence, these deferred tax assets are not more than likely to be realizable.

The Company had federal, California and other state net operating loss carryforwards of approximately $166.9 million, $30.0 million and $59.7 million at December 31, 2023, and $153.1 million, $19.1 million and $17.7 million at December 31, 2022, respectively. Federal losses do not expire, and California net operating and other state income net operating losses will begin to expire in 2038 and 2032, respectively, if not utilized. The Company also has federal general business credit and California research and development credit carryforwards totaling $36.5 million and $4.8 million at December 31, 2023, and $32.5 million and $4.2 million at December 31, 2022, respectively. The federal research and development credit carryforwards will begin to expire in 2039, unless previously utilized. The California research credits do not expire.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period (a "Section 382 ownership change"), utilization of its pre-change NOL carryforwards and the research and development credit carryforwards is subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state laws. The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change, subject to certain adjustments, by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards and research and development credit carryforwards before utilization and may be material. As of December 31, 2023, the Company determined that it has not experienced an ownership change and determined that NOLs and tax credits are not subject to a limitation pursuant to Section 382.

The Company recognizes the financial statements effects of a tax position when it is more likely than not, based on technical merits, that the position will be sustained upon examination.

A reconciliation of the Company’s unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Balance at beginning of year	$ 9,254	$ 6,399
(Decrease) related to prior year tax positions	—	—
Increases related to current year tax positions	1,200	2,855
Balance at end of year	$ 10,454	$ 9,254

The Company has considered the amounts and probabilities of the outcomes that can be realized upon ultimate settlement with the tax authorities and determined unrecognized tax benefits primarily related to credits should be established as noted in the summary roll-forward above. The Company does not expect that its uncertain tax positions will materially change in the next twelve months. The Company’s effective income tax rate would not be impacted if the unrecognized tax benefits were recognized in 2023 and 2022, as the Company is in a full valuation allowance position.

The Company files federal, state and foreign income tax returns in jurisdictions with varying statutes of limitations. All of the Company’s tax returns in all jurisdictions remain open to examination since inception. The Company’s policy is to recognize interest expense and penalties related to income tax matters as tax expense. As of December 31, 2023 and 2022, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties.

The Company has not provided U.S. income or foreign withholding taxes on the undistributed earnings of its foreign subsidiaries as of December 31, 2023 and 2022, because it intends to permanently reinvest such earnings outside of the U.S. If these foreign earnings were to be repatriated in the future, the related U.S. tax liability will be immaterial, due to the participation exemption put in place in the Tax Act.

15. Commitments and Contingencies

Certain of the Company's contractual arrangements with contract manufacturing organizations require binding forecasts or commitments to purchase minimum amounts for the manufacture of drug product supply, which may be material to the Company's financial statements.

The Company is subject to potential liabilities under government regulations and various claims and legal actions that are pending or may be asserted from time-to-time. These matters arise in the ordinary course and conduct of the Company’s business and may include, for example, commercial, intellectual property, and employment matters. The Company intends to defend itself vigorously in such matters and when warranted, take legal action against others. Furthermore, the Company regularly assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements.

An estimated loss contingency is accrued in the Company’s financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company does not accrue amounts for liabilities that it does not believe are probable. Litigation is inherently unpredictable, and unfavorable resolutions could occur. As a result, assessing contingencies is highly subjective and requires judgment about future events. During the periods presented, the Company has not recorded any accrual for loss contingencies associated with such government regulations, claims or legal actions, determined that an unfavorable outcome is probable or reasonably possible, or determined that the amount or range of any possible loss is reasonably estimable.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, due to the material weaknesses described below, as of December 31, 2023, our disclosure controls and procedures were not effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, due to the material weaknesses described below, our management concluded that our internal control over financial reporting was not effective at the reasonable assurance level as of December 31, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. We identified the following material weaknesses in our internal controls over financial reporting as of December 31, 2023:

- The Company did not design and maintain effective controls over the existence and valuation of inventory, specifically, the controls over existence of inventory located at third parties and the net realizable value assessment of on-hand inventory and future purchases under firm commitments. The Company's controls were not designed with sufficient level of precision and the level of evidence of reviews performed was insufficient.

- The Company did not design and maintain sufficiently precise management review controls to evaluate prospective financial information used to determine the fair value of developed technology and did not maintain evidence related to the management review performed. Furthermore, the Company did not design and maintain effective management review controls to identify and assess firm purchase commitments related to the acquisition.

The material weaknesses identified above did not result in any material misstatements to our financial statements or disclosures, and there were no changes to previously filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q. Notwithstanding our material weaknesses, we have concluded that the financial statements and other financial information included in this Annual Report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report which is included in Item 8 of this Annual Report on Form 10-K.

The scope of management's assessment of the effectiveness of internal control over financial reporting excluded the Bile Acid Portfolio Acquisition, which we acquired in an asset purchase on August 31, 2023 and is included in our consolidated financial statements as of and for the year ended December 31, 2023. The Bile Acid Portfolio Acquisition represented approximately 6% of total assets (excluding intangible assets) and 20% of total revenues, each as reflected in our consolidated financial statements as of and for the year ended December 31, 2023.

Remediation Plan for Material Weaknesses

Management is actively engaged in the planning for, and implementation of, remediation efforts to address the material weaknesses. The remediation plan includes adding controls to ensure timely accounting evaluation of firm commitments for inventory purchases and employee training related to internal control over financial reporting specifically focused on data used in the operation of management review controls and the execution of management review controls with an appropriate level of precision and documentation. The remediation actions will be monitored by the Audit Committee of our Board of Directors. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance on the timing of our implementation of these initiatives or that these initiatives will ultimately have the intended effects.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our plans for remediating the material weaknesses, described above, will constitute changes in our internal control over financial reporting, prospectively, when such remediation plans are effectively implemented.

Item 9B. Other Information

During our last fiscal quarter, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company's securities set forth in the table below.

			Type of Trading Arrangement			
Name and Position	**Action**	**Adoption/ Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Common Stock to be Sold**	**Expiration Date**

Christopher Peetz, Chief Executive Officer	Adopted	December 28, 2023	X		Up to 75,000	December 28, 2025
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.						
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.						

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained under the proposal captioned “Election of Directors” and captions “Information Regarding the Board of Directors and Corporate Governance,” “Executive Officers,” and “Delinquent Section 16(a) Reports,” if any, in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2024 Annual Meeting of Stockholders (“Definitive Proxy Statement”), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2023 and is incorporated herein by reference.

Code of Business Conduct and Ethics

We maintain a Code of Conduct that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Conduct is posted on our website at www.mirumpharma.com. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any principal executive officer, principal financial officer, principal accounting officer or controller, or any person performing similar functions that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K. Information contained in, or that can be accessed through, our website is not incorporated by reference herein, and you should not consider information on our website to be part of this Annual Report.

Item 11. Executive Compensation.

The information required by this item will be set forth under the caption "Executive Compensation" in our Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Definitive Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth under the captions “Transactions With Related Persons and Indemnification” and “Information Regarding the Board of Directors and Corporate Governance” in our Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth under the proposal captioned “Ratification of Selection of Independent Registered Public Accounting Firm” in our Definitive Proxy Statement and is incorporated here by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) Financial statements

The financial statements filed as part of this Annual Report are included in Part II, Item 8 of this Annual Report.

(2) Financial statement schedules

Financial statement schedules have been omitted in this Annual Report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) Exhibits

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
2.1#¥	Asset Purchase Agreement, dated July 16, 2023, by and between Mirum Pharmaceuticals, Inc. and Travere Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 17, 2023, and incorporated by reference herein).
3.1	Amended and Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 25, 2019, and incorporated by reference herein).
3.2	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 25, 2019, and incorporated by reference herein).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
4.2	Investors' Rights Agreement, dated November 5, 2018 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
4.3*	Description of Common Stock of the Registrant.
4.4	Indenture, dated as of April 17, 2023, between Mirum Pharmaceuticals, Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 17, 2023, and incorporated by reference herein).
4.5	Form of certificate representing the 4.00% Convertible Senior Notes due 2029 (included as Exhibit A to Exhibit 4.4 above) (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 17, 2023, and incorporated by reference herein).
10.1+	Mirum Pharmaceuticals, Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.1A+	Forms of grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.2+	Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
10.2A+	Forms of grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
10.2B+	Forms of restricted stock unit grant notice and award agreement under the Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
10.2C+	Forms of international grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.2D+	Forms of international director grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.2E+	Forms of international restricted stock unit grant notice and award agreement under the Mirum Pharmaceuticals, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the

	Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.3+	Mirum Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
10.3A+	Mirum Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan Terms and conditions – Non-U.S. Participants (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.4+*	Mirum Pharmaceuticals, Inc. 2020 Inducement plan, as amended August 24, 2023
10.4A+	Forms of grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2020 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's From 10-Q, filed with the SEC on May 7, 2020, and incorporated by reference herein).
10.4B+	Forms of restricted stock unit grant notice and award agreement under the Mirum Pharmaceuticals, Inc. 2020 Inducement Plan (incorporated by reference to Exhibit 10.3 to the Registrant's From 10-Q, filed with the SEC on May 7, 2020, and incorporated by reference herein).
10.4C+	Forms of international grant notice, stock option agreement and notice of exercise under the Mirum Pharmaceuticals, Inc. 2020 Inducement Plan (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.4D+	Forms of international restricted stock unit grant notice and award agreement under the Mirum Pharmaceuticals, Inc. 2020 Inducement Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.5+	Form of Indemnification Agreement by and between the Registrant and each director and executive officer (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on July 8, 2019, and incorporated by reference herein).
10.6+	Mirum Pharmaceuticals, Inc. Amended and Restated Severance Benefit Plan and form of Participation Agreement thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 30, 2023, and incorporated by reference herein).
10.7+	Amended and Restated Offer Letter by and between the Registrant and Christopher Peetz, dated May 15, 2019 (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.8+	Offer Letter by and between the Registrant and Pamela Vig, Ph.D., dated December 1, 2018 (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.9+	Offer Letter by and between the Registrant and Lara Longpre, dated December 1, 2018 (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.10+	Offer Letter by and between the Company and Eric Bjerkholt, dated August 8, 2023 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023, and incorporated by reference herein).
10.11+	Offer Letter by and between the Registrant and Peter Radovich, dated April 28, 2020 (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 9, 2021, and incorporated by reference herein).
10.12#¥	License Agreement by and between Lumena Pharmaceuticals, Inc. and Satiogen Pharmaceuticals, Inc., dated February 8, 2011 (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.12A#	Amendment to License Agreement by and between Lumena Pharmaceuticals, Inc. and Satiogen Pharmaceuticals, Inc., dated February 8, 2011 (filed as Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.13#¥	License Agreement by and between Lumena Pharmaceuticals, Inc. and Pfizer Inc., dated June 1, 2012 (filed as Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).

10.14#¥	License Agreement by and between Lumena Pharmaceuticals, Inc. and Sanofi-Aventis Deutschland GmbH, dated September 27, 2012 (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.14A#	Amendment No. 1 to License Agreement by and between Shire Orphan and Rare Disease GmbH (successor in interest of Lumena Pharmaceuticals, Inc.) and Sanofi-Aventis Deutschland GmbH, dated June 26, 2015 (filed as Exhibit 10.19 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.15#¥	Assignment and License Agreement by and between the Registrant and Shire International GmbH, dated November 5, 2018 (filed as Exhibit 10.20 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-232251), filed with the SEC on June 21, 2019, and incorporated by reference herein).
10.16	Office Lease by and between the Registrant and Hudson Metro Center, LLC, dated January 22, 2019, as amended by First Amendment by and between the Registrant and Hudson Metro Center, LLC, dated June 1, 2019, and as further amended by Second Amendment by and between the Registrant and Hudson Metro Center, LLC, dated November 22, 2019 (filed as Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-235825) filed with the SEC on January 6, 2020, and incorporated by reference herein).
10.16A*	Third Amendment to Office Lease, dated January 17, 2024, by and between the Registrant and Hudson Metro Center, LLC.
10.17*¥	Office Lease, dated January 17, 2024, by and between the Registrant and Hudson Metro Center, LLC.
10.18	Sales Agreement by and between the Registrant, Leerink Partners LLC and Cantor Fitzgerald & Co., dated November 2, 2023 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 2, 2023).
10.19*+	Mirum Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K, as filed with the SEC on March 8, 2023, and incorporated by reference herein).
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Mirum Pharmaceuticals Inc. Incentive Compensation Recoupment Policy.
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Indicates management contract or compensatory plan.

Pursuant to Item 601(b)(2) and Item 601(b)(10) of Regulation S-K, as applicable, certain portions of this exhibit have been omitted (indicated by "[*]" or "[…***…]") because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential.
¥ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.
† The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

MIRUM PHARMACEUTICALS, INC.

Date: March 15, 2024

By: /s/ Christopher Peetz

Christopher Peetz
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher Peetz and Eric Bjerkholt and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Christopher Peetz Christopher Peetz	Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2024
/s/ Eric Bjerkholt Eric Bjerkholt	Chief Financial Officer (Principal Financial Officer)	March 15, 2024
/s/ Jody Howe Jody Howe	Senior Vice President, Global Controller (Principal Accounting Officer)	March 15, 2024
/s/ Laura Brege Laura Brege	Director	March 15, 2024
/s/ Lon Cardon, Ph.D. Lon Cardon, Ph.D.	Director	March 15, 2024
/s/ William C. Fairey William C. Fairey	Director	March 15, 2024
/s/ Laurent Fischer, M.D. Laurent Fischer, M.D.	Director	March 15, 2024
/s/ Michael Grey Michael Grey	Director	March 15, 2024
/s/ Patrick Heron Patrick Heron	Director	March 15, 2024
/s/ Saira Ramasastry, M.S., M.Phil Saira Ramasastry, M.S., M.Phil	Director	March 15, 2024
/s/ Timothy Walbert Timothy Walbert	Director	March 15, 2024

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

General

The following description summarizes the terms of the common stock of Mirum Pharmaceuticals, Inc., or we, our or us. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this "Description of Common Stock," you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of the General Corporation Law of the State of Delaware. Our amended and restated certificate of incorporation authorizes us to issue 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. Our board of directors is authorized, without stockholder approval except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

Voting Rights

Our common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms.

Economic Rights

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock have the same rights and privileges and rank equally, share ratably and be identical in all respects for all matters, including those described below.

Dividends. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Liquidation Rights. On our liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share equally, identically and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights

The holders of shares of our common stock are not entitled to preemptive rights and are not subject to conversion, redemption or sinking fund provisions.

Anti-Takeover Provisions

The provisions of Delaware law, our amended and restated certificate of incorporation and amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide that stockholders may only take action at a duly called meeting of stockholders. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors or our chief executive officer. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the General Corporation Law of the State of Delaware

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws (including any right, obligation or remedy thereunder); (v) any action or proceeding as to which the General Corporation Law of the State of Delaware confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation and amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, unless we consent in writing to the selection of an alternative forum.

MIRUM PHARMACEUTICALS, INC.

2020 INDUCEMENT PLAN

ADOPTED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS: MARCH 18, 2020
AMENDED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS: DECEMBER 16, 2020
AMENDED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS: NOVEMBER 18, 2021
AMENDED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS: AUGUST 24, 2023

1. GENERAL.

(a) Eligible Award Recipients. The only persons eligible to receive grants of Awards under this Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a *bona fide* period of non-employment. Persons eligible to receive grants of Awards under this Plan are referred to in this Plan as "***Eligible Employees***." These Awards must be approved by either a majority of the Company's "***Independent Directors***" (as such term is defined in Nasdaq Marketplace Rule 5605(a)(2)) or the Company's compensation committee, provided such committee comprises solely Independent Directors (the "***Independent Compensation Committee***"), in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Marketplace Rules. Nasdaq Marketplace Rule 5635(c)(4), the related guidance under Nasdaq IM 5635-1 and any analogous rules or guidance effective after the date hereof are collectively referred to in this Plan as the "***Inducement Award Rules***."

(b) Available Awards. The Plan provides for the grant of the following types of Awards: (i) Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards and (iv) Restricted Stock Unit Awards. All Options shall be Nonstatutory Stock Options.

(c) Purpose. The Plan, through the grant of Awards, is intended to provide (i) an inducement material for certain individuals to enter into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Marketplace Rules, (ii) incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and (iii) a means by which Eligible Employees may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan; provided, however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee. Subject to those constraints and the other constraints of the Inducement Award Rules, the Board may delegate some of its powers of administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan and the Inducement Award Rules:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to an Award; provided, however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or the time at which cash or shares of Common Stock may be issued in settlement thereof).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under the Participant's then-outstanding Award without the Participant's written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable consistent with the Inducement Award Rules, including, without limitation, by adopting amendments relating to nonqualified deferred compensation under Section 409A of the Code and/or ensuring that the Plan or Awards granted under the Plan are exempt from, or compliant with, the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law, listing requirements or the Inducement Award Rules, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan. Except as provided above, rights under any Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion, and subject to any stockholder approval required under the Inducement Award Rules in connection with such amendment of an Award; *provided, however,* that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (B) to comply with other applicable laws, listing requirements or the Inducement Award Rules.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Eligible Employees who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(c) Delegation to Committee. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be construed as being to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(d) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) Repricing; Cancellation and Re-Grant of Awards. Neither the Board nor any Committee will have the authority to reduce the exercise, purchase or strike price of any outstanding Option or SAR, unless the stockholders of the Company have approved such an action within twelve months prior to such an event.

3. Shares Subject to the Plan.

(a) Share Reserve. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards from and after the Effective Date shall not exceed 4,000,000 shares. Shares may be issued under the terms of this Plan in connection with a merger or acquisition as permitted by Nasdaq Marketplace Rule 5635(c)(3) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If an Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to an Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired or retained by the Company in satisfaction of tax withholding obligations on an Award or as consideration for the exercise or purchase price of an Award will again become available for issuance under the Plan.

(c) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. Eligibility.

(a) Eligibility for Awards. Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Marketplace Rules or is otherwise permitted pursuant to Rule 5635(c) of the Nasdaq Marketplace Rules; *provided, however*, that Awards may not be granted to Eligible Employees who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Awards comply with the distribution requirements of Section 409A of the Code.

(b) Approval Requirements. All Awards must be granted either by a majority of the Company's Independent Directors or the Independent Compensation Committee.

5. Provisions relating to Options and SARs.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be Nonstatutory Stock Options. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. No Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. The exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date that is 90 days following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. If the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received on exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Awards and are hereby incorporated by reference into such Award Agreements.

6. Provisions of Awards Other than Options and SARs.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past or future services to the Company or an Affiliate, or (C) any other form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

7. Covenants of the Company.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency, as necessary, such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act or other securities or applicable laws, the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the tax treatment or time or manner of exercising such Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. Miscellaneous.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is domiciled or incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that such Participant is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; *provided, however,* that no shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(h) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A of the Code. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(k) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a) and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution. Except as otherwise provided in the Award Agreement, in the event of a Dissolution of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such Dissolution, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service; *provided, however*, that the Board may, in its sole discretion, cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the Dissolution is completed but contingent on its completion.

(c) Transaction. The following provisions shall apply to Awards in the event of a Transaction unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award. In the event of a Transaction, then, notwithstanding any other provision of the Plan, the Board shall take one or more of the following actions with respect to Awards, contingent upon the closing or completion of the Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Award or to substitute a similar stock award for the Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Award (and, if applicable, the time at which the Award may be exercised) to a date prior to the effective time of such Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five days prior to the effective date of the Transaction), with such Award terminating if not exercised (if applicable) at or prior to the effective time of the Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Award;

(v) cancel or arrange for the cancellation of the Award, to the extent not vested or not exercised prior to the effective time of the Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero ($0) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or other contingencies.

The Board need not take the same action or actions with respect to all Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of an Award.

(d) Change in Control. An Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Award Agreement for such Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant.

10. Termination or Suspension of the Plan.

The Board may suspend or terminate the Plan at any time. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. Effective Date of the Plan.

The Plan will come into existence on the Effective Date. No Award may be granted prior to the Effective Date.

12. Choice of Law.

The law of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. Definitions. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Award***" means an Option, a Stock Appreciation Right, a Restricted Stock Award or a Restricted Stock Unit Award.

(c) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) "***Board***" means the Board of Directors of the Company.

(e) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "***Cause***" shall have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause shall be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, (C) on account of the acquisition of securities of the Company by any individual who is, on the IPO Date, either an executive officer or a Director (either, an "***IPO Investor***") and/or any entity in which an IPO Investor has a direct or indirect interest (whether in the form of voting rights or participation in profits or capital contributions) of more than 50% (collectively, the "***IPO Entities***") or on account of the IPO Entities continuing to hold shares that come to represent more than 50% of the combined voting power of the Company's then outstanding securities as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation; or (D) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; *provided, however*, that a merger, consolidation or similar transaction will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the surviving Entity or its parent are owned by the IPO Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the IPO Entities;

(iv) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; *provided, however,* that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company and the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(h)"***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) "***Committee***" means a committee of one or more Independent Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j) "***Common Stock***" means the common stock of the Company, having one vote per share.

(k)"***Company***" means Mirum Pharmaceuticals, Inc., a Delaware corporation.

(l) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(m)"***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(n)"***Corporate Transaction***" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(o) "***Director***" means a member of the Board. Directors are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(p)"***Disability***" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(q)"***Dissolution***" means when the Company, after having executed a certificate of dissolution with the State of Delaware (or other applicable state), has completely wound up its affairs. Conversion of the Company into a Limited Liability Company (or any other pass-through entity) will not be considered a "Dissolution" for purposes of the Plan.

(r) "***Effective Date***" means March 18, 2020.

(s) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(t) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(u)"***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(v) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the IPO Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(w) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(x) "***IPO Date***" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock was priced for the initial public offering.

(y) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(z) "***Nonstatutory Stock Option***" means any stock option granted pursuant to Section 5 of the Plan that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(aa)“***Officer***” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(bb)“***Option***” means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(cc)“***Option Agreement***” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(dd)“***Optionholder***” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ee)“***Own,***” “***Owned,***” “***Owner,***” “***Ownership***” means a person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ff)“***Participant***” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(gg)“***Plan***” means this Mirum Pharmaceuticals, Inc. 2020 Inducement Plan.

(hh)“***Restricted Stock Award***” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(ii)“***Restricted Stock Award Agreement***” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(jj) “***Restricted Stock Unit Award***” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(kk)“***Restricted Stock Unit Award Agreement***” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(ll)“***Rule 16b-3***” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(mm)“***Securities Act***” means the Securities Act of 1933, as amended.

(nn)“***Stock Appreciation Right***” or “***SAR***” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(oo)"***Stock Appreciation Right Agreement***" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(pp) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(qq)"***Transaction***" means a Corporate Transaction or a Change in Control.

Office Lease

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

Between

HUDSON METRO CENTER, LLC, a Delaware limited liability company

as Landlord,

and

MIRUM PHARMACEUTICALS, INC., a Delaware corporation

as Tenant

OFFICE LEASE

This Office Lease (this "**Lease**"), dated as of the date set forth in Section 1.1, is made by and between **HUDSON METRO CENTER, LLC, a Delaware limited liability company** ("**Landlord**"), and **MIRUM PHARMACEUTICALS, INC., a Delaware corporation** ("**Tenant**"). The following exhibits are incorporated herein and made a part hereof: **Exhibit A** (Outline of Premises); **Exhibit B** (Work Letter); **Exhibit B-1** (Approved Space Plan); **Exhibit C** (Form of Confirmation Letter); **Exhibit D** (Rules and Regulations); **Exhibit E** (Judicial Reference); **Exhibit F** (Additional Provisions); **Exhibit F-1** (Letter of Credit); **Exhibit F-2** (Suite 200 Potential Offering Space); **Exhibit F-3** (Suite 220 Potential Offering Space); **Exhibit F-4** (Suite 230 Potential Offering Space); and **Exhibit F-5** (Suite 250 Potential Offering Space);

1 BASIC LEASE INFORMATION

1.1 Date:	__January 17______________, 2024.
1.2 Premises.	
1.2.1 "**Building**":	989 East Hillsdale Boulevard, Foster City, California, commonly known as 989 East Hillsdale Boulevard.
1.2.2 "**Premises**":	36,318 rentable square feet of space located on the third floor of the Building and commonly known as Suite 300, the outline and location of which is set forth in **Exhibit A**. If the Premises include any floor in its entirety, all corridors and restroom facilities located on such floor shall be considered part of the Premises.
1.2.3 "**Property**":	The Building, the parcel(s) of land upon which it is located, and, at Landlord's discretion, any parking facilities and other improvements serving the Building and the parcel(s) of land upon which such parking facilities and other improvements are located.
1.2.4 "**Project**":	The Property or, at Landlord's discretion, any project containing the Property and any other land, buildings or other improvements.
1.3 Term	
1.3.1 Term:	The term of this Lease (the "**Term**") shall begin on the Commencement Date and expire on the Expiration Date (or any earlier date on which this Lease is terminated as provided herein).
1.3.2 "**Commencement Date**":	The earlier of (i) the first date on which Tenant conducts business in the Premises, or (ii) the date on which the Tenant Improvement Work (defined in **Exhibit B**) is Substantially Complete (defined in **Exhibit B**), which is anticipated to be May 1, 2024. Notwithstanding the foregoing, Tenant may enter the Premises before the Commencement Date (but no earlier than 14 days prior to the Commencement Date), solely for the purpose of installing telecommunications and data cabling, equipment, furnishings and other personal property in the Premises. Other than the obligation to pay Monthly Rent (as defined below), all of Tenant's obligations hereunder shall apply during any period of such early entry. Notwithstanding the foregoing, Landlord may limit, suspend or terminate Tenant's rights to enter the Premises early pursuant to this Section 1.3.2 if Landlord reasonably determines that such entry is endangering individuals working in the Premises or is delaying completion of the Tenant Improvement Work
1.3.3 "**Expiration Date**":	The last day of the 63rd full calendar month beginning on the Commencement Date; provided, however, that if the Commencement Date is not the first day of a month, then the Expiration Date shall be the last day of the 63rd full

calendar month beginning immediately after the Commencement Date.

1.4 "**Base Rent**":

Period During Term	Annual Base Rent Per Rentable Square Foot (rounded to the nearest 100th of a dollar)	Monthly Base Rent Per Rentable Square Foot (rounded to the nearest 100th of a dollar)	Monthly Installment of Base Rent
Commencement Date through last day of 12th full calendar month of Term	$56.28	$4.69	$170,331.42
13th through 24th full calendar months of Term	$57.97	$4.83	$175,441.36
25th through 36th full calendar months of Term	$59.71	$4.98	$180,704.60
37th through 48th full calendar months of Term	$61.50	$5.12	$186,125.74
49th through 60th full calendar months of Term	$63.34	$5.28	$191,709.51
61st full calendar month of Term through Expiration Date	$65.24	$5.44	$197,460.80

Notwithstanding the foregoing, Base Rent shall be abated in the amount of $170,331.42 per month for each of the first four (4) full calendar months of the Term.

1.5 "**Base Year**" for Expenses: Calendar year 2024.

"**Base Year**" for Taxes: Calendar year 2024.

1.6 "**Tenant's Share**": 25.2863% (based upon a total of 143,627 rentable square feet in the Building).

1.7 "**Permitted Use**": General office use consistent with a first-class office building.

1.8. "**Security Deposit**": $00.00, as more particularly described in Section 21.

Prepaid Base Rent: $170,331.42, as more particularly described in Section 3.

1.9 Parking: 125 unreserved parking spaces, at the rate of $0.00 per space per month.

1.10 Address of Tenant: Before the Commencement Date:

Mirum Pharmaceuticals, Inc.
950 Tower Lane, Suite 1050
Foster City, California 94404

From and after the Commencement Date: the Premises.

1.11 Address of Landlord: Hudson Metro Center, LLC
c/o Hudson Pacific Properties

333 Twin Dolphin Drive, Suite 100
Redwood City, California 94065
Attn: Building manager

with copies to:

Hudson Metro Center, LLC
c/o Hudson Pacific Properties
333 Twin Dolphin Drive, Suite 100
Redwood City, California 94065
Attn: Managing Counsel

and

Hudson Metro Center, LLC
c/o Hudson Pacific Properties
11601 Wilshire Boulevard, Suite 900
Los Angeles, California 90025
Attn: Lease Administration

1.12	Broker(s):	Jones Lang LaSalle (“**Tenant’s Broker**”), representing Tenant, and CBRE, Inc. (“**Landlord’s Broker**”), representing Landlord.
1.13	Building HVAC Hours and Holidays:	“**Building HVAC Hours**” means 8:00 a.m. to 6:00 p.m., Monday through Friday, excluding the day of observation of New Year’s Day, Presidents Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, and, at Landlord’s discretion, any other locally or nationally recognized holiday that is observed by other Comparable Buildings (defined in Section 25.10) (collectively, “**Holidays**”).
1.14	“**Tenant Improvements**”:	Defined in **Exhibit B**, if any.
1.15	“**Guarantor**”:	None.

2 PREMISES AND COMMON AREAS.

2.1 **The Premises.**

2.1.1 Subject to the terms hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. Landlord and Tenant acknowledge that the rentable square footage of the Premises is as set forth in Section 1.2.2 and the rentable square footage of the Building is as set forth in Section 1.6. At any time Landlord may deliver to Tenant a notice substantially in the form of **Exhibit C**, as a confirmation of the information set forth therein. Tenant shall execute and return (or, by notice to Landlord, reasonably object to) such notice within five (5) business days after receiving it, and if Tenant fails to do so, Tenant shall be deemed to have executed and returned it without exception.

2.1.2 Except as expressly provided herein (including, without limitation, as set forth in **Exhibit B** hereto), the Premises are accepted by Tenant in their configuration and condition existing on the date hereof, without any obligation of Landlord to perform or pay for any alterations to the Premises, and without any representation or warranty regarding the configuration or condition of the Premises, the Building or the Project or their suitability for Tenant’s business. Nothing in this Section 2.1.2 shall limit Landlord’s obligations under Section 7.1.

2.2 **Common Areas.** Tenant may use, in common with Landlord and other parties and subject to the Rules and Regulations (defined in **Exhibit D**), any portions of the Property that are designated from time to time by Landlord for such use (the “**Common Areas**”).

3 RENT. Tenant shall pay all Base Rent and Additional Rent (defined below) (collectively, “**Rent**”) to Landlord or Landlord’s agent, without prior notice or demand or any setoff or deduction (except as expressly set forth herein), at the place Landlord may designate from time to time, in money of the United States of America that, at the time of payment, is legal tender for the payment of all obligations. As used herein, “**Additional Rent**” means all amounts, other than Base Rent, that Tenant is required to pay Landlord hereunder. Monthly payments of Base Rent and monthly payments of Additional Rent for Expenses (defined in Section 4.2.2), Taxes (defined in Section 4.2.3) and parking (collectively, “**Monthly Rent**”) shall be paid in advance on or before the first day of each calendar month during the Term; provided, however, that the installment of Base Rent for the first full calendar month for which Base Rent is payable

hereunder shall be paid upon Tenant's execution and delivery hereof. Except as otherwise provided herein, all other items of Additional Rent shall be paid within 30 days after Landlord's request for payment. Rent for any partial calendar month shall be prorated based on the actual number of days in such month. Without limiting Landlord's other rights or remedies, (a) if any installment of Rent is not received by Landlord or its designee within five (5) business days after its due date, Tenant shall pay Landlord a late charge equal to 5% of the overdue amount; and (b) any Rent that is not paid within 10 days after its due date shall bear interest, from its due date until paid, at the lesser of 18% per annum or the highest rate permitted by Law (defined in Section 5). Tenant's covenant to pay Rent is independent of every other covenant herein.

4 EXPENSES AND TAXES.

4.1 **General Terms.** In addition to Base Rent, Tenant shall pay, in accordance with Section 4.4, for each Expense Year (defined in Section 4.2.1), an amount equal to the sum of (a) Tenant's Share of any amount (the "**Expense Excess**") by which Expenses for such Expense Year exceed Expenses for the Base Year, plus (b) Tenant's Share of any amount (the "**Tax Excess**") by which Taxes for such Expense Year exceed Taxes for the Base Year. No decrease in Expenses or Taxes for any Expense Year below the corresponding amount for the Base Year shall entitle Tenant to any decrease in Base Rent or any credit against amounts due hereunder. Tenant's Share of the Expense Excess and Tenant's Share of the Tax Excess for any partial Expense Year shall be prorated based on the number of days in such Expense Year.

4.2 **Definitions.** As used herein, the following terms have the following meanings:

4.2.1"**Expense Year**" means each calendar year (other than the Base Year and any preceding calendar year) in which any portion of the Term occurs.

4.2.2"**Expenses**" means all expenses, costs and amounts that Landlord pays or accrues during the Base Year or any Expense Year because of or in connection with the ownership, management, maintenance, security, repair, replacement, restoration or operation of the Property. Landlord shall act in a reasonable manner in incurring Expenses. Without limiting the preceding sentence, Landlord shall not "double-count" any amount as an Expense or add a "mark-up" to any Expense; provided, however, that this sentence shall not limit (a) Landlord's right to include a management fee in Expenses pursuant to clause (vi) of the next succeeding sentence, or (b) the penultimate paragraph of this Section 4.2.2. Expenses shall include (i) the cost of supplying all utilities, the cost of operating, repairing, maintaining and renovating the utility, telephone, mechanical, sanitary, storm-drainage, and elevator systems, and the cost of maintenance and service contracts in connection therewith; (ii) the cost of licenses, certificates, permits and inspections, the cost of contesting any Laws that may affect Expenses, and the costs of complying with any governmentally-mandated transportation-management or similar program; (iii) the cost of all insurance premiums and deductibles (provided, however, that earthquake insurance deductibles shall not exceed 5.0% of the total insurable value of the Project per occurrence and any other insurance deductibles shall not exceed $100,000.00 per occurrence); (iv) the cost of landscaping and relamping; (v) the cost of parking-area operation, repair, restoration, and maintenance; (vi) a management fee in the amount (which fee may be imputed if Landlord has internalized management or otherwise acts as its own property manager and which fee is hereby acknowledged to be reasonable) of 3% of gross annual receipts from the Property (excluding the management fee), together with other fees and costs, including consulting fees, legal fees and accounting fees, of all contractors and consultants in connection with the management, operation, maintenance and repair of the Property; (vii) the fair rental value of any management office space; (viii) wages, salaries and other compensation, expenses and benefits, including taxes levied thereon, of all persons engaged in the operation, maintenance and security of the Property, and costs of training, uniforms, and employee enrichment for such persons; (ix) the costs of operation, repair, maintenance and replacement of all systems and equipment (and components thereof) of the Property; (x) the cost of janitorial, alarm, security and other services, replacement of wall and floor coverings, ceiling tiles and fixtures in Common Areas, maintenance and replacement of curbs and walkways, repair to roofs and re-roofing; (xi) rental or acquisition costs of supplies, tools, equipment, materials and personal property used in the maintenance, operation and repair of the Property; (xii) the cost of capital improvements or any other items that are (A) intended to reduce current or future Expenses, enhance the safety or security of the Property or its occupants, or enhance the environmental sustainability of the Property's operations, (B) replacements or modifications of the nonstructural portions of the Base Building (defined in Section 5) or Common Areas that are required to keep the Base Building or Common Areas in good condition, or (C) required under any Law; (xiii) the cost of tenant-relation programs reasonably established by Landlord; and (xiv) payments under any existing or future reciprocal easement agreement, transportation management agreement, cost-sharing agreement or other covenant, condition, restriction or similar instrument affecting the Property.

Notwithstanding the foregoing, Expenses shall not include: (a) capital expenditures not described in clauses (xi) or (xii) above (in addition, any capital expenditure shall be included in Expenses only if paid or accrued after the Base Year and shall be amortized (including actual or imputed interest on the amortized cost) over the lesser of (i) the useful life of the item purchased through such capital expenditure, as reasonably determined by Landlord, or (ii) the period of time that Landlord reasonably estimates will be required for any Expense savings resulting from such capital expenditure to equal such capital expenditure; provided, however, that any capital expenditure that is included in Expenses solely on the grounds that it is intended to reduce current or future Expenses shall be so amortized over the period of time described in the preceding clause (ii)); (b) depreciation; (c) interest and principal payments of mortgage or other non-operating debts of Landlord; (d) costs of repairs to the extent Landlord is reimbursed by insurance or condemnation proceeds; (e) except as provided in clause (xiii) above, costs of leasing space in the Building, including brokerage commissions, lease concessions, rental abatements and construction allowances granted to specific tenants; (f) costs of selling, financing or refinancing the Building; (g) fines, penalties or interest resulting from late payment of Taxes or Expenses; (h) organizational expenses of creating or operating the entity that constitutes Landlord; (i) damages paid to Tenant hereunder or to other tenants of the Building under their respective leases; (j) amounts (other than management fees) (on an arm's length competitive basis) paid to Landlord's affiliates for services, but only to the extent such amounts exceed the prices charged for such services by parties having similar skill and experience; (k) fines or penalties resulting from any violations of Law, negligence or willful misconduct of Landlord or its employees, agents or contractors; (l) advertising and promotional expenses; (m) Landlord's charitable and political contributions; (n) ground lease rental; (o) attorney's fees and other expenses incurred in connection with negotiations or disputes with tenants or other occupants of the Building; (p) costs of services or benefits made available to other tenants of the Building but not to Tenant; (q) costs of purchasing or leasing major sculptures, paintings or other artwork (as opposed to decorations purchased or leased by Landlord for display in the Common Areas of the Building); (r) any expense for which Landlord has received actual reimbursement from a third party (other than from a tenant of the Building pursuant to its lease); (s) costs of curing defects in design or original construction of the Property; (t) costs that Landlord is entitled to recover under a warranty, except to the extent it would not be fiscally prudent to pursue legal action to recover such costs; (u) expenses (other than Parking Expenses (defined below)) of operating any commercial concession at the Project; (v) Parking Expenses (defined below), except to the extent Parking Expenses exceed parking revenues on an annual basis (as used herein, "**Parking Expenses**" means costs of operating, maintaining and repairing the Parking Facility, including costs of parking equipment, tickets, supplies, signs, cleaning, resurfacing, restriping, parking-garage management fees, and the wages, salaries, employee benefits and taxes for individuals working exclusively in the Parking Facility; provided, however, that Parking Expenses shall exclude (i) capital expenses, and (ii) costs of electricity, janitorial service, elevator maintenance and insurance); (w) reserves; (x) bad debt expenses; (y) costs of cleaning up Hazardous Materials, except for routine cleanup performed as part of the ordinary operation and maintenance of the Property (as used herein, "**Hazardous Materials**" means any material now or hereafter defined or regulated by any Law or governmental authority as radioactive, toxic, hazardous, or waste, or a chemical known to the state of California to cause cancer or reproductive toxicity, including (1) petroleum and any of its constituents or byproducts, (2) radioactive materials, (3) asbestos in any form or condition, and (4) materials regulated by any of the following, as amended from time to time, and any rules promulgated thereunder: the Comprehensive Environmental Response, Compensation and Liability Act of 1980, 42 U.S.C. §§9601 et seq.; the Resource Conservation and Recovery Act, 42 U.S.C. §§6901, et seq.; the Toxic Substances Control Act, 15 U.S.C. §§2601, et seq.; the Clean Water Act, 33 U.S.C. §§1251 et seq; the Clean Air Act, 42 U.S.C. §§7401 et seq.; The California Health and Safety Code; The California Water Code; The California Labor Code; The California Public Resources Code; and The California Fish and Game Code.); or (z) wages, salaries, fees or fringe benefits ("**Labor Costs**") paid to executive personnel or officers or partners of Landlord (provided, however, that if such individuals provide services directly related to the operation, maintenance or ownership of the Property that, if provided directly by a general manager or property manager or his or her general support staff, would normally be chargeable as an operating expense of a comparable office building, then the Labor Costs of such individuals may be included in Expenses to the extent of the percentage of their time that is spent providing such services to the Property).

If, during any portion of the Base Year or any Expense Year, the Building is not 100% occupied (or a service provided by Landlord to Tenant is not provided by Landlord to a tenant that provides such service itself, or any tenant of the Building is entitled to free rent, rent abatement or the like), Expenses for such year shall be determined as if the Building had been 100% occupied (and all services provided by Landlord to Tenant had been provided by Landlord to all tenants, and no tenant of the Building had been entitled to free rent, rent abatement or the like) during such portion of such year. Notwithstanding any contrary provision hereof, Expenses for the Base Year shall exclude (a) any market-wide cost increases resulting from extraordinary circumstances, including Force Majeure (defined in Section 25.2), boycotts, strikes, conservation surcharges, embargoes or shortages, and (b) at Landlord's option, the cost of any repair or replacement that Landlord reasonably expects will not recur on an annual or more frequent basis.

If Landlord does not carry earthquake, terrorism or another type of insurance for the Building during the Base Year but carries such type of insurance for the Building during any Expense Year, then, for purposes of determining the Expense Excess for such Expense Year, Expenses for the Base Year shall be deemed to be increased by the amount of the premium Landlord would have incurred for such type of insurance during the Base Year if Landlord had maintained such type of insurance for the same period of time during the Base Year as such insurance is maintained by Landlord during such Expense Year (which shall be the amount incurred for such expense for the first year such expense is incurred if the Base Year amount cannot be reasonably determined). If, in any Expense Year, Landlord provides a new type of service (as opposed to an expansion in scope of a service or a change in a type of service) that (i) is not required by Law, (ii) is not then generally provided by the landlords of Comparable Buildings (defined in Section 25.10), (iii) is not then being provided in order to enhance the health, safety or security of the tenants, occupants and users of the Building as a result of circumstances that Landlord reasonably believes are specific to the Building and do not exist at Comparable Buildings, and (iv) was not provided by Landlord during the Base Year, then, for purposes of determining the Expense Excess for such Expense Year, Expenses for the Base Year shall be deemed to be increased by the amount that Landlord would have incurred for such service during the Base Year if Landlord had provided such service for the same period of time during the Base Year as such service is provided by Landlord during such Expense Year (which shall be the amount incurred for such expense for the first year such expense is incurred if the Base Year amount cannot be reasonably determined).

4.2.3"**Taxes**" means all federal, state, county or local governmental or municipal taxes, fees, charges, assessments, levies, licenses or other impositions, whether general, special, ordinary or extraordinary, that are paid or accrued during the Base Year or any Expense Year (without regard to any different fiscal year used by such governmental or municipal authority) because of or in connection with the ownership, leasing or operation of the Property. Taxes shall include (a) real estate taxes; (b) general and special assessments; (c) transit taxes; (d) leasehold taxes; (e) personal property taxes imposed upon the fixtures, machinery, equipment, apparatus, systems, appurtenances, furniture and other personal property used in connection with the Property; (f) any tax on the rent, right to rent or other receipts from any portion of the Property or as against the business of leasing any portion of the Property; (g) any assessment, tax, fee, levy or charge imposed by any governmental agency, or by any non-governmental entity pursuant to any private cost-sharing agreement, in order to fund the provision or enhancement of any fire-protection, street-, sidewalk- or road-maintenance, refuse-removal or other service that is (or, before the enactment of Proposition 13, was) normally provided by governmental agencies to property owners or occupants without charge (other than through real property taxes); and (h) payments in lieu of taxes under any tax increment financing agreement, abatement agreement, agreement to construct improvements, or other agreement with any governmental body or agency or taxing authority. Any costs and expenses (including reasonable attorneys' and consultants' fees) incurred in attempting to protest, reduce or minimize Taxes shall be included in Taxes for the year in which they are incurred. Notwithstanding any contrary provision hereof, Taxes shall exclude (i) all excess profits taxes, franchise taxes, gift taxes, capital stock taxes, inheritance and succession taxes, transfer taxes, estate taxes, federal and state income taxes, and other taxes to the extent (x) applicable to Landlord's general or net income (as opposed to rents or receipts attributable to operations at the Property), or (y) measured solely by the square footage, rent, fees, services, tenant allowances or similar amounts, rights or obligations described or provided in or under any particular lease, license or similar agreement or transaction at the Building; (ii) any Expenses, and (iii) any items required to be paid or reimbursed by Tenant under Section 4.5.

4.3 **Allocation.** Landlord, in its reasonable discretion, may equitably allocate Expenses among office, retail or other portions or occupants of the Property. If Landlord incurs Expenses or Taxes for the Property together with another property, Landlord, in its reasonable discretion, shall equitably allocate such shared amounts between the Property and such other property.

4.4 **Calculation and Payment of Expense Excess and Tax Excess**.

4.4.1 **Statement of Actual Expenses and Taxes; Payment by Tenant.** Landlord shall give to Tenant, after the end of each Expense Year, a statement (the "**Statement**") setting forth the actual Expenses, Taxes, Expense Excess and Tax Excess for such Expense Year. If the amount paid by Tenant for such Expense Year pursuant to Section 4.4.2 is less or more than the sum of Tenant's Share of the actual Expense Excess plus Tenant's Share of the actual Tax Excess (as such amounts are set forth in such Statement), Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the Rent then or next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Tenant shall pay Landlord the amount of such underpayment, or Landlord shall pay Tenant the amount of such overpayment (less any Rent due), within 30 days after delivery of such Statement. Any failure of Landlord to timely deliver the Statement for any Expense Year shall not diminish either party's rights under this Section 4. Notwithstanding the foregoing, if Landlord fails to furnish a Statement by April 30 of the second (2nd) calendar year following the Expense Year to which such Statement applies, Tenant shall not be required to pay Landlord any underpayment for such Expense Year, except as provided in Section 4.4.3.

4.4.2**Statement of Estimated Expenses and Taxes.** Landlord shall give to Tenant, for each Expense Year, a statement (the "**Estimate Statement**") setting forth Landlord's reasonable estimates of the Expenses, Taxes, Expense Excess (the "**Estimated Expense Excess**") and Tax Excess (the "**Estimated Tax Excess**") for such Expense Year. Upon receiving an Estimate Statement, Tenant shall pay, with its next installment of Base Rent coming due at least 30 days after such receipt, an amount equal to the excess of (a) the amount obtained by multiplying (i) the sum of Tenant's Share of the Estimated Expense Excess plus Tenant's Share of the Estimated Tax Excess (as such amounts are set forth in such Estimate Statement), by (ii) a fraction, the numerator of which is the number of months that have elapsed in the applicable Expense Year (including the month of such payment) and the denominator of which is 12, over (b) any amount previously paid by Tenant for such Expense Year pursuant to this Section 4.4.2. Until Landlord delivers a new Estimate Statement (which Landlord may do at any time), Tenant shall pay monthly, with the monthly Base Rent installments, an amount equal to one-twelfth (1/12) of the sum of Tenant's Share of the Estimated Expense Excess plus Tenant's Share of the Estimated Tax Excess, as such amounts are set forth in the previous Estimate Statement. Any failure of Landlord to timely deliver any

Estimate Statement shall not diminish Landlord's rights to receive payments and revise any previous Estimate Statement under this Section 4.

4.4.3 **Retroactive Adjustment of Taxes.** Notwithstanding any contrary provision hereof, if, after Landlord's delivery of any Statement, an increase or decrease in Taxes occurs for the applicable Expense Year or for the Base Year (whether by reason of reassessment, error, or otherwise), Taxes for such Expense Year or the Base Year, as the case may be, and the Tax Excess for such Expense Year shall be retroactively adjusted. If, as a result of such adjustment, it is determined that Tenant has under- or overpaid Tenant's Share of such Tax Excess, Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the Rent then or next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Tenant shall pay Landlord the amount of such underpayment, or Landlord shall pay Tenant the amount of such overpayment (less any Rent due), within 30 days after such adjustment is made.

4.5 **Charges for Which Tenant Is Directly Responsible.** Notwithstanding any contrary provision hereof, Tenant, promptly upon demand, shall pay (or if paid by Landlord, reimburse Landlord for) each of the following to the extent levied against Landlord or Landlord's property: (a) any tax based upon or measured by the cost or value of Tenant's trade fixtures, equipment, furniture or other personal property; (b) any rent tax, sales tax, service tax, transfer tax, value added tax, use tax, business tax, gross income tax, gross receipts tax, or other tax, assessment, fee, levy or charge measured solely by the square footage, Rent, services, tenant allowances or similar amounts, rights or obligations described or provided in or under this Lease; (c) any tax assessed upon the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of any portion of the Property; and (d) any tax assessed on this transaction or on any document to which Tenant is a party that creates an interest or estate in the Premises.

4.6 **Books and Records.** Within 60 days after receiving any Statement (the "**Review Notice Period**"), Tenant may give Landlord notice ("**Review Notice**") stating that Tenant elects to review Landlord's calculation of the Expense Excess and/or Tax Excess for the Expense Year to which such Statement applies and identifying with reasonable specificity the records of Landlord reasonably relating to such matters that Tenant desires to review. Within a reasonable time after receiving a timely Review Notice (and, at Landlord's option, an executed confidentiality agreement as described below), Landlord shall deliver to Tenant, or make available for inspection at a location reasonably designated by Landlord, copies of such records. Within 60 days after such records are made available to Tenant (the "**Objection Period**"), Tenant may deliver to Landlord notice (an "**Objection Notice**") stating with reasonable specificity any objections to the Statement, in which event Landlord and Tenant shall work together in good faith to resolve Tenant's objections. Tenant may not deliver more than one Review Notice or more than one Objection Notice with respect to any Statement. If Tenant fails to give Landlord a Review Notice before the expiration of the Review Notice Period or fails to give Landlord an Objection Notice before the expiration of the Objection Period, Tenant shall be deemed to have approved the Statement. Notwithstanding any contrary provision hereof, Landlord shall not be required to deliver or make available to Tenant records relating to the Base Year, and Tenant may not object to Expenses or Taxes for the Base Year, other than in connection with the first review for an Expense Year performed by Tenant pursuant to this Section 4.6. If Tenant retains an agent to review Landlord's records, the agent must be with a CPA firm licensed to do business in the State of California with experience reviewing books and records kept for Comparable Buildings and its fees shall not be contingent, in whole or in part, upon the outcome of the review. Tenant shall be responsible for all costs of such review; provided, however, that if Landlord and Tenant determine that the sum of Expenses and Taxes for the Expense Year in question was overstated by more than 5%, Landlord, within 30 days after receiving paid invoices therefor from Tenant, shall reimburse Tenant for the reasonable amounts paid by Tenant to third parties in connection with such review (not to exceed $5,000.00). The records and any related information obtained from Landlord shall be treated as confidential, and as applicable only to the Premises, by Tenant, its auditors, consultants, and any other parties reviewing the same on behalf of Tenant (collectively, "**Tenant's Auditors**"). Before making any records available for review, Landlord may require Tenant and Tenant's Auditors to execute a reasonable confidentiality agreement, in which event Tenant shall cause the same to be executed and delivered to Landlord within 30 days after receiving it from Landlord, and if Tenant fails to do so, the Objection Period shall be reduced by one day for each day by which such execution and delivery follows the expiration of such 30-day period. Notwithstanding any contrary provision hereof, Tenant may not examine Landlord's records or dispute any Statement if any Rent remains unpaid past its due date. If, for any Expense Year, Landlord and Tenant determine that the sum of Tenant's Share of the actual Expense Excess plus Tenant's Share of the actual Tax Excess is less or more than the amount reported, Tenant shall receive a credit in the amount of its overpayment, or pay Landlord the amount of its underpayment, against or with the Rent next due hereunder; provided, however, that if this Lease has expired or terminated and Tenant has vacated the Premises, Landlord shall pay Tenant the amount of its overpayment (less any Rent due), or Tenant shall pay Landlord the amount of its underpayment, within 30 days after such determination.

5 USE; COMPLIANCE WITH LAWS.

5.1 Tenant shall not (a) use the Premises for any purpose other than the Permitted Use, or (b) do anything in or about the Premises that violates any of the Rules and Regulations, damages the reputation of the Project, interferes with, injures or annoys other occupants of the Project, or constitutes a nuisance. Tenant, at its expense, shall comply with all Laws relating to (i) the operation of its business at the Project, (ii) the use, occupancy and, other than with respect to elements of the Base Building, the condition and configuration of the Premises, or (iii) any Supplemental Systems (defined below) serving the Premises, whether located inside or outside of the Premises. If, in order to comply with any such Law, Tenant must obtain or deliver any permit, certificate or other document evidencing such compliance, Tenant shall provide a copy of such document to Landlord promptly after obtaining or delivering it. If a change to any Common Area or the Base Building becomes required under Law (or if any such requirement is enforced) as a result of any Tenant-Requested Improvement (defined below) that is not of a type customarily required for general office use, any trade fixture that is not of a type customarily required for general office use or because any use of the Premises that is not general office use, then Tenant, upon demand, shall (x) at Landlord's option, either make such change at Tenant's cost or pay Landlord the cost of making such change, and (y) pay Landlord a coordination fee equal to 5% of the cost of such change. As used herein, "**Law**" means any existing or future law, ordinance, regulation or requirement of any governmental authority having jurisdiction over the Project or the parties. As used herein, "**Supplemental System**" means any Unit (defined in Section 25.5), supplemental fire-suppression system, kitchen (including any hot water heater, dishwasher, garbage disposal, insta-hot dispenser, or plumbing), shower or similar facility, or any other system that would not customarily be considered part of the base building of a first-class multi-tenant office building. As used herein, "**Base Building System**" means any mechanical (including HVAC), electrical, plumbing or fire/life-safety system serving the Building, other than a Supplemental System. As used herein, "**Base Building**" means the structural portions of the Building, together with the Base Building Systems. As used herein, "**Tenant-Requested Improvement**" means any Leasehold Improvements (defined in Section 7.1 below) installed by or for the benefit of Tenant, whether pursuant to this Lease or pursuant to any prior lease or other agreement to which Tenant was a party.

5.2 Landlord, at its expense (subject to Section 4), shall cause the Base Building and the Common Areas to comply with all Laws (including the Americans with Disabilities Act ("**ADA**")) to the extent that (a) such compliance is necessary for Tenant to use the Premises for general office use in a normal and customary manner and for Tenant's employees and visitors to have reasonably safe access to and from the Premises, or (b) Landlord's failure to cause such compliance would impose liability upon Tenant under Law; provided, however, that Landlord shall not be required to cause or pay for such compliance to the extent that (x) Tenant is required to cause or pay for such compliance under Section 5.1 or 7.3 or any other provision hereof, or (y) non-compliance arises under any provision of the ADA other than Title III thereof. Notwithstanding the foregoing, Landlord may contest any alleged violation in good faith, including by applying for and obtaining a waiver or deferment of compliance, asserting any defense allowed by Law, and appealing any order or judgment to the extent permitted by Law; provided, however, that (i) no cost or liability shall be imposed upon Tenant as a result of such contest, and (ii) after exhausting any rights to contest or appeal, Landlord shall perform any work necessary to comply with any final order or judgment.

5.3 To the extent that there is any inconsistency between the terms of this Section 5 and **Exhibit B** hereto, **Exhibit B** shall control.

6 SERVICES.

6.1 **Standard Services.** Landlord shall provide the following services on all days (unless otherwise stated below): (a) subject to limitations imposed by Law, customary heating, ventilation and air conditioning ("**HVAC**") in season during Building HVAC Hours, stubbed to the Premises; (b) electricity supplied by the applicable public utility, stubbed to the Premises; (c) water supplied by the applicable public utility (i) for use in lavatories and any drinking facilities located in Common Areas within the Building, and (ii) stubbed to the Building core for use in any plumbing fixtures located in the Premises; (d) janitorial services to the Premises, except on weekends and Holidays; (e) elevator service (subject to scheduling by Landlord for any freight service); and (f) access to the Building for Tenant and its employees, 24 hours per day/7 days per week, subject to the terms hereof and such security or monitoring systems as Landlord may reasonably impose, including sign-in procedures and/or presentation of identification cards.

6.2 **Above-Standard Use.** Landlord shall provide HVAC service outside Building HVAC Hours if Tenant gives Landlord such prior notice and pays Landlord such hourly cost per zone as Landlord may require. The parties acknowledge that, as of the date hereof, Landlord's charge for HVAC service outside Building HVAC Hours is $85.00 per hour, subject to change from time to time to Landlord's then Building-standard rate. Tenant shall not, without Landlord's prior consent, use equipment that may affect the temperature maintained by the air conditioning system or consume above-Building-standard amounts of any water furnished for the Premises by Landlord pursuant to Section 6.1. If Tenant's consumption of electricity or water exceeds the rate Landlord reasonably deems to be standard for the Building, Tenant shall pay Landlord, upon billing, the cost of such excess consumption, including any costs of installing, operating and maintaining any equipment that is installed in order to supply or measure such excess electricity or water. The connected electrical load of Tenant's incidental-use equipment shall not exceed the Building-standard electrical design load, and Tenant's electrical usage shall not exceed the capacity of the feeders to the Project or the risers or wiring installation.

6.3 **Interruption.** Subject to Section 11, any failure to furnish, delay in furnishing, or diminution in the quality or quantity of any service resulting from any application of Law, failure of equipment, performance of maintenance, repairs, improvements or alterations, utility interruption, or event of Force Majeure (each, a "**Service Interruption**") shall not render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder. Notwithstanding the foregoing, if all or a material portion of the Premises is made untenantable or inaccessible for more than three (3) consecutive business days after notice from Tenant to Landlord by a Service Interruption that (a) does not result from a Casualty (defined in Section 11), a Taking (defined in Section 13) or an Act of Tenant (defined in Section 10.1), and (b) can be corrected through Landlord's reasonable efforts, then, as Tenant's sole remedy, Monthly Rent shall abate for the period beginning on the day immediately following such 3-business-day period and ending on the day such Service Interruption ends, but only in proportion to the percentage of the rentable square footage of the Premises made untenantable or inaccessible and not occupied by Tenant.

7 REPAIRS AND ALTERATIONS.

7.1 **Repairs.** Subject to Section 11, Tenant, at its expense, shall perform all maintenance and repairs (including replacements) to the Premises, and keep the Premises in as good condition and repair as existed when Tenant took possession and as thereafter improved, except for reasonable wear and tear and repairs that are Landlord's express responsibility hereunder. Tenant's maintenance and repair obligations shall include (a) all leasehold improvements in the Premises, including any Tenant Improvements, any Alterations (defined in Section 7.2), and any leasehold improvements installed pursuant to any prior lease (the "**Leasehold Improvements**"), but excluding the Base Building; (b) any Supplemental Systems serving the Premises, whether located inside or outside of the Premises; and (c) all Lines (defined in Section 23) and trade fixtures. Notwithstanding the foregoing, if a Default (defined in Section 19.1) or an emergency exists, Landlord may, at its option, perform such maintenance and repairs on Tenant's behalf, in which case Tenant shall pay Landlord, upon demand, the cost of such work plus a coordination fee equal to 5% of such cost. Landlord shall perform all maintenance and repairs (including replacements) to, and keep in good condition and repair, (i) the roof and exterior walls and windows of the Building (so that the components of the Building remain water-tight), (ii) the Base Building, and (iii) the Common Areas.

7.2 **Alterations.** Tenant may not make any improvement, alteration, addition or change to the Premises or to any mechanical, plumbing or HVAC facility or other system serving the Premises (an "**Alteration**") without Landlord's prior consent, which consent shall be requested by Tenant not less than 30 days before commencement of work and shall not be unreasonably withheld, conditioned or delayed by Landlord. Notwithstanding the foregoing, Landlord's prior consent shall not be required for any Alteration that is decorative only (*e.g.,* carpet installation or painting) and not visible from outside the Premises, provided that Landlord receives 10 business days' prior notice. For any Alteration, (a) Tenant, before beginning work, shall deliver to Landlord, and obtain Landlord's approval of, plans and specifications; (b) Landlord, in its discretion, may require Tenant to obtain security for performance satisfactory to Landlord; (c) Tenant shall deliver to Landlord "as built" drawings (in CAD format, if requested by Landlord), completion affidavits, full and final lien waivers, and all governmental approvals; and (d) Tenant shall pay Landlord upon demand (i) Landlord's reasonable out-of-pocket expenses incurred in reviewing the work, and (ii) a coordination fee equal to 10% of the cost of the work; provided, however, that this clause (d) shall not apply to any Tenant Improvements.

7.3 **Tenant Work.** Before beginning any repair or Alteration or any work affecting Lines (collectively, "**Tenant Work**"), Tenant shall deliver to Landlord, and obtain Landlord's approval of, (a) names of contractors, subcontractors, mechanics, laborers and materialmen; (b) evidence of contractors' and subcontractors' insurance in amounts and coverages as Landlord may reasonably require; and (c) any required governmental permits. Tenant shall perform all Tenant Work (i) in a good and workmanlike manner using materials of a quality reasonably approved by Landlord; (ii) in compliance with any approved plans and specifications, all Laws, the National Electric Code, and Landlord's construction rules and regulations; and (iii) in a manner that does not impair the Base Building. If, as a result of any Tenant Work, Landlord becomes required under Law to perform any inspection, give any notice, or cause such Tenant Work to be performed in any particular manner, Tenant shall comply with such requirement and promptly provide Landlord with reasonable documentation of such compliance. Landlord's approval of Tenant's plans and specifications shall not relieve Tenant from any obligation under this Section 7.3. In performing any Tenant Work, Tenant shall not use contractors, services, labor, materials or equipment that, in Landlord's reasonable judgment, would disturb labor harmony with any workforce or trades engaged in performing other work or services at the Project.

8 LANDLORD'S PROPERTY. All Leasehold Improvements shall become Landlord's property upon installation and without compensation to Tenant. Notwithstanding the foregoing, if any Tenant-Requested Improvements (other than any Unit, which shall be governed by Section 25.5) are not, in Landlord's reasonable judgment, Building-standard, then before the expiration or earlier termination hereof, Tenant shall, at Landlord's election and at Tenant's expense, and except as otherwise notified by Landlord, remove such Tenant-Requested Improvements (other than the Excluded Items, defined below), repair any resulting damage to the Premises or Building, and restore the affected portion of the Premises to its configuration and condition existing before the installation of such Tenant-Requested Improvements. If

Tenant fails to timely perform any work required under the preceding sentence, Landlord may perform such work at Tenant's expense. As used herein, the term "**Excluded Items**" means the Tenant Improvement Work shown with reasonable specificity on the Approved Space Plan (as initially described in Section 2.3 of **Exhibit B** hereto). When Landlord approves any Tenant-Requested Improvements or Alterations (or, in the case of any Tenant-Requested Improvements or Alterations not requiring Landlord's approval hereunder, within 10 business days after Tenant's request), Landlord shall identify any such Tenant-Requested Improvements or Alterations that, in Landlord's judgment, are not Building-standard.

9 LIENS. Tenant shall keep the Project free from any lien arising out of any work performed, material furnished or obligation incurred by or on behalf of Tenant. Tenant shall remove any such lien within 10 business days after notice from Landlord, and if Tenant fails to do so, Landlord, without limiting its remedies, may pay the amount necessary to cause such removal, whether or not such lien is valid. The amount so paid, together with reasonable attorneys' fees and expenses, shall be reimbursed by Tenant upon demand.

10 INDEMNIFICATION; INSURANCE.

10.1 **Waiver and Indemnification.** Tenant waives all claims against Landlord, its Security Holders (defined in Section 17), Landlord's managing agent(s), their (direct or indirect) owners, and the beneficiaries, trustees, officers, directors, employees and agents of each of the foregoing (including Landlord, the "**Landlord Parties**") for (i) any damage to person or property (or resulting from the loss of use thereof), except to the extent such damage is caused by any negligence, willful misconduct or breach of this Lease of or by any Landlord Party, or (ii) any failure to prevent or control any criminal or otherwise wrongful conduct by any third party (not acting as Landlord's agent) or to apprehend any such third party who has engaged in such conduct. Tenant shall indemnify, defend, protect, and hold the Landlord Parties harmless from any obligation, loss, claim, action, liability, penalty, damage, cost or expense (including reasonable attorneys' and consultants' fees and expenses) (each, a "**Claim**") that is imposed or asserted by any third party and arises from (a) any cause in, on or about the Premises, or (b) any negligence, willful misconduct or breach of this Lease of or by Tenant, any party claiming by, through or under Tenant, their (direct or indirect) owners, or any of their respective beneficiaries, trustees, officers, directors, employees, agents, contractors, licensees or invitees (each, an "**Act of Tenant**"), except to the extent such Claim arises from any negligence, willful misconduct or breach of this Lease of or by any Landlord Party. Landlord shall indemnify, defend, protect, and hold Tenant, its (direct or indirect) owners, and their respective beneficiaries, trustees, officers, directors, employees and agents (including Tenant, the "**Tenant Parties**") harmless from any Claim that is imposed or asserted by any third party and arises from any negligence, willful misconduct or breach of this Lease of or by any Landlord Party, except to the extent such Claim arises from any negligence, willful misconduct or breach of this Lease of or by any Tenant Party.

10.2 **Tenant's Insurance.** Tenant shall maintain the following coverages in the following amounts:

10.2.1Commercial General Liability Insurance, written on an occurrence basis, with a combined single limit for bodily injury and property damages of not less than Five Million Dollars ($5,000,000) per occurrence and Six Million Dollars ($6,000,000), in the annual aggregate, which shall apply separately to each location of Tenant, including products liability coverage if applicable, blanket contractual coverage including written contracts, and personal and bodily injury coverage, covering the insuring provisions of this Lease and the performance of Tenant of the indemnity and exemption of Landlord from liability agreements set forth in this Lease.

10.2.2Property Insurance covering (i) all improvements in the Premises ("**Tenant-Insured Improvements**") and (ii) all office furniture, trade fixtures, office equipment, free-standing cabinet work, movable partitions, merchandise and all other items of Tenant's property in the Premises installed by, for, or at the expense of Tenant. Such insurance shall be written on a special cause of loss or all risk form for physical loss or damage, for the full replacement cost value (subject to deductible amounts not exceeding $10,000.00) new without deduction for depreciation of the covered items and in amounts that meet any co-insurance clauses of the policies of insurance, and shall include coverage for damage or other loss caused by fire or other peril, including vandalism and malicious mischief, theft, water damage of any type, including sprinkler leakage, bursting or stoppage of pipes, and explosion (and providing business interruption, loss of income and extra expense insurance covering any failure or interruption of Tenant's business equipment (including, without limitation, telecommunications equipment) and covering all other perils, failures or interruptions sufficient to cover a period of interruption of not less than twelve (12) months).

10.2.3Workers' Compensation statutory limits and Employers' Liability limits of $1,000,000.

10.3 **Form of Policies.** The minimum limits of insurance required to be carried by Tenant shall not limit Tenant's liability. Such insurance shall be issued by an insurance company that has an A.M. Best rating of not less than A-VIII. Tenant's Commercial General Liability Insurance shall (a) name the Landlord Parties and any other party designated by Landlord ("**Additional Insured Parties**") as additional insureds; and (b) be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and non-contributing with Tenant's insurance. Landlord shall be designated as a loss payee with respect to Tenant's Property Insurance on any Tenant-Insured Improvements. Tenant shall deliver to Landlord, on or before the Commencement Date and at least 15 days before the expiration dates thereof, certificates from Tenant's insurance company on the forms currently designated "ACORD 25" (Certificate of Liability Insurance) and "ACORD 28" (Evidence of Commercial Property Insurance) or the equivalent. Attached to the ACORD 25 (or equivalent) there shall be an endorsement (or an excerpt from the policy) naming the Additional Insured Parties as additional insureds, and attached to the ACORD 28 (or equivalent) there shall be an endorsement (or an excerpt from the policy) designating Landlord as a loss payee with respect to Tenant's Property Insurance on any Tenant-Insured Improvements, and each such endorsement (or policy excerpt) shall be binding on Tenant's insurance company. Tenant agrees that if Tenant does not take out and maintain such insurance or furnish Landlord with certificates of coverage in a timely manner, Landlord may (but shall not be required to) procure said insurance on Tenant's behalf and charge Tenant the cost thereof, which amount shall be payable by Tenant upon demand with interest (at the rate that is at the lesser of 18% per annum or the highest rate permitted by Law) from the date such sums are expended. Tenant shall have the right to provide such insurance coverage pursuant to blanket policies obtained by Tenant, provided such blanket policies expressly afford coverage to the Premises and to Tenant as required by this Lease.

10.4 **Subrogation.** Notwithstanding any provision in this Lease to the contrary (but subject to the provisions set forth in Section 11 below as well as the provisions set forth in Sections 4 and 8 of **Exhibit D** hereto) each party waives, and shall cause its insurance carrier to waive, any right of recovery against the other party, any of its (direct or indirect) owners, or any of their respective beneficiaries, trustees, officers, directors, employees or agents for any loss of or damage to property which loss or damage is (or, if the insurance required hereunder had been carried, would have been) covered by the waiving party's property insurance. For purposes of this Section 10.4 only, (a) any deductible with respect to a party's insurance shall be deemed covered by, and recoverable by such party under, valid and collectable policies of insurance, and (b) any contractor retained by Landlord to install, maintain or monitor a fire or security alarm for the Building shall be deemed an agent of Landlord.

10.5 **Additional Insurance Obligations.** Tenant shall maintain such increased amounts of the insurance required to be carried by Tenant under this Section 10, and such other types and amounts of insurance covering the Premises and Tenant's operations therein, as may be reasonably requested by Landlord, but not in excess of the amounts and types of insurance then being required by landlords of Comparable Buildings. Tenant agrees that it will not, at any time, during the Term, carry any stock of goods or do anything in or about the Premises that will in any way tend to increase Landlord's insurance rates upon the Project. Tenant agrees to pay Landlord forthwith upon demand the amount of any increase in Landlord's premiums for insurance that may be carried during the Term of this Lease, or the amount of insurance to be carried by Landlord on the Project resulting from the foregoing, or from Tenant doing any act in or about the Premises that does so increase the insurance rates, whether or not Landlord shall have consented to such act on the part of Tenant. Tenant shall, at its own expense, comply with the requirements of Landlord's insurance providers applicable to the Premises including, without limitation, the installation of fire extinguishers or an automatic dry chemical extinguishing system.

10.6 **Landlord's Insurance**. Landlord may, as a cost to be included in Expenses (subject to the terms of Section 4 hereof), procure and maintain at all times during the Term of this Lease, a policy or policies of insurance covering loss or damage to the Project in the amount of the full replacement cost without deduction for depreciation thereof, providing protection against all perils included within the classification of fire and extended coverage, vandalism coverage and malicious mischief, sprinkler leakage, water damage, and special extended coverage on the building. Additionally, Landlord may carry: (i) commercial general liability and umbrella/excess liability insurance and (ii) earthquake and/or flood damage insurance; and (iii) rental income insurance; and (iv) any other forms of insurance Landlord may deem appropriate or any lender may require. The costs of all insurance carried by Landlord shall be included in Expenses (subject to the terms of Section 4 hereof).

11 CASUALTY DAMAGE. With reasonable promptness after discovering any damage to the Premises (other than trade fixtures), or to any Common Area or portion of the Base Building necessary for access to or tenantability of the Premises, resulting from any fire or other casualty (a "**Casualty**"), Landlord shall notify Tenant of Landlord's reasonable estimate of the time required to substantially complete repair of such damage (the "**Landlord Repairs**"). If, according to such estimate, the Landlord Repairs cannot be substantially completed within 210 days after they are commenced, either party may terminate this Lease upon 60 days' notice to the other party delivered within 10 days after Landlord's delivery of such estimate. Within 90 days after discovering any damage to the Project resulting from any Casualty, Landlord may, whether or not the Premises are affected, terminate this Lease by notifying Tenant if (i) any Security Holder terminates any ground lease or requires that any insurance proceeds be used to pay any mortgage debt; (ii) any damage to Landlord's property is not fully covered by Landlord's insurance policies; (iii) Landlord decides to rebuild the Building or Common Areas so that it or they will be substantially different structurally or architecturally; (iv) the damage occurs during the last 12 months of the Term; or (v) any owner, other than Landlord, of any damaged portion of the Project does not intend to repair such damage. If this Lease is not terminated pursuant to this Section 11, Landlord shall promptly and diligently perform the Landlord

Repairs, subject to reasonable delays for insurance adjustment and other events of Force Majeure. The Landlord Repairs shall restore the Premises (other than trade fixtures) and any Common Area or portion of the Base Building necessary for access to or tenantability of the Premises to substantially the same condition that existed when the Casualty occurred, except for (a) any modifications required by Law or any Security Holder, and (b) any modifications to the Common Areas that are deemed desirable by Landlord, are consistent with the character of the Project, and do not materially impair access to or tenantability of the Premises. Notwithstanding Section 10.4, Tenant shall assign to Landlord (or its designee) all insurance proceeds payable to Tenant under Tenant's insurance required under Section 10.2 with respect to any Tenant-Insured Improvements, and if the estimated or actual cost of restoring any Tenant-Insured Improvements exceeds the insurance proceeds received by Landlord from Tenant's insurance carrier, Tenant shall pay such excess to Landlord within 15 days after Landlord's demand. No Casualty and no restoration performed as required hereunder shall render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder; provided, however, that if the Premises (other than trade fixtures) or any Common Area or portion of the Base Building necessary for access to or tenantability of the Premises is damaged by a Casualty, then, during any time that, as a result of such damage, any portion of the Premises is inaccessible or untenantable and is not occupied by Tenant, Monthly Rent shall be abated in proportion to the rentable square footage of such portion of the Premises. If Landlord does not substantially complete the Landlord Repairs by the Outside Restoration Date (defined below), Tenant may terminate this Lease by notifying Landlord within 15 days after the Outside Restoration Date and before the substantial completion of the Landlord Repairs. As used herein, "**Outside Restoration Date**" means the date occurring two (2) months after the later of (a) the expiration of the time set forth in Landlord's estimate described in the first sentence of this Section 11, or (b) the date occurring 210 days after the commencement of the Landlord Repairs; provided, however, that the Outside Restoration Date shall be extended to the extent of (i) any delay caused by the insurance adjustment process, (ii) any delay caused by Tenant or any party claiming by, through or under Tenant, and (iii) any other delay (up to 90 days) caused by events of Force Majeure. Notwithstanding the foregoing, if Landlord determines in good faith that it will be unable to substantially complete the Landlord Repairs by the Outside Restoration Date, Landlord may cease its performance of the Landlord Repairs and provide Tenant with notice (the "**Restoration Date Extension Notice**") stating such inability and identifying the date on which Landlord reasonably believes such substantial completion will occur, in which event Tenant may terminate this Lease by notifying Landlord within five (5) business days after receiving the Restoration Date Extension Notice. If Tenant does not terminate this Lease within such 5-business day period, the Outside Restoration Date shall be automatically amended to be the date identified in the Restoration Date Extension Notice.

12 NONWAIVER. No provision hereof shall be deemed waived by either party unless it is waived by such party expressly and in writing, and no waiver of any breach of any provision hereof shall be deemed a waiver of any subsequent breach of such provision or any other provision hereof. Landlord's acceptance of Rent shall not be deemed a waiver of any preceding breach of any provision hereof, other than Tenant's failure to pay the particular Rent so accepted, regardless of Landlord's knowledge of such preceding breach at the time of such acceptance. No acceptance of payment of an amount less than the Rent due hereunder shall be deemed a waiver of Landlord's right to receive the full amount of Rent due, whether or not any endorsement or statement accompanying such payment purports to effect an accord and satisfaction. No receipt of monies by Landlord from Tenant after the giving of any notice, the commencement of any suit, the issuance of any final judgment, or the termination hereof shall affect such notice, suit or judgment, or reinstate or extend the Term or Tenant's right of possession hereunder.

13 CONDEMNATION. If any part of the Premises, Building or Project is taken for any public or quasi-public use by power of eminent domain or by private purchase in lieu thereof (a "**Taking**") for more than 180 consecutive days, Landlord may terminate this Lease. If more than 25% of the rentable square footage of the Premises, or any Common Area or portion of the Base Building necessary for access to or tenantability of the Premises, is Taken for more than 180 consecutive days, Tenant may terminate this Lease. Any such termination shall be effective as of the date possession must be surrendered to the authority, and the terminating party shall provide termination notice to the other party within 45 days after receiving written notice of such surrender date. Except as provided above in this Section 13, neither party may terminate this Lease as a result of a Taking. Tenant shall not assert, and hereby assigns to Landlord, any claim it may have for compensation because of any Taking; provided, however, that Tenant may file a separate claim for any Taking of Tenant's personal property or any trade fixtures that Tenant is entitled to remove upon the expiration hereof, and for moving expenses, so long as such claim does not diminish the award available to Landlord or any Security Holder and is payable separately to Tenant. If this Lease is terminated pursuant to this Section 13, all Rent shall be apportioned as of the date of such termination. If a Taking occurs and this Lease is not so terminated, Monthly Rent shall be abated for the period of such Taking in proportion to the percentage of the rentable square footage of the Premises, if any, that is subject to, or rendered inaccessible or untenantable by, such Taking and not occupied by Tenant.

14 ASSIGNMENT AND SUBLETTING.

14.1 **Transfers.** Tenant shall not, without Landlord's prior consent, assign, mortgage, pledge, hypothecate, encumber, permit any lien to attach to, or otherwise transfer this Lease or any interest hereunder, permit any assignment or other transfer hereof or any interest hereunder by operation of law, enter into any sublease or license agreement, otherwise permit the occupancy or use of any part of the

Premises by any persons other than Tenant and its employees and contractors, or permit a Change of Control (defined in Section 14.6) to occur (each, a "**Transfer**"). If Tenant desires Landlord's consent to any Transfer, Tenant shall provide Landlord with (i) notice of the terms of the proposed Transfer, including its proposed effective date (the "**Contemplated Effective Date**"), a description of the portion of the Premises to be transferred (the "**Contemplated Transfer Space**"), a calculation of the Transfer Premium (defined in Section 14.3), and a copy of all existing executed and/or proposed documentation pertaining to the proposed Transfer, and (ii) current financial statements of the proposed transferee (or, in the case of a Change of Control, of the proposed new controlling party(ies)) certified by an officer or owner thereof and any other information reasonably required by Landlord in order to evaluate the proposed Transfer (collectively, the "**Transfer Notice**"). Within 20 days after receiving the Transfer Notice, Landlord shall notify Tenant of (a) its consent to the proposed Transfer, (b) its refusal to consent to the proposed Transfer, or (c) its exercise of its rights under Section 14.4. Any Transfer made without Landlord's prior consent shall, at Landlord's option, be void and shall, at Landlord's option, constitute a Default. Concurrently with Tenant's delivery of the Transfer Notice, Tenant shall pay Landlord a fee of $1,500.00 for Landlord's review of any proposed Transfer, whether or not Landlord consents to it.

14.2 **Landlord's Consent.** Subject to Section 14.4, Landlord shall not unreasonably withhold or condition its consent to any proposed Transfer. Without limiting other reasonable grounds for withholding consent, it shall be deemed reasonable for Landlord to withhold its consent to a proposed Transfer if:

14.2.1The proposed transferee is not a party of reasonable financial strength in light of the responsibilities to be undertaken in connection with the Transfer on the date the Transfer Notice is received; or

14.2.2The proposed transferee has a character or reputation or is engaged in a business that is not consistent with the quality of the Building or the Project; or

14.2.3The proposed transferee is a governmental entity or a nonprofit organization; or

14.2.4Intentionally Omitted; or

14.2.5The proposed transferee or any of its Affiliates, on the date the Transfer Notice is received, leases or occupies (or, at any time during the 4-month period ending on the date the Transfer Notice is received, has provided Landlord with a written proposal or request for proposal to lease) space in the Project and Landlord has (or believes in good faith, based on the scheduled expiration dates of existing leases and/or its rights to relocate existing tenants, that it will have) space available that, in its good faith judgment, will meet the proposed transferee's leasing needs; or

14.2.6 The use to be made of the Contemplated Transfer Space is a use which would be prohibited by any other portion of this Lease or a use which conflicts with any applicable so-called "exclusive" then in favor of another tenant of the Building or Project.

Notwithstanding any contrary provision hereof, (a) if Landlord consents to any Transfer pursuant to this Section 14.2 but Tenant does not enter into such Transfer within six (6) months thereafter, such consent shall no longer apply and such Transfer shall not be permitted unless Tenant again obtains Landlord's consent thereto pursuant and subject to the terms of this Section 14; and (b) if Landlord withholds its consent in breach of this Section 14.2, Tenant's sole remedies shall be contract damages (subject to Section 20) or specific performance, and Tenant waives all other remedies, including any right to terminate this Lease.

14.3 **Transfer Premium.** If Landlord consents to a Transfer (other than a Change of Control or a Permitted Transfer in which case this Section 14.3 shall not be applicable), Tenant shall pay Landlord an amount equal to 50% of any Transfer Premium (defined below). As used herein, "**Transfer Premium**" means (a) in the case of an assignment, any consideration (including payment for Leasehold Improvements) paid by the assignee for such assignment, less any reasonable and customary expenses directly incurred by Tenant on account of such assignment, including brokerage fees, legal fees, and Landlord's review fee, and (b) in the case of a sublease, license or other occupancy agreement, for each month of the term of such agreement, the amount by which all rent and other consideration paid by the transferee to Tenant pursuant to such agreement (less all reasonable and customary expenses directly incurred by Tenant on account of such agreement, including brokerage fees, legal fees, construction costs and Landlord's review fee) exceeds the Monthly Rent payable by Tenant hereunder with respect to the Contemplated Transfer Space. Payment of Landlord's share of the Transfer Premium shall be made (x) in the case of an assignment, within 30 days after Tenant receives the consideration described above, and (y) in the case of a sublease, license or other occupancy agreement, for each month of the term of such agreement, within 30 days after Tenant receives the rent and other consideration described above.

14.4 **Landlord's Right to Recapture.** Notwithstanding any contrary provision hereof, except in the case of a Permitted Transfer (defined in Section 14.8), a Change of Control, or a sublease (including any expansion rights) of less than 50% of the rentable square footage of the then existing Premises for a term (including any extension options) of less than 50% of the balance of the Term remaining on the

Contemplated Effective Date (excluding any unexercised extension options), Landlord, by notifying Tenant within 20 days after receiving the Transfer Notice, may terminate this Lease with respect to the Contemplated Transfer Space as of the Contemplated Effective Date; provided, however, that such termination shall not be effective if Tenant, by notifying Landlord within five (5) days after receiving Landlord's notice of termination, withdraws the Transfer Notice. If Tenant does not timely withdraw the Transfer Notice, and if the Contemplated Transfer Space is less than the entire Premises, then Base Rent, Tenant's Share, and the number of parking spaces to which Tenant is entitled under Section 1.9 shall be deemed adjusted on the basis of the percentage of the rentable square footage of the portion of the Premises retained by Tenant. Upon request of either party, the parties shall execute a written agreement prepared by Landlord memorializing such termination.

14.5 **Effect of Consent.** If Landlord consents to a Transfer, (i) such consent shall not be deemed a consent to any further Transfer, (ii) Tenant shall deliver to Landlord, promptly after execution, an executed copy of all documentation pertaining to the Transfer in form reasonably acceptable to Landlord, and (iii) Tenant shall deliver to Landlord, upon Landlord's request, a complete statement, certified by an independent CPA or Tenant's chief financial officer, setting forth in detail the computation of any Transfer Premium. In the case of an assignment, the assignee shall assume in writing, for Landlord's benefit, all of Tenant's obligations hereunder. No Transfer, with or without Landlord's consent, shall relieve Tenant or any guarantor hereof from any liability hereunder. Notwithstanding any contrary provision hereof, Tenant, with or without Landlord's consent, shall not enter into, or permit any party claiming by, through or under Tenant to enter into, any sublease, license or other occupancy agreement that provides for payment based in whole or in part on the net income or profit of the subtenant, licensee or other occupant thereunder.

14.6 **Change of Control.** As used herein, "**Change of Control**" means (a) if Tenant is a closely held professional service firm, the withdrawal or change (whether voluntary, involuntary or by operation of law) of more than 50% of its equity owners within a 12-month period; and (b) in all other cases, any transaction(s) resulting in the acquisition of a Controlling Interest (defined below) in Tenant by one or more parties that neither owned, nor are Affiliates (defined below) of one or more parties that owned, a Controlling Interest in Tenant immediately before such transaction(s). As used herein, "**Controlling Interest**" means control over an entity, other than control arising from the ownership of voting securities listed on a recognized securities exchange. As used herein, "**control**" means the direct or indirect power to direct the ordinary management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise. As used herein, "**Affiliate**" means, with respect to any party, a person or entity that controls, is under common control with, or is controlled by such party.

14.7 **Effect of Default.** If Tenant is in Default, Landlord is irrevocably authorized, as Tenant's agent and attorney-in-fact, to direct any transferee under any sublease, license or other occupancy agreement to make all payments under such agreement directly to Landlord (which Landlord shall apply towards Tenant's obligations hereunder) until such Default is cured. Such transferee shall rely upon any representation by Landlord that Tenant is in Default, whether or not confirmed by Tenant.

14.8 **Permitted Transfers.** Notwithstanding any contrary provision hereof, if Tenant is not in Default, Tenant may, without Landlord's consent pursuant to Section 14.1, permit a Change of Control to occur, sublease any portion of the Premises to an Affiliate of Tenant or assign this Lease to (a) an Affiliate of Tenant (other than pursuant to a merger or consolidation), (b) a successor to Tenant by merger or consolidation, or (c) a successor to Tenant by purchase of all or substantially all of Tenant's assets (a "**Permitted Transfer**"), provided that (i) at least 10 business days before the Transfer (provided that if such pre-Transfer notice and delivery are prohibited by a confidentiality agreement or by Law, then within 10 business days after the Transfer), Tenant notifies Landlord of the Transfer and delivers to Landlord any documents or information reasonably requested by Landlord relating thereto, including reasonable documentation that the Transfer satisfies the requirements of this Section 14.8; (ii) in the case of a sublease, the subtenant executes and delivers to Landlord, at least 10 business days before taking occupancy, an agreement reasonably acceptable to Landlord which (A) requires the subtenant to assume all of Tenant's release, waiver, indemnity and insurance obligations hereunder with respect to the Contemplated Transfer Space and to be bound by each provision hereof that limits the liability of any Landlord Party, and (B) provides that if either a Landlord Party or the subtenant institutes a suit against the other for violation of or to enforce such agreement, or in connection with any matter relating to the sublease or the subtenant's occupancy of the Contemplated Transfer Space, the prevailing party shall be entitled to all of its costs and expenses, including reasonable attorneys' fees; (iii) in the case of an assignment pursuant to clause (a) or (c) above, the assignee executes and delivers to Landlord, at least 10 business days before the assignment (provided that if such pre-assignment execution and delivery are prohibited by a confidentiality agreement or by Law, then within 10 business days after the assignment), a commercially reasonable instrument pursuant to which the assignee assumes, for Landlord's benefit, all of Tenant's obligations hereunder; (iv) in the case of an assignment pursuant to clause (b) above, (A) the successor entity has a net worth (as determined in accordance with GAAP, but excluding intellectual property and any other intangible assets ("**Net Worth**")) immediately after the Transfer that is not less than Tenant's Net Worth immediately before the Transfer, and (B) if Tenant is a closely held professional service firm, at least 50% of its equity owners existing 12 months before the Transfer are also equity owners of the successor entity; (v) except in the case of a Change of Control, the transferee is qualified to conduct business in the State of California; (vi) in the case of a Change of Control, (A) Tenant is not a closely held professional service firm and (B) Tenant's

Net Worth immediately after the Change of Control is not less than its Net Worth immediately before the Change of Control; and (vii) the Transfer is made for a good faith operating business purpose and not in order to evade the requirements of this Section 14.

15 SURRENDER. Upon the expiration or earlier termination hereof, and subject to Sections 8 and 11 and this Section 15, Tenant shall surrender possession of the Premises to Landlord in as good condition and repair as existed when Tenant took possession and as thereafter improved, except for reasonable wear and tear and repairs that are Landlord's express responsibility hereunder. Before such expiration or termination, Tenant, without expense to Landlord, shall (a) remove from the Premises all debris and rubbish and all furniture, equipment, trade fixtures, Lines, free-standing cabinet work, movable partitions and other articles of personal property that are owned or placed in the Premises by Tenant or any party claiming by, through or under Tenant (except for any Lines not required to be removed under Section 23), and (b) repair all damage to the Premises and Building resulting from such removal. If Tenant fails to timely perform such removal and repair, Landlord may do so at Tenant's expense (including storage costs). If Tenant fails to remove such property from the Premises, or from storage, within 30 days after notice from Landlord, any part of such property shall be deemed, at Landlord's option, either (x) conveyed to Landlord without compensation, or (y) abandoned.

16 HOLDOVER. If Tenant fails to surrender the Premises upon the expiration or earlier termination hereof, Tenant's tenancy shall be subject to the terms and conditions hereof; provided, however, that such tenancy shall be a tenancy at sufferance only, for the entire Premises, and Tenant shall pay Monthly Rent (on a per-month basis without reduction for any partial month) at a rate equal to 150% of the Monthly Rent applicable during the last calendar month of the Term. Nothing in this Section 16 shall limit Landlord's rights or remedies or be deemed a consent to any holdover. If Landlord is unable to deliver possession of the Premises to, or perform improvements for, a new tenant as a result of Tenant's holdover, Tenant shall be liable for all resulting damages, including lost profits, incurred by Landlord but only to the extent that such damages result from the occurrence or continuation of such holdover more than 30 days after notice from Landlord that Landlord has entered into, or will enter into, a lease with such new tenant.

17 SUBORDINATION; ESTOPPEL CERTIFICATES; FINANCIALS. This Lease shall be subject and subordinate to all existing and future ground or underlying leases, mortgages, trust deeds and other encumbrances against the Building or Project, all renewals, extensions, modifications, consolidations and replacements thereof (each, a "**Security Agreement**"), and all advances made upon the security of such mortgages or trust deeds, unless in each case the holder of such Security Agreement (each, a "**Security Holder**") requires in writing that this Lease be superior thereto. Upon any termination or foreclosure (or any delivery of a deed in lieu of foreclosure) of any Security Agreement, Tenant, upon request, shall attorn, without deduction or set-off, to the Security Holder or purchaser or any successor thereto and shall recognize such party as the lessor hereunder provided that such party agrees not to disturb Tenant's occupancy so long as Tenant timely pays the Rent and otherwise performs its obligations hereunder. Within 10 business days after Landlord's request, Tenant shall execute such further commercially reasonable instruments as Landlord may reasonably deem necessary to evidence the subordination or superiority of this Lease to any Security Agreement. Tenant waives any right it may have under Law to terminate or otherwise adversely affect this Lease or Tenant's obligations hereunder upon a foreclosure. Within 10 business days after Landlord's request, Tenant shall execute and deliver to Landlord a commercially reasonable estoppel certificate in favor of such parties as Landlord may reasonably designate, including current and prospective Security Holders and prospective purchasers. Within 10 days after Tenant's receipt of Landlord's written request (but no more than once each calendar year), Tenant shall provide Landlord with its current financial statement and its financial statements for the prior three (3) calendar or fiscal years (if Tenant's fiscal year is other than a calendar year). Any such statements shall be prepared in accordance with generally accepted accounting principles and, if the normal practice of Tenant, shall be audited by an independent certified public accountant.

18 ENTRY BY LANDLORD. At all reasonable times and upon no less than 24 hours prior notice to Tenant, or in an emergency, Landlord may enter the Premises to (i) inspect the Premises; (ii) show the Premises to prospective purchasers, current or prospective Security Holders or insurers, or, during the last 12 months of the Term (or while an uncured Default exists), prospective tenants; (iii) post notices of non-responsibility; or (iv) perform maintenance, repairs or alterations. At any time and without notice to Tenant, Landlord may enter the Premises to perform required services; provided, however, that except in an emergency, Landlord shall provide Tenant with reasonable prior notice (which notice, notwithstanding Section 25.1, may be delivered by e-mail, fax, telephone or orally and in person) of any entry to perform a service that is not performed on a monthly or more frequent basis. If reasonably necessary, Landlord may temporarily close any portion of the Premises to perform maintenance, repairs or alterations. In an emergency, Landlord may use any means it deems proper to open doors to and in the Premises. Except in an emergency, Landlord shall use reasonable efforts to minimize interference with Tenant's use of the Premises. Without limiting the foregoing, except in an emergency, any unreasonably noisy or otherwise disruptive work performed by Landlord in the Premises pursuant to this Section 18 shall be performed outside of normal business hours. Except in an emergency, Tenant may have one of its employees accompany Landlord if Tenant makes such employee available when Landlord enters the Premises. No entry into or closure of any portion of the Premises pursuant to this Section 18 shall render Landlord liable to Tenant, constitute a constructive eviction, or excuse Tenant from any obligation hereunder.

19 DEFAULTS; REMEDIES.

19.1 **Events of Default.** The occurrence of any of the following shall constitute a "**Default**":

19.1.1Any failure by Tenant to pay any Rent (or deliver any Security Deposit, Letter of Credit, or similar credit enhancement required hereunder) when due unless such failure is cured within five (5) business days after Landlord's written notice to Tenant; or

19.1.2Except where a specific time period is otherwise set forth for Tenant's cure herein (in which event Tenant's failure to cure within such time period shall be a Default), and except as otherwise provided in this Section 19.1, any breach by Tenant of any other provision hereof where such breach continues for 30 days after notice from Landlord; provided that if such breach cannot reasonably be cured within such 30-day period, Tenant shall not be in Default as a result of such breach if Tenant diligently commences such cure within such period, thereafter diligently pursues such cure, and completes such cure within 60 days after Landlord's notice; or

19.1.3Intentionally Omitted; or

19.1.4Any breach by Tenant of Section 17 or 18 where such breach continues for more than two (2) business days after notice from Landlord; or

19.1.5Tenant becomes in breach of Section 25.3(c) or (d).

If Tenant breaches a particular provision hereof (other than a provision requiring payment of Rent) on three (3) separate occasions during any 12-month period, Tenant's subsequent breach of such provision shall be, at Landlord's option, an incurable Default. The notice periods provided herein are in lieu of, and not in addition to, any notice periods provided by Law, and Landlord shall not be required to give any additional notice in order to be entitled to commence an unlawful detainer proceeding.

19.2 **Remedies Upon Default.** Upon any Default, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity (which shall be cumulative and nonexclusive), the option to pursue any one or more of the following remedies (which shall be cumulative and nonexclusive) without any additional notice or demand:

19.2.1Landlord may terminate this Lease, in which event Landlord may recover from Tenant the following:

(a)The worth at the time of award of the unpaid Rent which had been earned at the time of such termination; plus

(b)The worth at the time of award of the amount by which the unpaid Rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(c)The worth at the time of award of the amount by which the unpaid Rent for the balance of the Term after the time of award exceeds the amount of such Rent loss that Tenant proves could be reasonably avoided; plus

(d)Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations hereunder or which in the ordinary course of things would be likely to result therefrom, including brokerage commissions, advertising expenses, expenses of remodeling any portion of the Premises for a new tenant (whether for the same or a different use), and any special concessions made to obtain a new tenant; plus

(e)At Landlord's option, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Law.

As used in Sections 19.2.1(a) and (b), the "**worth at the time of award**" shall be computed by allowing interest at the rate specified in Section 3(b) above. As used in Section 19.2.1(c), the "**worth at the time of award**" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus 1%.

19.2.2Landlord shall have the remedy described in California Civil Code § 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover Rent as it becomes due, if lessee has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies hereunder, including the right to recover all Rent as it becomes due.

19.2.3Landlord shall at all times have the rights and remedies (which shall be cumulative with each other and cumulative and in addition to those rights and remedies available under Sections 19.2.1

and 19.2.2, or any Law or other provision hereof), without prior demand or notice except as required by Law, to seek any declaratory, injunctive or other equitable relief, and specifically enforce this Lease, or restrain or enjoin a violation or breach of any provision hereof.

19.3 **Efforts to Relet.** Unless Landlord provides Tenant with express notice to the contrary, no re-entry, repair, maintenance, change, alteration, addition, reletting, appointment of a receiver or other action or omission by Landlord shall (a) be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, or (b) operate to release Tenant from any of its obligations hereunder. Tenant waives, for Tenant and for all those claiming by, through or under Tenant, California Civil Code § 3275, California Code of Civil Procedure §§ 1174(c) and 1179, and any existing or future rights to redeem or reinstate, by order or judgment of any court or by any legal process or writ, this Lease or Tenant's right of occupancy of the Premises after any termination hereof.

19.4 **Landlord Default.** Landlord shall not be in default hereunder unless it breaches a provision hereof and such breach continues for 30 days after notice from Tenant; provided that if such breach cannot reasonably be cured within such 30-day period, Landlord shall not be in default as a result of such breach if Landlord diligently commences such cure within such period, thereafter diligently pursues such cure, and completes such cure within 60 days after Tenant's notice. Upon any such default by Landlord, Tenant shall have all remedies available to it at law or in equity, except as otherwise provided herein. Before exercising any remedies for a default by Landlord, Tenant shall give notice and a reasonable time to cure to any Security Holder of which Tenant has been notified.

20 LANDLORD EXCULPATION. Notwithstanding any contrary provision hereof, (a) the liability of the Landlord Parties to Tenant shall be limited to an amount equal to Landlord's interest in the Building; (b) Tenant shall look solely to Landlord's interest in the Building for the recovery of any judgment or award against any Landlord Party; (c) no Landlord Party shall have any liability for any judgment or deficiency, and Tenant waives and releases such liability on behalf of itself and all parties claiming by, through or under Tenant; and (d) no Landlord Party shall be liable for any injury or damage to, or interference with, Tenant's business, including loss of profits, loss of rents or other revenues, loss of business opportunity, loss of goodwill or loss of use, or for any form of special or consequential damage. For purposes of this Section 20, "**Landlord's interest in the Building**" shall include rents paid by tenants, insurance proceeds, condemnation proceeds, and proceeds from the sale of the Building (collectively, "**Owner Proceeds**"); provided, however, that Tenant shall not be entitled to recover Owner Proceeds from any Landlord Party (other than Landlord) or any other third party after they have been distributed or paid to such party; provided further, however, that nothing in this sentence shall diminish any right Tenant may have under Law, as a creditor of Landlord, to initiate or participate in an action to recover Owner Proceeds from a third party on the grounds that such third party obtained such Owner Proceeds when Landlord was, or could reasonably be expected to become, insolvent or in a transfer that was preferential or fraudulent as to Landlord's creditors.

21 SECURITY DEPOSIT. Concurrently with its execution and delivery hereof, Tenant shall deposit with Landlord the Security Deposit, if any, as security for Tenant's performance of its obligations hereunder. If Tenant breaches any provision hereof and either (i) such breach continues beyond any applicable notice and cure period, or (ii) this Lease expires or terminates, Landlord may, at its option, without limiting its remedies and without notice to Tenant, apply all or part of the Security Deposit to cure such breach and compensate Landlord for any loss or damage caused by such breach, including any damage for which recovery may be made under California Civil Code § 1951.2. If Landlord so applies any portion of the Security Deposit, Tenant, within five (5) business days after demand therefor, shall restore the Security Deposit to its original amount. The Security Deposit is not an advance payment of Rent or measure of damages. Any unapplied portion of the Security Deposit shall be returned to Tenant within 60 days after the latest to occur of (a) the expiration of the Term, (b) Tenant's surrender of the Premises as required hereunder, or (c) Landlord's cure of any breach by Tenant of any provision hereof; provided, however, that if Landlord estimates in good faith that Tenant may be required to make a payment to Landlord under Section 4.4.1, Landlord may retain such unapplied portion of the Security Deposit, to the extent of the estimated amount of such payment, until the date occurring 60 days after determination of the final Rent due from Tenant. Landlord shall not be required to keep the Security Deposit separate from its other accounts.

22 RELOCATION. [Intentionally Omitted].

23 COMMUNICATIONS AND COMPUTER LINES. All Lines installed pursuant to this Lease shall be (a) installed in accordance with Section 7; and (b) clearly marked with adhesive plastic labels (or plastic tags attached to such Lines with wire) to show Tenant's name, suite number, and the purpose of such Lines (i) every six (6) feet outside the Premises (including the electrical room risers and any Common Areas), and (ii) at their termination points. Landlord may designate specific contractors for work relating to vertical Lines. Sufficient spare cables and space for additional cables shall be maintained for other occupants, as reasonably determined by Landlord. Unless otherwise notified by Landlord, Tenant, at its expense and before the expiration or earlier termination hereof, shall remove all Lines and repair any resulting damage. As used herein, "**Lines**" means all communications or computer wires and cables serving the Premises installed or paid for by Tenant pursuant to this Lease.

24 PARKING. Tenant may park in the Building's parking facilities (the "**Parking Facility**"), in common with other tenants of the Building, upon the following terms and conditions. Tenant shall not use more than the number of unreserved and/or reserved parking spaces set forth in Section 1.9. Tenant shall comply with all rules and regulations established by Landlord from time to time (and provided to Tenant in writing) for the orderly operation and use of the Parking Facility, including any sticker or other identification system and the prohibition of vehicle repair and maintenance activities in the Parking Facility. Landlord may, in its discretion, allocate and assign parking passes among Tenant and the other tenants in the Building so long as such allocation does not reduce the number of parking spaces allocated to Tenant pursuant to Section 1.9 above. Tenant's use of the Parking Facility shall be at Tenant's sole risk, and Landlord shall have no liability for damage to or theft of any vehicles or other property occurring in the Parking Facility or otherwise in connection with any use of the Parking Facility by Tenant or its employees or invitees. Landlord may alter the size, configuration, design, layout or any other aspect of the Parking Facility, and, in connection therewith, temporarily deny or restrict access to the Parking Facility, in each case without abatement of Rent or liability to Tenant. Landlord may delegate its responsibilities hereunder to a parking operator, in which case (i) such parking operator shall have all the rights of control reserved herein by Landlord, (ii) Tenant shall enter into a parking agreement with such parking operator (subject to the parties' respective rights and obligations hereunder, including without limitation, those relating to the parking rate set forth in Section 1.9 above) and (iii) Landlord shall have no liability for claims arising through acts or omissions of such parking operator except to the extent caused by Landlord's negligence or willful misconduct. Tenant's parking rights under this Section 24 are solely for the benefit of Tenant's employees and invitees and such rights may not be transferred without Landlord's prior consent, except pursuant to a Transfer permitted under Section 14.

25 MISCELLANEOUS.

25.1 **Notices.** Except as provided in Section 18, no notice, demand, statement, designation, request, consent, approval, election or other communication given hereunder ("**Notice**") shall be binding upon either party unless (a) it is in writing; (b) it is (i) sent by certified or registered mail, postage prepaid, return receipt requested, (ii) delivered by a nationally recognized courier service, or (iii) delivered personally; and (c) it is sent or delivered to the address set forth in Section 1.10 or 1.11, as applicable, or to such other place (other than a P.O. box) as the recipient may from time to time designate in a Notice to the other party. Any Notice shall be deemed received on the earlier of the date of actual delivery or the date on which delivery is refused, or, if Tenant is the recipient and has vacated its notice address without providing a new notice address, three (3) days after the date the Notice is deposited in the U.S. mail or with a courier service as described above. No provision of this Lease requiring a particular Notice to be in writing shall limit the generality of clause (a) of the first sentence of this Section 25.1.

25.2 **Force Majeure.** If either party is prevented from performing any obligation hereunder by any strike, act of God, fire, war, terrorist act, shortage of labor or materials, governmental action (including, without limitation, governmentally required evacuations), epidemic, pandemic, public health emergency, civil commotion or other cause beyond such party's reasonable control ("**Force Majeure**"), such obligation shall be excused during (and any time period for the performance of such obligation shall be extended by) the period of such prevention; provided, however, that this Section 25.2 shall not (a) permit Tenant to hold over in the Premises after the expiration or earlier termination hereof, or (b) excuse (or extend any time period for the performance of) (i) any obligation to remit money or deliver credit enhancement, (ii) any obligation under Section 10 or 25.3, or (iii) any of Tenant's obligations whose breach would interfere with another occupant's use, occupancy or enjoyment of its premises or the Project or result in any liability on the part of any Landlord Party.

25.3 **Representations and Covenants.** Tenant represents, warrants and covenants that (a) Tenant is, and at all times during the Term will remain, duly organized, validly existing and in good standing under the Laws of the state of its formation and qualified to do business in the state of California; (b) neither Tenant's execution of nor its performance under this Lease will cause Tenant to be in violation of any agreement or Law; (c) Tenant (and any guarantor hereof) has not, and at no time during the Term will have, (i) made a general assignment for the benefit of creditors, (ii) filed a voluntary petition in bankruptcy, (iii) suffered (A) the filing by creditors of an involuntary petition in bankruptcy that is not dismissed within 30 days, (B) the appointment of a receiver to take possession of all or substantially all of its assets, or (C) the attachment or other judicial seizure of all or substantially all of its assets, (iv) admitted in writing its inability to pay its debts as they come due, or (v) made an offer of settlement, extension or composition to its creditors generally; and (d) no party that (other than through the passive ownership of interests traded on a recognized securities exchange) constitutes, owns, controls, or is owned or controlled by Tenant, any guarantor hereof or any subtenant of Tenant is, or at any time during the Term will be, (i) in violation of any Laws relating to terrorism or money laundering, or (ii) among the parties identified on any list compiled pursuant to Executive Order 13224 for the purpose of identifying suspected terrorists or on the most current list published by the U.S. Treasury Department Office of Foreign Assets Control at its official website, http://www.treas.gov/ofac/tllsdn.pdf or any replacement website or other replacement official publication of such list.

25.4 **Signs.** Landlord shall include Tenant's name in any tenant directory located in the lobby on the first floor of the Building. If any part of the Premises is located on a multi-tenant floor, Landlord, at

Tenant's cost, shall provide identifying suite signage for Tenant comparable to that provided by Landlord on similar floors in the Building. Tenant may not install (a) any signs outside the Premises, or (b) without Landlord's prior consent in its sole and absolute discretion, any signs, window coverings, blinds or similar items that are visible from outside the Premises.

25.5 **Supplemental HVAC.** If the Premises are served by any supplemental HVAC unit (a "**Unit**"), then (a) Tenant shall pay the costs of all electricity consumed in the Unit's operation, together with the cost of installing a meter to measure such consumption; (b) Tenant, at its expense, shall (i) operate and maintain the Unit in compliance with all applicable Laws and such reasonable rules and procedures as Landlord may impose; (ii) keep the Unit in as good working order and condition as existed upon installation (or, if later, when Tenant took possession of the Premises), subject to normal wear and tear and damage resulting from Casualty; (iii) maintain in effect, with a contractor reasonably approved by Landlord, a contract for the maintenance and repair of the Unit, which contract shall require the contractor, at least once every three (3) months, to inspect the Unit and provide to Tenant a report of any defective conditions, together with any recommendations for maintenance, repair or parts-replacement; (iv) follow all reasonable recommendations of such contractor; and (v) promptly provide to Landlord a copy of such contract and each report issued thereunder; (c) the Unit shall become Landlord's property upon installation and without compensation to Tenant; provided, however, that upon Landlord's request at the expiration or earlier termination hereof, Tenant, at its expense, shall remove the Unit and repair any resulting damage (and if Tenant fails to timely perform such work, Landlord may do so at Tenant's expense); (d) the Unit shall be deemed (i) a Leasehold Improvement (except for purposes of Section 8), and (ii) for purposes of Section 11, part of the Premises; (e) if the Unit exists on the date of mutual execution and delivery hereof, Tenant accepts the Unit in its "as is" condition, without representation or warranty as to quality, condition, fitness for use or any other matter; (f) if the Unit connects to the Building's condenser water loop (if any), then Tenant shall pay to Landlord, as Additional Rent, Landlord's standard one-time fee for such connection and Landlord's standard monthly per-ton usage fee; and (g) if any portion of the Unit is located on the roof, then (i) Tenant's access to the roof shall be subject to such reasonable rules and procedures as Landlord may impose; (ii) Tenant shall maintain the affected portion of the roof in a clean and orderly condition and shall not interfere with use of the roof by Landlord or any other tenants or licensees; and (iii) Landlord may relocate the Unit and/or temporarily interrupt its operation, without liability to Tenant, as reasonably necessary to maintain and repair the roof or otherwise operate the Building. The parties acknowledge and agree that, as of the date of this Lease, no Unit currently serves the Premises.

25.6 **Attorneys' Fees.** In any action or proceeding between the parties, including any appellate or alternative dispute resolution proceeding, the prevailing party may recover from the other party all of its costs and expenses in connection therewith, including reasonable attorneys' fees and costs.

25.7 **Brokers.** Tenant represents to Landlord that it has dealt only with Tenant's Broker as its broker in connection with this Lease. Tenant shall indemnify, defend, and hold Landlord harmless from all claims of any brokers, other than Tenant's Broker, claiming to have represented Tenant in connection with this Lease. Landlord shall indemnify, defend and hold Tenant harmless from all claims of any brokers, including Landlord's Broker, claiming to have represented Landlord in connection with this Lease.

25.8 **Governing Law; WAIVER OF TRIAL BY JURY.** This Lease shall be construed and enforced in accordance with the Laws of the State of California. THE PARTIES WAIVE, TO THE FULLEST EXTENT PERMITTED BY LAW, THE RIGHT TO TRIAL BY JURY IN ANY LITIGATION ARISING OUT OF OR RELATING TO THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM FOR INJURY OR DAMAGE OR ANY EMERGENCY OR STATUTORY REMEDY.

25.9 **Waiver of Statutory Provisions.** Each party waives California Civil Code §§ 1932(2), 1933(4) and 1945. Tenant waives (a) any rights under (i) California Civil Code §§ 1932(1), 1941, 1942, 1950.7 or any similar or replacement section or Law, or (ii) California Code of Civil Procedure §§ 1263.260 or 1265.130 or any similar or replacement section or Law; and (b) any right to terminate this Lease under California Civil Code § 1995.310 or any similar or replacement section or Law. Tenant further expressly waives California Civil Code Section 1479, and agrees that Landlord shall have the right to designate which portion of Tenant's obligations under this Lease are satisfied by a partial payment or to allocate any payment by Tenant to outstanding obligations of Tenant in any order it desires (i.e., Landlord may allocate payments to the earliest amounts outstanding or the most recent, at its discretion).

25.10 **Interpretation.** As used herein, the capitalized term "Section" refers to a section hereof unless otherwise specifically provided herein. As used in this Lease, the terms "herein," "hereof," "hereto" and "hereunder" refer to this Lease and the term "include" and its derivatives are not limiting. Any reference herein to "any part" or "any portion" of the Premises, the Property or any other property shall be construed to refer to all or any part of such property. As used herein in connection with insurance, the term "deductible" includes self-insured retention. Wherever this Lease prohibits either party from engaging in any particular conduct, this Lease shall be deemed also to require such party to cause each of its employees and agents (and, in the case of Tenant, each of its licensees, invitees and subtenants, and any other party claiming by, through or under Tenant) to refrain from engaging in such conduct. Wherever this Lease requires Landlord to provide a customary service or to act in a reasonable manner (whether in incurring an expense, establishing a rule or regulation, providing an approval or consent, or performing any other act), this Lease shall be deemed also to provide that whether such service is customary or such conduct is reasonable shall be determined by reference to the practices of owners of buildings ("**Comparable Buildings**") that (i) are comparable to the Building in size, age, class, quality and location, and (ii) at Landlord's option, have been, or are being prepared to be, certified under the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar rating system. Tenant waives the benefit of any rule that a written agreement shall be construed against the drafting party.

25.11 **Entire Agreement.** This Lease sets forth the entire agreement between the parties relating to the subject matter hereof and supersedes any previous agreements (none of which shall be used to interpret this Lease). Tenant acknowledges that in entering into this Lease it has not relied upon any representation, warranty or statement, whether oral or written, not expressly set forth herein. This Lease can be modified only by a written agreement signed by both parties.

25.12 **Other.** Landlord, at its option, may cure any Default, without waiving any right or remedy or releasing Tenant from any obligation, in which event Tenant shall pay Landlord, upon demand, the cost of such cure. If any provision hereof is void or unenforceable, no other provision shall be affected. Submission of this instrument for examination or signature by Tenant does not constitute an option or offer to lease, and this instrument is not binding until it has been executed and delivered by both parties. The voluntary or other surrender of this Lease by Tenant, whether accepted by Landlord or not, or a mutual termination thereof, shall not work a merger, and at the option of Landlord shall operate as an assignment to Landlord of all subleases or subtenancies affecting the Premises or terminate any or all such sublessees or subtenancies. If Tenant is comprised of two or more parties, their obligations shall be joint and several. Time is of the essence with respect to the performance of every provision hereof in which time of performance is a factor. So long as Tenant performs its obligations hereunder, Tenant shall have peaceful and quiet possession of the Premises against any party claiming by, through or under Landlord, subject to the terms hereof. Landlord may transfer its interest herein, in which event (a) to the extent the transferee assumes in writing Landlord's obligations arising hereunder after the date of such transfer (including the return of any Security Deposit), Landlord shall be released from, and Tenant shall look solely to the transferee for the performance of, such obligations; and (b) Tenant shall attorn to the transferee. If Tenant (or any party claiming by, through or under Tenant) pays directly to the provider for any energy consumed at the Property, Tenant, promptly upon request, shall deliver to Landlord (or, at Landlord's option, execute and deliver to Landlord an instrument enabling Landlord to obtain from such provider) any data about such consumption that Landlord, in its reasonable judgment, is required for benchmarking purposes or to disclose to a prospective buyer, tenant or mortgage lender under any applicable Law. Landlord reserves all rights not expressly granted to Tenant hereunder, including the right to make alterations to the Project provided that such alterations neither (a) materially prevent Tenant from accessing the Premises, nor (b) materially reduce the quality of the Project below that of Comparable Buildings (as identified before the performance of such alterations). No rights to any view or to light or air over any property are granted to Tenant hereunder. The expiration or earlier termination hereof shall not relieve either party of any obligation that accrued before, or continues to accrue after, such expiration or termination. Each party hereto, and their respective successors and assigns shall be authorized to rely upon the signatures of all of the parties hereto which are delivered by facsimile, PDF or DocuSign (or the like) as constituting a duly authorized, irrevocable, actual, current delivery hereof with original ink signatures of each person and entity. This Lease may be executed in counterparts, each of which shall be deemed an original part and all of which together shall constitute a single agreement.

[SIGNATURES ARE ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be executed the day and date first above written.

LANDLORD:

HUDSON METRO CENTER, LLC, a Delaware limited liability company

By: Hudson Pacific Properties, L.P.,
a Maryland limited partnership,
its sole member

By: Hudson Pacific Properties, Inc.,
a Maryland corporation,
its general partner

By: /s/ Mark Lammas

Name: Mark Lammas

Title: President

TENANT:

MIRUM PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Chris Peetz

Name: Chris Peetz

Title: President & CEO
[chairman][president][vice-president]

By: /s/ Eric Bjerkholt

Name: Eric Berkholt

Title: CFO
[secretary][assistant secretary][chief financial officer][assistant treasurer]

EXHIBIT A

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

OUTLINE OF PREMISES

EXHIBIT B

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

WORK LETTER

As used in this **Exhibit B** (this "**Work Letter**"), the following terms shall have the following meanings:

(i) "**Tenant Improvements**" means all improvements to be constructed in the Premises pursuant to this Work Letter;

(ii) "**Tenant Improvement Work**" means the construction of the Tenant Improvements, together with any related work (including demolition) that is necessary to construct the Tenant Improvements; and

(iii) "**Agreement**" means the lease of which this Work Letter is a part.

1 COST OF TENANT IMPROVEMENT WORK. Except as provided in Sections 2.7.4 and 3.2.2.B below, the Tenant Improvement Work shall be performed at Landlord's expense.

2 ARCHITECTURAL PLANS.

2.1 **Selection of Architect**. Landlord shall retain the architect/space planner of Landlord's choice (the "**Architect**") to prepare the Architectural Drawings (defined in Section 2.5 below).

2.2 [Intentionally Omitted.]

2.3 **Approved Space Plan.** Landlord and Tenant acknowledge that they have approved the space plan for the Premises dated January 9, 2024 prepared by DSK (the "**Approved Space Plan**"), attached hereto as **Exhibit B-1**. All materials and finishes contemplated by the Approved Space Plan shall be deemed to be Building-standard unless otherwise expressly provided therein.

2.4 **Additional Programming Information.** Tenant shall deliver to Landlord, in writing, all information (including all interior and special finishes) that, when combined with the Approved Space Plan, will be sufficient to complete the Architectural Drawings, together with all information (including all electrical requirements, telephone requirements, special HVAC requirements, and plumbing requirements) that, when combined with the Approved Space Plan, will be sufficient to complete the Engineering Drawings (defined in Section 3.2.1 below) (collectively, the "**Additional Programming Information**"). The Additional Programming Information shall not increase the cost of the Tenant Improvement Work (as reasonably estimated by Landlord) and shall be (a) consistent with the Approved Space Plan, (b) consistent with Landlord's requirements for avoiding aesthetic, engineering or other conflicts with the design and function of the balance of the Building (collectively, the "**Landlord Requirements**"), and (c) otherwise subject to Landlord's reasonable approval. Landlord shall provide Tenant with notice approving or reasonably disapproving the Additional Programming Information within five (5) business days after the later of Landlord's receipt thereof or the mutual execution and delivery of this Agreement. If Landlord disapproves the Additional Programming Information, Landlord's notice of disapproval shall describe with reasonable specificity the basis for such disapproval and Tenant shall modify the Additional Programming Information and resubmit it for Landlord's approval. Such procedure shall be repeated as necessary until Landlord has approved the Additional Programming Information. Such approved Additional Programming Information shall be referred to herein as the "**Approved Additional Programming Information**." If requested by Tenant, Landlord, in its sole and absolute discretion, may assist Tenant, or cause the Architect and/or other contractors or consultants of Landlord to assist Tenant, in preparing all or a portion of the Additional Programming Information; provided, however, that, whether or not the Additional Programming Information is prepared with such assistance, Tenant shall be solely responsible for the timely preparation and delivery of the Additional Programming Information and for all elements thereof.

2.5 **Architectural Drawings.** After approving the Additional Programming Information, Landlord shall cause the Architect to prepare and deliver to Tenant the final architectural (and, if applicable, structural) working drawings for the Tenant Improvement Work that are in a form that (a) when combined with any Approved Additional Programming Information that is not expressly incorporated into such working drawings, will be sufficient to enable the Contractor (defined in Section 3.1 below) and its subcontractors to bid on the Tenant Improvement Work, and (b) when combined with any Engineering

Drawings that satisfy the Engineering Requirements (defined in Section 3.2.1 below), will be sufficient to obtain the Permits (defined in Section 3.3 below) (the "**Architectural Drawings**"). The Architectural Drawings shall conform to the Approved Space Plan and the Approved Additional Programming Information. The Architect's preparation and delivery of the Architectural Drawings shall occur within 15 business days after the later of Landlord's approval of the Additional Programming Information or the mutual execution and delivery of this Agreement. Tenant shall approve or disapprove the Architectural Drawings by notice to Landlord. If Tenant disapproves the Architectural Drawings, Tenant's notice of disapproval shall specify any revisions Tenant desires in the Architectural Drawings. After receiving such notice of disapproval, Landlord shall cause the Architect to revise the Architectural Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to cause the Architect to make any revision to the Architectural Drawings that (a) would increase the cost of the Tenant Improvement Work (as reasonably estimated by Landlord), (b) conflicts with the Approved Space Plan or the Landlord Requirements, or (c) is otherwise reasonably disapproved by Landlord. Such revision and resubmission shall occur within five (5) business days after the later of Landlord's receipt of Tenant's notice of disapproval or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 15 business days after the later of such receipt or such mutual execution and delivery) if such revision is material. Such procedure shall be repeated as necessary until Tenant has approved the Architectural Drawings. Such approved Architectural Drawings shall be referred to herein as the "**Approved Architectural Drawings**."

2.6 [Intentionally Omitted.]

2.7 **Revisions to Approved Architectural Drawings, Approved Additional Programming Information, or Approved Space Plan.**

2.7.1 **Approved Architectural Drawings.** If Tenant requests any revision to the Approved Architectural Drawings, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, and, if Landlord approves such revision, Landlord shall have such revision made and delivered to Tenant, together with notice of any resulting change in the estimated total cost associated with the Tenant Improvement Work, within 10 business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 15 business days after the later of such receipt or such execution and delivery) if such revision is material, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Architectural Drawings without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Architectural Drawings within two (2) business days after receiving Landlord's request for approval thereof. For purposes hereof, any change order affecting the Approved Architectural Drawings shall be deemed a revision to the Approved Architectural Drawings.

2.7.2 **Approved Additional Programming Information.** If Tenant requests Landlord's approval of any revision to the Approved Additional Programming Information, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, together with notice of any resulting change in the estimated total cost associated with the Tenant Improvement Work, within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement, whereupon Tenant, within two (2) business days, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Additional Programming Information without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Additional Programming Information within two (2) business days after receiving Landlord's request for approval thereof.

2.7.3 **Approved Space Plan.** If Tenant requests Landlord's approval of any revision to the Approved Space Plan, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, together with notice of any resulting change in the estimated total cost associated with the Tenant Improvement Work, within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Space Plan without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Space Plan within two (2) business days after receiving Landlord's request for approval thereof.

2.7.4 **Costs of Revisions.** Tenant shall reimburse Landlord, immediately upon demand, for any increase in the total cost associated with the Tenant Improvement Work that results from any revision to the Approved Architectural Drawings requested by Tenant, any revision to the Approved Additional Programming Information made by Tenant, or any revision to the Approved Space Plan requested or made by Tenant, including, in each case, any cost of preparing or reviewing such revision.

2.8 **Tenant's Approval Deadline.** Tenant shall approve the Architectural Drawings pursuant to Section 2.5 above on or before Tenant's Approval Deadline (defined below). As used in this Work Letter, "**Tenant's Approval Deadline**" means the date occurring 35 business days after the mutual execution and delivery of this Agreement; provided, however, that Tenant's Approval Deadline shall be extended by one (1) day for each day, if any, by which Tenant's approval of the Architectural Drawings pursuant to Section 2.5 above is delayed by any failure of Landlord to perform its obligations under this Section 2.

3 CONSTRUCTION.

3.1 **Contractor.** Landlord shall retain a contractor of its choice (the "**Contractor**") to perform the Tenant Improvement Work. In addition, Landlord may select and/or approve of any subcontractors, mechanics and materialmen used in connection with the performance of the Tenant Improvement Work.

3.2 **Engineering Drawings.**

3.2.1 **Preparation.** Landlord shall cause the engineering working drawings for the mechanical, electrical, plumbing, fire-alarm and fire sprinkler work in the Premises (the "**Engineering Drawings**") to (a) be prepared by one or more of the Architect, the Contractor, and/or engineers or other consultants selected and/or retained by the Architect, the Contractor or Landlord, and (b) conform to the Approved Space Plan, the Approved Additional Programming Information, the first sentence of Section 4 below, and any then-existing Approved Architectural Drawings (collectively, the "**Engineering Requirements**").

3.2.2 **Design Build.** Except as provided in Section 3.2.3 below:

A. Delivery and Approval. The Engineering Drawings shall be delivered to Tenant within 15 business days after the later of Tenant's approval of the Architectural Drawings pursuant to Section 2.5 above or the mutual execution and delivery of this Agreement. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), the Engineering Drawings within two (2) business days after the latest of (a) Tenant's receipt of the Engineering Drawings, (b) Tenant's approval of the Architectural Drawings, or (c) the mutual execution and delivery of this Agreement. After receiving any such notice of reasonable disapproval, Landlord shall cause the Contractor to revise the Engineering Drawings and resubmit them to Tenant, taking into account the reasons for Tenant's disapproval; provided, however, that Landlord shall not be required to make any revision to the Engineering Drawings that conflicts with the Engineering Requirements or the Landlord Requirements or is otherwise reasonably disapproved by Landlord. Such procedure shall be repeated as necessary until Tenant has reasonably approved the Engineering Drawings. Such approved Engineering Drawings shall be referred to herein as the "**Approved Engineering Drawings**".

B. Revisions. If Tenant requests any revision to the Approved Engineering Drawings, Landlord shall provide Tenant with notice approving or reasonably disapproving such revision, and, if Landlord approves such revision, Landlord shall have such revision made and delivered to Tenant, together with notice of any resulting change in the estimated total cost associated with the Tenant Improvement Work, within five (5) business days after the later of Landlord's receipt of such request or the mutual execution and delivery of this Agreement if such revision is not material, and within such longer period of time as may be reasonably necessary (but not more than 10 business days after the later of such receipt or such execution and delivery) if such revision is material, whereupon Tenant, within one (1) business day, shall notify Landlord whether it desires to proceed with such revision. If Landlord has begun performing the Tenant Improvement Work, then, in the absence of such authorization, Landlord shall have the option to continue such performance disregarding such revision. Landlord shall not revise the Approved Engineering Drawings without Tenant's consent, which shall not be unreasonably withheld or conditioned. Tenant shall approve, or reasonably disapprove (and state, with reasonable specificity, its reasons for disapproving), any revision to the Approved Engineering Drawings within two (2) business days after receiving Landlord's request for approval thereof. Any change order affecting the Approved Engineering Drawings shall be deemed a revision to the Approved Engineering Drawings. Tenant shall reimburse Landlord, immediately upon demand, for any increase in the total cost associated with the Tenant Improvement Work that results from any revision to the Approved Engineering Drawings requested by Tenant, including the cost of preparing such revision.

3.2.3 **Design Bid Build.** If Landlord, at its option, causes the Engineering Drawings to be delivered to Tenant on or before the date on which the Architectural Drawings are first delivered to Tenant pursuant to Section 2.5 above, then (a) Section 3.2.2 above shall not apply; (b) Tenant's review and approval of, and any revisions to, the Engineering Drawings shall be governed by Sections 2.5 and 2.7 above as if the Engineering Drawings were part of the Architectural Drawings; and (c) the Engineering Drawings, as approved by Tenant pursuant to Section 2.5 above, shall be referred to herein as the "**Approved Engineering Drawings**".

3.3 **Permits.** Landlord shall cause the Contractor to submit the Approved Architectural Drawings and the Approved Engineering Drawings (collectively, the "**Approved Construction Drawings**") to the appropriate municipal authorities and otherwise apply for and obtain from such authorities all permits necessary for the Contractor to complete the Tenant Improvement Work (the "**Permits**").

3.4 **Construction.**

3.4.1 **Performance of Tenant Improvement Work.** Landlord shall cause the Contractor to perform the Tenant Improvement Work in accordance with the Approved Construction Drawings.

3.4.2 **Contractor's Warranties.** Tenant waives all claims against Landlord relating to any defects in the Tenant Improvements; provided, however, that if, within 30 days after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any non-latent defect in the Tenant Improvements, or if, within 11 months after substantial completion of the Tenant Improvement Work, Tenant provides notice to Landlord of any latent defect in the Tenant Improvements, then Landlord shall promptly cause such defect to be corrected.

4 COMPLIANCE WITH LAW; SUITABILITY FOR TENANT'S USE. Landlord shall (a) cause the Approved Space Plan, the Additional Programming Information, the Architectural Drawings and the Engineering Drawings (collectively, the "**Plans**") to comply with Law; provided, however, that Landlord shall not be responsible for any violation of Law resulting from any particular use of the Premises (as distinguished from general office use). Tenant shall be responsible for ensuring that the Plans are suitable for Tenant's use of the Premises, and neither the preparation of the Plans by Landlord's consultants nor Landlord's approval of the Plans shall relieve Tenant from such responsibility. To the extent that Landlord is responsible under this Section 4 for causing the Plans to comply with Law, Landlord may contest any alleged violation of Law in good faith, including by seeking a waiver or deferment of compliance, asserting any defense allowed by Law, and exercising any right of appeal (provided that Tenant incurs no liability as a result of such contest and that, after completing such contest, Landlord makes any modification to the Plans or any alteration to the Premises that is necessary to comply with any final order or judgment).

5 COMPLETION.

5.1 **Substantial Completion.** For purposes of Section 1.3.2 of this Agreement, and subject to Section 5.2 below, the Tenant Improvement Work shall be deemed to be "**Substantially Complete**" upon the completion of the Tenant Improvement Work pursuant to the Approved Construction Drawings (as reasonably determined by Landlord), with the exception of any details of construction, mechanical adjustment or any other similar matter the non-completion of which does not materially interfere with Tenant's use of the Premises.

5.2 **Tenant Cooperation; Tenant Delay.** Tenant shall use reasonable efforts to cooperate with Landlord, the Architect, the Contractor, and Landlord's other consultants to complete all phases of the Plans, obtain the Permits and complete the Tenant Improvement Work as soon as possible, and Tenant shall meet with Landlord, in accordance with a schedule determined by Landlord, to discuss the parties' progress. Without limiting the foregoing, if (i) the Tenant Improvements include the installation of electrical connections for furniture stations to be installed by Tenant, and (ii) any electrical or other portions of such furniture stations must be installed in order for Landlord to obtain any governmental approval required for occupancy of the Premises, then (x) Tenant, upon five (5) business days' notice from Landlord, shall promptly install such portions of such furniture stations in accordance with Sections 7.2 and 7.3 of this Lease, and (y) during the period of Tenant's entry into the Premises for the purpose of performing such installation, all of Tenant's obligations under this Agreement relating to the Premises shall apply, except for the obligation to pay Monthly Rent. In addition, without limiting the foregoing, if the Substantial Completion of the Tenant Improvement Work is delayed (a "**Tenant Delay**") as a result of (a) any failure of Tenant to approve the Architectural Drawings pursuant to Section 2.5 above on or before Tenant's Approval Deadline; (b) any failure of Tenant to timely approve the Engineering Drawings, pursuant to Section 3.2.2.A above, for any reason other than their failure to satisfy the Engineering Requirements; (c) any failure of Tenant to timely approve any other matter requiring Tenant's approval; (d) any breach by

Tenant of this Work Letter or this Agreement; (e) any request by Tenant for any revision to, or for Landlord's approval of any revision to, any portion of the Plans that has previously been approved by both parties (except to the extent that such delay results from a breach by Landlord of its obligations under Section 2.7 or 3.2.2.B above); (f) [Intentionally Omitted]; (g) [Intentionally Omitted]; or (h) any other act or omission of Tenant or any of its agents, employees or representatives, then, notwithstanding any contrary provision of this Agreement, and regardless of when the Tenant Improvement Work is actually Substantially Completed, the Tenant Improvement Work shall be deemed to be Substantially Completed on the date on which the Tenant Improvement Work would have been Substantially Completed if no such Tenant Delay had occurred. Notwithstanding the foregoing, Landlord shall not be required to tender possession of the Premises to Tenant before the Tenant Improvement Work has been Substantially Completed, as determined without giving effect to the preceding sentence. Notwithstanding the foregoing, if Landlord fails to notify Tenant of any Tenant Delay within one (1) day after the date Landlord knew of such Tenant Delay, Tenant shall not be responsible for any such Tenant Delay with respect to the period of time commencing two (2) days after the date when Landlord knew that such Tenant Delay existed and ending on the date that Landlord notified Tenant of such Tenant Delay. Notwithstanding Section 25.1 of this Lease, Landlord's notice to Tenant of any Tenant Delay may be given orally, by e-mail, or by any other method.

6 MISCELLANEOUS. Notwithstanding any contrary provision of this Agreement, if Tenant Defaults under this Agreement before the Tenant Improvement Work is completed, Landlord's obligations under this Work Letter shall be excused until such Default is cured and Tenant shall be responsible for any resulting delay in the completion of the Tenant Improvement Work. This Work Letter shall not apply to any space other than the Premises.

EXHIBIT B-1

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

APPROVED SPACE PLAN

EXHIBIT C

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

CONFIRMATION LETTER

_____________________, 20__

To: _______________________
____
____
____

Re: Office Lease (the "**Lease**") dated ______________, 20____, between **HUDSON METRO CENTER, LLC, a Delaware limited liability company** ("**Landlord**"), and **MIRUM PHARMACEUTICALS, INC., a Delaware corporation** ("**Tenant**"), concerning Suite 300 on the third floor of the building located at 989 East Hillsdale Boulevard, Foster City, California.

Dear _________________:

In accordance with the Lease, Tenant accepts possession of the Premises and confirms the following:

1. The Commencement Date is _____________ and the Expiration Date is _______________.

2. The exact number of rentable square feet within the Premises is 36,318 square feet.

3. Tenant's Share, based upon the exact number of rentable square feet within the Premises, is 25.2863%.

Please acknowledge the foregoing by signing all three (3) counterparts of this letter in the space provided below and returning two (2) fully executed counterparts to my attention. Please note that, pursuant to Section 2.1.1 of the Lease, if Tenant fails to execute and return (or, by notice to Landlord, reasonably object to) this letter within five (5) business days after receiving it, Tenant shall be deemed to have executed and returned it without exception. Each party hereto, and their respective successors and assigns shall be authorized to rely upon the signatures of all of the parties hereto which are delivered by facsimile, PDF or DocuSign (or the like) as constituting a duly authorized, irrevocable, actual, current delivery hereof with original ink signatures of each person and entity. This Confirmation Letter may be executed in counterparts, each of which shall be deemed an original part and all of which together shall constitute a single agreement.

"Landlord":

HUDSON METRO CENTER, LLC, a Delaware limited liability company

By: Hudson Pacific Properties, L.P.,
a Maryland limited partnership,
its sole member

By: Hudson Pacific Properties, Inc.,
a Maryland corporation,
its general partner

By:
Name:
Title:

Agreed and Accepted as of ________, 20_.

"Tenant":

MIRUM PHARMACEUTICALS, INC., a Delaware corporation

Exhibit C

By:
Name:
Title:

Exhibit C

EXHIBIT D

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

RULES AND REGULATIONS

Tenant shall comply with the following rules and regulations (as modified or supplemented from time to time, the "**Rules and Regulations**"). Landlord shall not be responsible to Tenant for the nonperformance of any of the Rules and Regulations by any other tenants or occupants of the Project. In the event of any conflict between the Rules and Regulations and the other provisions of this Lease, the latter shall control.

1. Tenant shall not alter any lock or install any new or additional locks or bolts on any doors or windows of the Premises without obtaining Landlord's prior consent. Tenant shall bear the cost of any lock changes or repairs required by Tenant. Two (2) keys will be furnished by Landlord for the Premises, and any additional keys required by Tenant must be obtained from Landlord at a reasonable cost to be established by Landlord. Upon the termination of this Lease, Tenant shall restore to Landlord all keys of stores, offices and toilet rooms furnished to or otherwise procured by Tenant, and if any such keys are lost, Tenant shall pay Landlord the cost of replacing them or of changing the applicable locks if Landlord deems such changes necessary.

2. All doors opening to public corridors shall be kept closed at all times except for normal ingress and egress to the Premises.

3. Landlord may close and keep locked all entrance and exit doors of the Building during such hours as are customary for Comparable Buildings. Tenant shall cause its employees, agents, contractors, invitees and licensees who use Building doors during such hours to securely close and lock them after such use. Any person entering or leaving the Building during such hours, or when the Building doors are otherwise locked, may be required to sign the Building register, and access to the Building may be refused unless such person has proper identification or has a previously arranged access pass. Landlord will furnish passes to persons for whom Tenant requests them. Tenant shall be responsible for all persons for whom Tenant requests passes and shall be liable to Landlord for all acts of such persons. Landlord and its agents shall not be liable for damages for any error with regard to the admission or exclusion of any person to or from the Building. In case of invasion, mob, riot, public excitement or other commotion, Landlord may prevent access to the Building or the Project during the continuance thereof by any means it deems appropriate for the safety and protection of life and property.

4. No furniture, freight or equipment shall be brought into the Building without prior notice to Landlord. All moving activity into or out of the Building shall be scheduled with Landlord and done only at such time and in such manner as Landlord designates. Landlord may prescribe the weight, size and position of all safes and other heavy property brought into the Building and also the times and manner of moving the same in and out of the Building. Safes and other heavy objects shall, if considered necessary by Landlord, stand on supports of such thickness as is necessary to properly distribute the weight. Landlord will not be responsible for loss of or damage to any such safe or property. Any damage to the Building, its contents, occupants or invitees resulting from Tenant's moving or maintaining any such safe or other heavy property shall be the sole responsibility and expense of Tenant (notwithstanding Sections 7 and 10.4 of this Lease).

5. No furniture, packages, supplies, equipment or merchandise will be received in the Building or carried up or down in the elevators, except between such hours, in such specific elevator and by such personnel as shall be designated by Landlord.

6. Employees of Landlord shall not perform any work or do anything outside their regular duties unless under special instructions from Landlord.

7. No sign, advertisement, notice or handbill shall be exhibited, distributed, painted or affixed by Tenant on any part of the Premises or the Building without Landlord's prior consent. Tenant shall not disturb, solicit, peddle or canvass any occupant of the Project.

8. The toilet rooms, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, and no foreign substance shall be thrown therein. Notwithstanding Sections 7 and 10.4 of this Lease, Tenant shall bear the expense of any breakage, stoppage or damage resulting from any violation of this rule by Tenant or any of its employees, agents, contractors, invitees or licensees.

9. Tenant shall not overload the floor of the Premises, or mark, drive nails or screws or drill into the partitions, woodwork or drywall of the Premises, or otherwise deface the Premises, without Landlord's prior consent. Tenant shall not purchase bottled water, ice, towel, linen, maintenance or other like services from any person not approved by Landlord.

10. Except for vending machines intended for the sole use of Tenant's employees and invitees, no vending machine or machines other than fractional horsepower office machines shall be installed, maintained or operated in the Premises without Landlord's prior consent.

11. Tenant shall not, without Landlord's prior consent, use, store, install, disturb, spill, remove, release or dispose of, within or about the Premises or any other portion of the Project, any asbestos-containing materials, any solid, liquid or gaseous material now or subsequently considered toxic or hazardous under the provisions of 42 U.S.C. Section 9601 et seq. or any other applicable environmental Law, or any inflammable, explosive or dangerous fluid or substance; provided, however, that Tenant may use, store and dispose of such substances in such amounts as are typically found in similar premises used for general office purposes provided that such use, storage and disposal does not damage any part of the Premises, Building or Project and is performed in a safe manner and in accordance with all Laws. Tenant shall comply with all Laws pertaining to and governing the use of such materials by Tenant and shall remain solely liable for the costs of abatement and removal. No burning candle or other open flame shall be ignited or kept by Tenant in or about the Premises, Building or Project.

12. Tenant shall not, without Landlord's prior consent, use any method of heating or air conditioning other than that supplied by Landlord or any Unit.

13. Tenant shall not use or keep any foul or noxious gas or substance in or on the Premises, or occupy or use the Premises in a manner offensive or objectionable to Landlord or other occupants of the Project by reason of noise, odors or vibrations, or interfere with other occupants or those having business therein, whether by the use of any musical instrument, radio, CD player or otherwise. Tenant shall not throw anything out of doors, windows or skylights or down passageways.

14. Tenant shall not bring into or keep within the Project, the Building or the Premises any animals (other than service animals), birds, aquariums, or, except in areas designated by Landlord, bicycles or other vehicles.

15. No cooking shall be done in the Premises, nor shall the Premises be used for lodging, for living quarters or sleeping apartments, or for any improper, objectionable or immoral purposes. Notwithstanding the foregoing, Underwriters' laboratory-approved equipment and microwave ovens may be used in the Premises for heating food and brewing coffee, tea, hot chocolate and similar beverages for employees and invitees, provided that such use complies with all Laws.

16. The Premises shall not be used for manufacturing or for the storage of merchandise except to the extent such storage may be incidental to the Permitted Use. Tenant shall not occupy the Premises as an office for a messenger-type operation or dispatch office, public stenographer or typist, or for the manufacture or sale of liquor, narcotics or tobacco, or as a medical office, a barber or manicure shop, or an employment bureau, without Landlord's prior consent. Tenant shall not engage or pay any employees in the Premises except those actually working for Tenant in the Premises, nor advertise for laborers giving an address at the Premises.

17. Landlord may exclude from the Project any person who, in Landlord's judgment, is intoxicated or under the influence of liquor or drugs, or who violates any of these Rules and Regulations.

18. Tenant shall not loiter in or on the entrances, corridors, sidewalks, lobbies, courts, halls, stairways, elevators, vestibules or any Common Areas for the purpose of smoking tobacco products or for any other purpose, nor in any way obstruct such areas, and shall use them only as a means of ingress and egress for the Premises.

19. Tenant shall not waste electricity, water or air conditioning, shall cooperate with Landlord to ensure the most effective operation of the Building's heating and air conditioning system, and shall not attempt to adjust any controls. Tenant shall install and use in the Premises only ENERGY STAR rated equipment, where available. Tenant shall use recycled paper in the Premises to the extent consistent with its business requirements.

20. Tenant shall store all its trash and garbage inside the Premises. No material shall be placed in the trash or garbage receptacles if, under Law, it may not be disposed of in the ordinary and customary manner of disposing of trash and garbage in the vicinity of the Building. All trash, garbage and refuse disposal shall be made only through entryways and elevators provided for such purposes at such times as Landlord shall designate. Tenant shall comply with Landlord's recycling program, if any.

21. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency. Tenant shall not, without Landlord's prior written consent (which consent may be granted or withheld in Landlord's sole and absolute discretion), knowingly allow any employee, contractor or agent to carry any type of gun or other firearm in or about the Premises, the Building or the Project.

22. Any persons employed by Tenant to do janitorial work (a) shall be subject to Landlord's prior consent; (b) shall not, in Landlord's reasonable judgment, disturb labor harmony with any workforce or trades engaged in performing other work or services at the Project; and (c) while in the Building and outside of the Premises, shall be subject to the control and direction of the Building manager (but not as an agent or employee of such manager or Landlord), and Tenant shall be responsible for all acts of such persons.

23. No awning or other projection shall be attached to the outside walls of the Building without Landlord's prior consent. Other than Landlord's Building-standard window coverings, no curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises. All electrical ceiling fixtures hung in the Premises or spaces along the perimeter of the Building must be fluorescent and/or of a quality, type, design and a warm white bulb color approved in advance by Landlord. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without Landlord's prior consent. Tenant shall abide by Landlord's regulations concerning the opening and closing of window coverings.

24. Tenant shall not obstruct any sashes, sash doors, skylights, windows or doors that reflect or admit light or air into the halls, passageways or other public places in the Building, nor shall Tenant place any bottles, parcels or other articles on the windowsills.

25. Tenant must comply with requests by Landlord concerning the informing of their employees of items of importance to the Landlord.

26. Tenant must comply with the State of California "No-Smoking" law set forth in California Labor Code Section 6404.5 and with any local "No-Smoking" ordinance that is not superseded by such law.

27. Tenant shall cooperate in any reasonable safety or security program developed by Landlord or required by Law.

28. All office equipment of an electrical or mechanical nature shall be placed by Tenant in the Premises in settings approved by Landlord, to absorb or prevent any vibration, noise or annoyance.

29. Tenant shall not use any hand trucks except those equipped with rubber tires and rubber side guards.

30. No auction, liquidation, fire sale, going-out-of-business or bankruptcy sale shall be conducted in the Premises without Landlord's prior consent.

31. Without Landlord's prior consent, Tenant shall not use the name of the Project or Building or use pictures or illustrations of the Project or Building in advertising or other publicity or for any purpose other than as the address of the business to be conducted by Tenant in the Premises.

Landlord may from time to time (upon no less than 10 business days' notice) modify or supplement these Rules and Regulations in a manner that, in Landlord's reasonable judgment, is appropriate for the management, safety, care and cleanliness of the Premises, the Building, the Common Areas and the Project, for the preservation of good order therein, and for the convenience of other occupants and tenants thereof, provided that no such modification or supplement shall materially reduce Tenant's rights or materially increase Tenant's obligations hereunder. Landlord may waive any of these Rules and Regulations for the benefit of any tenant, but no such waiver shall be construed as a waiver of such Rule and Regulation in favor of any other tenant nor prevent Landlord from thereafter enforcing such Rule and Regulation against any tenant. Notwithstanding the foregoing, no rule that is added to the initial Rules and Regulations shall be enforced against Tenant in a manner that unreasonably discriminates in favor of any other similarly situated tenant.

EXHIBIT E

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

JUDICIAL REFERENCE

IF THE JURY-WAIVER PROVISIONS OF SECTION 25.8 OF THIS LEASE ARE NOT ENFORCEABLE UNDER CALIFORNIA LAW, THE PROVISIONS SET FORTH BELOW SHALL APPLY.

(a) It is the desire and intention of the parties to agree upon a mechanism and procedure under which controversies and disputes arising out of this Lease or related to the Premises will be resolved in a prompt and expeditious manner. Accordingly, subject to the exclusions set forth in (b) below, any and every action, proceeding or cross-claim brought by either party hereto against the other (and/or against its officers, directors, employees, agents or subsidiaries or affiliated entities) on any matters arising out of or in any way connected with this Lease, Tenant's use or occupancy of the Premises and/or any claim of injury or damage, whether sounding in contract, tort, or otherwise, shall be heard and resolved by a referee under the provisions of the California Code of Civil Procedure, Sections 638 — 645.1, inclusive (as same may be amended, or any successor statute(s) thereto) (the "Referee Sections").

(b) Excluded from the requirement of judicial reference set forth above are (i) actions to seek emergency injunctive relief, preliminary injunctive relief, unlawful or forcible detainer, or a prejudgment writ of attachment and (ii) any dispute for which an alternative dispute resolution procedure is otherwise expressly provided in the Lease (including any exhibits thereto). The actions described in (i) above may be brought in the trial court in the county in which the Premises are located; provided, however, that as soon as practicable after the trial court rules on one or more of the above issues, the parties shall refer the lawsuit, and any remaining issues, controversies, or disputes to a referee, as provided in this section and the Referee Sections.

(c) Any fee to initiate the judicial reference proceedings and all fees charged and costs incurred by the referee shall be paid by the party initiating such procedure (except that if a reporter is requested by either party, then a reporter shall be present at all proceedings where requested and the fees of such reporter – except for copies ordered by the other parties – shall be borne by the party requesting the reporter); provided however, that allocation of the costs and fees, including any initiation fee, of such proceeding shall be ultimately determined in accordance with Section 25.6 of this Lease.

(d) The exclusive venue of the proceedings shall be in the county in which the Premises are located.

(e) Within 10 days of receipt by any party of a request to resolve any dispute or controversy pursuant to this **Exhibit E**, the parties shall agree upon a single referee who shall try all issues, whether of fact or law, and report a finding and judgment on such issues as required by the Referee Sections. If the parties are unable to agree upon a referee within such 10-day period, then any party may thereafter file a lawsuit in the county in which the Premises are located for the purpose of appointment of a referee under the Referee Sections. If the referee is appointed by the court, the referee shall be a neutral and impartial retired judge with substantial experience in the relevant matters to be determined, from the panels offered by JAMS or ADR Services, Inc. The proposed referee may be challenged by any party for any of the grounds listed in the Referee Sections. The referee shall have the power to decide all issues of fact and law and report his or her decision on such issues, and to issue all recognized remedies available at law or in equity for any cause of action that is before the referee, including an award of attorneys' fees and costs in accordance with this Lease. The referee shall not, however, have the power to award punitive damages, nor shall the referee have the power to award any other damages that are not permitted by the express provisions of this Lease, and the parties waive any right to recover such damages.

(f) The parties may conduct all discovery as provided in the California Code of Civil Procedure, and the referee shall oversee discovery and may enforce all discovery orders in the same manner as any trial court judge, with rights to regulate discovery and to issue and enforce subpoenas, protective orders and other limitations on discovery available under California Law.

(g) The reference proceeding shall be conducted in accordance with California Law (including the rules of evidence), and in all regards, the referee shall follow California Law applicable at the time of the reference proceeding. The parties shall promptly and diligently cooperate with one another and the referee, and shall perform such acts as may be necessary to obtain a prompt and expeditious resolution of the dispute or controversy in accordance with the terms of this **Exhibit E**. In this regard, the parties agree that the parties and the referee shall use best efforts to ensure that (a) discovery, including all expert

discovery (but excluding motions regarding discovery) be concluded within six (6) months of the date of the appointment of the referee, and (b) a trial date be set so that the trial proceeding is held no more than nine (9) months after the date of the appointment of the referee.

(h) In accordance with Section 644 of the California Code of Civil Procedure, the decision of the referee upon the whole issue must stand as the decision of the court, and upon the filing of the statement of decision with the clerk of the court, or with the judge if there is no clerk, judgment may be entered thereon in the same manner as if the action had been tried by the court. Any decision of the referee and/or judgment or other order entered thereon shall be appealable to the same extent and in the same manner that such decision, judgment, or order would be appealable if rendered by a judge of the superior court in which venue is proper hereunder. The referee shall in his/her statement of decision set forth his/her findings of fact and conclusions of law. The parties intend this general reference agreement to be specifically enforceable in accordance with the Code of Civil Procedure. Nothing in this **Exhibit E** shall prejudice the right of any party to obtain provisional relief or other equitable remedies from a court of competent jurisdiction as shall otherwise be available under the Code of Civil Procedure and/or applicable court rules.

EXHIBIT F

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

ADDITIONAL PROVISIONS

1. **California Civil Code Section 1938.** Pursuant to California Civil Code § 1938, Landlord hereby states that the Premises have not undergone inspection by a Certified Access Specialist (CASp) (defined in California Civil Code § 55.52).

Accordingly, pursuant to California Civil Code § 1938(e), Landlord hereby further hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises".

In accordance with the foregoing, Landlord and Tenant agree that if Tenant requests a CASp inspection of the Premises, then Tenant shall pay (i) the fee for such inspection, and (ii) except as may be otherwise expressly provided in this Lease (including, without limitation, Section 5 of the Lease), the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises.

2. **Letter of Credit.**

2.1. **General Provisions.** Concurrently with its execution and delivery of this Lease, Tenant shall deliver to Landlord, as collateral for Tenant's performance of its obligations under this Lease, a standby, unconditional, irrevocable, transferable letter of credit (the "**Letter of Credit**") that (a) is substantially in the form of **Exhibit F-1** (or another form approved by Landlord in its sole and absolute discretion), (b) is in the amount of **$250,000.00** (the "**Letter of Credit Amount**"), (c) names Landlord as beneficiary, and (d) is issued (or confirmed) by a financial institution that meets the Minimum Financial Requirement (defined below) and is otherwise acceptable to Landlord in its reasonable discretion. For purposes hereof, a financial institution shall be deemed to meet the "**Minimum Financial Requirement**" at a particular time only if such financial institution then (i) has not been placed into receivership by the FDIC, and (ii) has a financial strength that, in Landlord's good faith judgment, is not less than that which is then generally required by Landlord and its Affiliates as a condition to accepting letters of credit in support of new leases. Tenant shall cause the Letter of Credit to be continuously maintained in effect (whether through replacement, renewal or extension) in the Letter of Credit Amount through the date (the "**Final LC Expiration Date**") occurring 60 days after the scheduled expiration date of the Term, as it may be extended from time to time.

2.2. **Replacement of Letter of Credit.**

A. If the Letter of Credit held by Landlord expires or terminates before the Final LC Expiration Date (whether by reason of a stated expiration date or a notice of termination or non-renewal given by the issuing bank), Tenant shall deliver to Landlord, not later than 60 days before such expiration or termination, a new Letter of Credit, or a certificate of renewal or extension of the Letter of Credit held by Landlord, in an amount not less than the Letter of Credit Amount (less the amount of any unapplied Proceeds (defined in Section 2.3 below) then held by Landlord) and otherwise satisfying all of the requirements set forth in the first sentence of Section 2.1 above (the "**LC Requirements**").

B. If, at any time before the Final LC Expiration Date, the financial institution that issued (or confirmed) the Letter of Credit held by Landlord does not meet the Minimum Financial Requirement, then Tenant, within five (5) business days after Landlord's demand, shall deliver to Landlord, in replacement of such Letter of Credit, a new Letter of Credit that (i) is issued (or confirmed) by a financial institution that meets the Minimum Financial Requirement and is otherwise acceptable to Landlord in its reasonable discretion, and (ii) is in an amount not less than the Letter of Credit Amount (less the amount of any unapplied Proceeds then held by Landlord) and otherwise satisfies all of the LC Requirements, whereupon Landlord shall return to Tenant the Letter of Credit that is being replaced.

C. If, at any time before the Final LC Expiration Date, the amount of the Letter of Credit held by Landlord is less than the Letter of Credit Amount (less the amount of any unapplied Proceeds then held by Landlord), then Tenant, within five (5) business days after Landlord's demand, shall either (i) deliver to Landlord an additional Letter of Credit that is in an amount not less than the amount of such shortfall and otherwise satisfies all of the LC Requirements, or (ii) deliver to Landlord, in replacement of the Letter of Credit held by Landlord, a new Letter of Credit that is in an amount not less than the Letter of Credit Amount (less the amount of any unapplied Proceeds then held by Landlord) and otherwise satisfies all of the LC Requirements (whereupon, in the case of this clause (ii), Landlord shall return to Tenant the Letter of Credit that is being replaced).

2.3. **Drawings Under Letter of Credit; Use of Proceeds.** If Tenant breaches any provision of this Lease (including any provision of Section 2.2 above) and this Lease thereafter expires or terminates or Tenant Defaults under the terms of this Lease, Landlord, without limiting its remedies and without notice to Tenant, may draw upon the Letter of Credit and either (a) use all or part of the proceeds of the Letter of Credit ("**Proceeds**") to cure such breach or such Default and compensate Landlord for any loss or damage caused by such breach or such Default, including any damage for which recovery may be made under California Civil Code § 1951.2, or (b) hold the Proceeds, without segregation, until they are applied as provided in the preceding clause (a) or paid to Tenant pursuant to Section 2.4 below.

2.4. **Payment of Unapplied Proceeds to Tenant.** Upon receiving any new or additional Letter of Credit (or any certificate of renewal or extension of a Letter of Credit) satisfying the applicable requirements of Section 2.2 above, Landlord shall pay to Tenant any unapplied Proceeds then held by Landlord, except to the extent, if any, that the amount of the Letter of Credit then held by Landlord is less than the Letter of Credit Amount. In addition, any unapplied Proceeds shall be paid to Tenant within 60 days after the latest to occur of (a) the expiration of the Term, (b) Tenant's surrender of the Premises as required under this Lease, or (c) determination of the final Rent due from Tenant.

2.5. **Nature of Letter of Credit and Proceeds.** Landlord and Tenant acknowledge and agree that, subject to the terms of this Section 2, neither the Letter of Credit nor any Proceeds are (i) the property of Tenant or its bankruptcy estate, or (ii) intended to serve as, or in lieu of, a security deposit.

2.6. **Reduction in Letter of Credit Amount**. Subject to the terms of this Section 2.6, at any time after the end of the 37th full calendar month of the Term and upon written notice to Landlord ("**LOC Reduction Notice**"), Tenant may reduce the Letter of Credit Amount so that the reduced Letter of Credit Amount thereafter shall be **$125,000.00**; provided, however, that, Tenant shall have no right to reduce the Letter of Credit Amount unless Tenant is not in Default as of the date Tenant delivers the LOC Reduction Notice. Any reduction in the Letter of Credit Amount shall be accomplished by Tenant's delivery to Landlord of a substitute letter of credit satisfying the requirements of this Section 2 in the reduced amount or an amendment to the existing Letter of Credit reflecting the reduced amount.

3. **Extension Option.**

3.1. **Grant of Option; Conditions.** Tenant shall have the right (the "**Extension Option**") to extend the Term for one (1) additional period of three (3) years beginning on the day immediately following the expiration date of the Lease and ending on the third anniversary of such expiration date (the "**Extension Term**"), if:

(a) not less than 12 and not more than 15 full calendar months before the expiration date of the Lease, Tenant delivers written notice to Landlord (the "**Extension Notice**") electing to exercise the Extension Option;

(b) no Default exists when Tenant delivers the Extension Notice;

(c) no part of the Premises is sublet (other than to an affiliate of Tenant) when Tenant delivers the Extension Notice; and

(d) the Lease has not been assigned (other than pursuant to a Permitted Transfer) before Tenant delivers the Extension Notice.

3.2. **Terms Applicable to Extension Term.**

A. During the Extension Term, (a) the Base Rent rate per rentable square foot shall be equal to the Prevailing Market rate per rentable square foot; (b) Base Rent shall increase, if at all, in accordance with the increases assumed in the determination of Prevailing Market rate; and (c) Base Rent shall be payable in monthly installments in accordance with the terms and conditions of the Lease.

B. During the Extension Term Tenant shall pay Tenant's Share of Expenses and Taxes for the Premises in accordance with the Lease.

3.3. **Procedure for Determining Prevailing Market.**

A. Initial Procedure. Within 30 days after receiving the Extension Notice, Landlord shall give Tenant written notice of Landlord's estimate of the Prevailing Market rate for the Extension Term ("**Landlord's Estimate**"). Within 30 days of receiving Landlord's Estimate, Tenant shall give Landlord either (i) written notice ("**Tenant's Binding Notice**") accepting Landlord's Estimate, or (ii) written notice ("**Tenant's Rejection Notice**") rejecting such estimate and stating Tenant's estimate of the Prevailing Market rate for the Extension Term. If Tenant gives Landlord a Tenant's Rejection Notice, Landlord, within 15 days thereafter, shall give Tenant either (i) written notice ("**Landlord's Binding Notice**") accepting Tenant's estimate of the Prevailing Market rate for the Extension Term stated in Tenant's Rejection Notice, or (ii) written notice ("**Landlord's Rejection Notice**") rejecting such estimate. If Landlord gives Tenant a Landlord's Rejection Notice, Landlord and Tenant shall work together in good faith to agree in writing upon the Prevailing Market rate for the Extension Term. If, within 30 days after delivery of a Landlord's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate, the provisions of Section 3.3.B below shall apply.

B. Dispute Resolution Procedure.

1. If, within 30 days after delivery of a Landlord's Rejection Notice, the parties fail to agree in writing upon the Prevailing Market rate, Landlord and Tenant, within five (5) days thereafter, shall each simultaneously submit to the other, in a sealed envelope, its good faith estimate of the Prevailing Market rate for the Extension Term (collectively, the "**Estimates**"). If Landlord's and Tenant's Estimates are within 5% of each other, then the Prevailing Market rate for the Extension Term shall be the average of such Estimates and shall be final and binding on both parties (and may be entered in a court of competent jurisdiction). Otherwise, within seven (7) days after the exchange of Estimates, Landlord and Tenant shall each select a broker or agent (an "**Agent**") to determine which of the two Estimates most closely reflects the Prevailing Market rate for the Extension Term. Each Agent so selected shall be licensed as a real estate broker or agent and in good standing with the California Department of Real Estate, and shall have had at least five (5) years' experience within the previous 10 years as a commercial real estate broker or agent working in Foster City, California, with working knowledge of current rental rates and leasing practices relating to buildings similar to the Building.

2. If each party selects an Agent in accordance with Section 3.3.B.1 above, the parties shall cause their respective Agents to work together in good faith to agree upon which of the two Estimates most closely reflects the Prevailing Market rate for the Extension Term. The Estimate, if any, so agreed upon by such Agents shall be final and binding on both parties as the Prevailing Market rate for the Extension Term and may be entered in a court of competent jurisdiction. If the Agents fail to reach such agreement within 20 days after their selection, then, within 10 days after the expiration of such 20-day period, the parties shall instruct the Agents to select a third Agent meeting the above criteria (and if the Agents fail to agree upon such third Agent within 10 days after being so instructed, either

party may cause a court of competent jurisdiction to select such third Agent). Promptly upon selection of such third Agent, the parties shall instruct such Agent (or, if only one of the parties has selected an Agent within the 7-day period described above, then promptly after the expiration of such 7-day period the parties shall instruct such Agent) to determine, as soon as practicable but in any case within 14 days after his selection, which of the two Estimates most closely reflects the Prevailing Market rate. Such determination by such Agent (the "**Final Agent**") shall be final and binding on both parties as the Prevailing Market rate for the Extension Term and may be entered in a court of competent jurisdiction. If the Final Agent believes that expert advice would materially assist him, he may retain one or more qualified persons to provide such expert advice. The parties shall share equally in the costs of the Final Agent and of any experts retained by the Final Agent. Any fees of any other broker, agent, counsel or expert engaged by Landlord or Tenant shall be borne by the party retaining such broker, agent, counsel or expert.

C. Adjustment. If the Prevailing Market rate has not been determined by the commencement date of the Extension Term, Tenant shall pay Base Rent for the Extension Term upon the terms and conditions in effect during the last month ending on or before the expiration date of the Lease until such time as the Prevailing Market rate has been determined. Upon such determination, the Base Rent for the Extension Term shall be retroactively adjusted. If such adjustment results in an under- or overpayment of Base Rent by Tenant, Tenant shall pay Landlord the amount of such underpayment, or receive a credit in the amount of such overpayment, with or against the next Base Rent due under the Lease.

3.4. **Extension Amendment.** If Tenant is entitled to and properly exercises its Extension Option, and if the Prevailing Market rate for the Extension Term is determined in accordance with Section 3.3 above, Landlord, within a reasonable time thereafter, shall prepare and deliver to Tenant an amendment (the "**Extension Amendment**") reflecting changes in the Base Rent, the Term, the expiration date of the Lease, and other appropriate terms in accordance with this Section 3, and Tenant shall execute and return (or provide Landlord with reasonable objections to) the Extension Amendment within 15 days after receiving it. Notwithstanding the foregoing, upon determination of the Prevailing Market rate for the Extension Term in accordance with Section 3.3 above, an otherwise valid exercise of the Extension Option shall be fully effective whether or not the Extension Amendment is executed.

3.5. **Definition of Prevailing Market.** For purposes of this Extension Option, "**Prevailing Market**" shall mean the arms-length, fair-market, annual rental rate per rentable square foot under extension and renewal leases and amendments entered into on or about the date on which the Prevailing Market is being determined hereunder for space comparable to the Premises in the Building and office buildings comparable to the Building in the Foster City, California area. The determination of Prevailing Market shall take into account (i) any material economic differences between the terms of the Lease and any comparison lease or amendment, such as rent abatements, construction costs and other concessions, and the manner, if any, in which the landlord under any such lease is reimbursed for operating expenses and taxes; (ii) any material differences in configuration or condition between the Premises and any comparison space, including any cost that would have to be incurred in order to make the configuration or condition of the comparison space similar to that of the Premises; and (iii) any reasonably anticipated changes in the Prevailing Market rate from the time such Prevailing Market rate is being determined and the time such Prevailing Market rate will become effective under the Lease.

3.6. **Intentionally Omitted**.

4. **Monument Signage**.

4.1. So long as (i) Tenant is not in Default under the terms of the Lease; (ii) Tenant is in occupancy of the Premises; (iii) Tenant has not assigned the Lease or sublet any part of the Premises (other than pursuant to a Permitted Transfer), (iv) Tenant notifies Landlord prior to December 31, 2024, of its desire to have a Panel (as hereinafter defined) (individually a "**Signage Condition**" and collectively, the "**Signage Conditions**"), Tenant shall have the right, subject to the terms hereof, to have its name placed (the "**Panel**") on the shared Building monument sign located at the East Hillsdale entrance to the Building (the "**Monument Sign**"). The installation of the Panel shall be subject to (a) the approval of any governmental authority having jurisdiction and (b) the existing rights of existing tenants in the Building. The location of the Panel shall be subject to Landlord's reasonable discretion. The Panel shall (1) be designed by Landlord, (2) contain the Tenant's name, (3) be of a similar size and style as the names of other tenants on the Monument Sign and be harmonious with the design standards of the Building and Monument Sign, (4) be affixed to the Monument Sign in a manner consistent with the other tenant names on the Monument Sign, (5) if the other tenant names on the Monument Sign are currently illuminated, be illuminated in a similar manner. Following receipt of all necessary governmental approvals and so long as the Signage Conditions are satisfied, Landlord, at Tenant's sole cost and expense, shall fabricate, construct and thereafter install the Panel on the Monument Sign. All costs for which Tenant is responsible under this <u>Section 4.1</u> shall be paid by Tenant to Landlord within 30 days of written request by Landlord.

4.2. Although Landlord will perform the maintenance and repair to the Monument Sign and the Panel, Tenant shall be liable for all costs related to such maintenance, and, if applicable, illumination thereof. In the event that additional names are listed on the Monument Sign, all future costs of maintenance and repair shall be prorated between Tenant and the other parties that are listed on the Monument Sign. All costs for which Tenant is responsible under this <u>Section 4.2</u> shall be paid by Tenant to Landlord within 30 days of written request by Landlord.

4.3. Upon expiration or earlier termination of the Lease or if during the Term (and any extensions thereof) any of the Signage Conditions are no longer satisfied, then Tenant's rights granted herein will terminate and Tenant, at its cost within 30 days after request by Landlord, shall remove Tenant's Panel from the Monument Sign and restore the affected portion of the Monument Sign to the condition it was in prior to installation of Tenant's Panel, ordinary wear and tear excepted. If Tenant does not perform such work within such 30-day period, then Landlord may do so, at Tenant's cost, and Tenant shall reimburse Landlord for the cost of such work within 30 days after request therefore. The provisions of this <u>Section 4.3</u> shall survive expiration or earlier termination of the Lease.

4.4. Landlord may, at anytime during the Term (or any extension thereof), upon 30 days prior written notice to Tenant, relocate the position of Tenant's Panel. The cost of such relocation of Tenant's Panel shall be at the cost and expense of Landlord.

5. **<u>Right of First Offer</u>.**

5.1. **Grant of Option; Conditions.**

A. Subject to the terms of this <u>Section 5</u>, Tenant shall have a right of first offer ("**Right of First Offer**") with respect to each of the following suites (and with respect to each portion of each such suite) (each such suite or portion thereof, a "**Potential Offering Space**"): (i) the 6,741 rentable square feet known as Suite 200 on the second floor of the Building shown on the demising plan attached to the Lease as **<u>Exhibit F-2</u>**; (ii) the 5,092 rentable square feet known as Suite 220 on the second floor of the Building shown on the demising plan attached to the Lease as **<u>Exhibit F-3</u>**; (iii) the 5,333 rentable square feet known as Suite 230 on the second floor of the Building shown on the demising plan attached to the Lease as **<u>Exhibit F-4</u>**; and (iv) the 19,430 rentable square feet known as Suite 250 on the second floor of the Building shown on the demising plan attached to the Lease as **<u>Exhibit F-5</u>**. Tenant's Right of First Offer shall be exercised as follows: At any time after Landlord has determined that a Potential Offering Space has become Available (defined below), but before leasing such Potential Offering Space to a third party, Landlord, subject to the terms of this <u>Section 5</u>, shall provide Tenant with a written notice (for purposes of this <u>Section 5</u>, an "**Advice**") advising Tenant of the material terms on which Landlord is prepared to lease such Potential Offering Space (sometimes referred to herein as an "**Offering Space**") to Tenant, which terms shall be consistent with <u>Section 5.2</u> below. For purposes hereof, a Potential Offering Space shall be deemed to become "**Available**" as follows: (i) if such Potential Offering Space is not leased to a third party as of the date of mutual execution and delivery of this Lease, such Potential Offering Space shall be deemed to become Available when Landlord has located a prospective tenant that may be interested in leasing such Potential Offering Space; and (ii) if such Potential Offering Space is leased to a third party as of, or at any time after, the date of mutual execution and delivery of this Lease, such Potential Offering Space shall be deemed to become Available when Landlord has determined that such third-party tenant, and any occupant of such Potential Offering Space claiming under such third-party tenant, will not extend or renew the term of its lease, or enter into a new lease, for such Potential Offering Space. Upon receiving an

Advice, Tenant may lease the Offering Space, in its entirety only, under the terms set forth in the Advice, by delivering to Landlord a written notice of exercise (for purposes of this Section 5, a "**Notice of Exercise**") within five (5) days after receiving the Advice.

B. If Tenant receives an Advice but does not deliver a Notice of Exercise within the period of time required under Section 5.1.A above, Landlord may lease the Offering Space to any party on any terms determined by Landlord in its sole and absolute discretion**.**

C. Notwithstanding any contrary provision hereof, (i) Landlord shall not be required to provide Tenant with an Advice if any of the following conditions exists when Landlord would otherwise deliver the Advice; and (ii) if Tenant receives an Advice from Landlord, Tenant shall not be entitled to lease the Offering Space based on such Advice if any of the following conditions exists:

(1) a Default exists;

(2) all or any portion of the Premises is sublet;

(3) the Lease has been assigned (other than to an Affiliate or pursuant to a Permitted Transfer); or

(4) Tenant is not occupying the Premises.

If, by operation of the preceding sentence, Landlord is not required to provide Tenant with an Advice, or Tenant, after receiving an Advice, is not entitled to lease the Offering Space based on such Advice, then Landlord may lease the Offering Space to any party on any terms determined by Landlord in its sole and absolute discretion.

5.2. **Terms for Offering Space.**

A. The term for the Offering Space shall be coterminous with the term for the balance of the Premises.

B. The term for the Offering Space shall commence on the commencement date stated in the Advice and thereupon the Offering Space shall be considered a part of the Premises subject to the provisions of the Lease; provided, however, that the provisions of the Advice shall prevail to the extent they conflict with the provisions of the Lease.

C. Tenant shall pay Monthly Rent for the Offering Space in accordance with the provisions of the Advice. The Advice shall reflect the Prevailing Market (defined in Section 5.5 below) rate for the Offering Space as determined in Landlord's reasonable judgment.

D. Except as may be otherwise provided in the Advice, (i) the Offering Space (including improvements and personalty, if any) shall be accepted by Tenant in its configuration and condition existing on the earlier of the date Tenant takes possession of the Offering Space or the commencement date for the Offering Space; and (ii) if Landlord is delayed in delivering possession of the Offering Space by any holdover or unlawful possession of the Offering Space by any party, Landlord shall use reasonable efforts to obtain possession of the Offering Space and any obligation of Landlord to tender possession of, permit entry to, or perform alterations to the Offering Space shall be deferred until after Landlord has obtained possession of the Offering Space.

5.3. **Termination of Right of First Offer; Ongoing Right.**

A. Notwithstanding any contrary provision hereof, Landlord shall not be required to provide Tenant with an Advice, and Tenant shall not be entitled to exercise its Right of First Offer, after the date that is 18 full calendar months prior to the Expiration Date.

B. If Landlord leases a Potential Offering Space to a third party as permitted under Section 5.1 above and subsequently determines that such Potential Offering Space has again become Available, then the provisions of this Section 5 shall apply again to such Potential Offering Space.

5.4. **Offering Amendment.** If Tenant validly exercises its Right of First Offer, Landlord, within a reasonable period of time thereafter, shall prepare and deliver to Tenant an amendment (the "**Offering Amendment**") adding the Offering Space to the Premises on the terms set forth in the Advice and reflecting the changes in the Base Rent, the rentable square footage of the Premises, Tenant's Share, and other appropriate terms in accordance with this Section 5. Tenant shall execute and return the Offering Amendment to Landlord within 15 days after receiving it, but an otherwise valid exercise of the Right of First Offer shall be fully effective whether or not the Offering Amendment is executed.

5.5. **Definition of Prevailing Market.** For purposes of this Section 5, "**Prevailing Market**" means the arms-length, fair-market, annual rental rate per rentable square foot, under renewal and expansion leases and amendments entered into on or about the date on which the Prevailing Market is being determined hereunder, for space comparable to the Offering Space in the Building and office buildings comparable to the Building in the Foster City, California area. The determination of Prevailing Market shall take into account (i) any material economic differences between the terms of the Lease and any comparison lease or amendment, such as rent abatements, construction costs and other concessions, and the manner, if any, in which the landlord under any such lease is reimbursed for operating expenses and taxes; and (ii) any material differences in configuration or condition between the Offering Space and any comparison space.

5.6. **Subordination.** Notwithstanding any contrary provision hereof, Tenant's Right of First Offer shall be subject and subordinate to the expansion rights (whether such rights are designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Project existing on the date hereof.

6. **Contingency.** This Lease is expressly contingent upon Landlord, as landlord, and Tenant, as tenant, entering into a termination agreement (the "**Termination Agreement**") for space described as Suite 1050 on the 10^{th} floor located at 950 Tower Lane, Foster City, California. If the Termination Agreement has not been executed and delivered by Landlord and Tenant (in each parties sole and absolute discretion) on or before February 29, 2024, then this Lease shall be null and void and of no force or effect.

7. **Environmental Indemnity**. Landlord will indemnify, defend, hold harmless and reimburse Tenant and Tenant's trustees, members, principals, beneficiaries, partners, officers, directors, employees and agents (Tenant and such other entities collectively are, for purposes of this Section 7, the "**Tenant Related Parties**") from and against any and all fines and reasonable direct remedial costs and expenses (including reasonable legal expenses and consultants' fees) (collectively, for purposes of this Section 7, "**Costs**") that Tenant may incur due to a clean-up, abatement, removal, or other remedial response required of Tenant by an appropriate governmental authority resulting from or caused by the introduction, production, use, generation, storage, treatment, disposal, discharge, release or other handling or disposition of any Hazardous Materials in or about the Premises, Building, Property and/or Project. However, this indemnity provision will not apply to any Costs (a) caused by the negligence or intentional misconduct of Tenant or any other Tenant Related Parties or the contractors or invitees of Tenant or the Tenant Related Parties, or (b) to the extent costs result from (i) any Hazardous Materials introduced to, produced, used, stored, treated, handled or generated at (or disposed, discharged or released at or from) the Premises, Building, Property and/or Project by, or disturbed, distributed or exacerbated by, Tenant, any other Tenant Related Parties or the contractors or the invitees thereof, (ii) any default by Tenant of the terms of the Lease and/or (iii) any act of (or to be taken by) Tenant, any other Tenant Related Parties or the contractors or the invitees thereof. In addition, the foregoing indemnity obligation shall not bind any party that acquires Landlord's interest in the Property by foreclosure or deed in lieu of foreclosure, except to the extent of any Costs incurred as a result of any clean-up, abatement, removal, or other remedial response that such party was required under applicable law to perform, but failed to perform, after such acquisition. Nothing in this Section 7 shall be interpreted as imposing any liability on Landlord for any other costs or expenses incurred by Tenant or any of the Tenant Related Parties (including, without limitation, lost sales or profits of such parties) relating to the presence of Hazardous Materials at the Premises, Building, Property and/or Project.

EXHIBIT F-1

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

LETTER OF CREDIT

____
[Name of Financial Institution]

Irrevocable Standby
Letter of Credit
No. ______________________
Issuance Date:_____________
Expiration Date:____________
Applicant:__________________

Beneficiary

[*Insert Name of Landlord*]
[*Insert Building management office address*]
____
____
____

Ladies/Gentlemen:

We hereby establish our Irrevocable Standby Letter of Credit in your favor for the account of the above referenced Applicant in the amount of two hundred fifty thousand U.S. Dollars ($250,000.00) available for payment at sight by your draft drawn on us when accompanied by the following documents:

1. An original copy of this Irrevocable Standby Letter of Credit.

2. Beneficiary's dated statement purportedly signed by an authorized signatory or agent reading: "This draw in the amount of ______________________ U.S. Dollars ($____________) under your Irrevocable Standby Letter of Credit No. ____________________ represents funds due and owing to us pursuant to the terms of that certain lease by and between ______________________, as landlord, and _____________, as tenant, and/or any amendment to the lease or any other agreement between such parties related to the lease."

It is a condition of this Irrevocable Standby Letter of Credit that it will be considered automatically renewed for a one year period upon the expiration date set forth above and upon each anniversary of such date, unless at least 60 days prior to such expiration date or applicable anniversary thereof, we notify you in writing, by certified mail return receipt requested or by recognized overnight courier service, that we elect not to so renew this Irrevocable Standby Letter of Credit. A copy of any such notice shall also be sent, in the same manner, to: _____________________________ , Attention: Treasury Department. In addition to the foregoing, we understand and agree that you shall be entitled to draw upon this Irrevocable Standby Letter of Credit in accordance with 1 and 2 above in the event that we elect not to renew this Irrevocable Standby Letter of Credit and, in addition, you provide us with a dated statement purportedly signed by an authorized signatory or agent of Beneficiary stating that the Applicant has failed to provide you with an acceptable substitute irrevocable standby letter of credit in accordance with the terms of the above referenced lease. We further acknowledge and agree that: (a) upon receipt of the documentation required herein, we will honor your draws against this Irrevocable Standby Letter of Credit without inquiry into the accuracy of Beneficiary's signed statement and regardless of whether Applicant disputes the content of such statement; (b) this Irrevocable Standby Letter of Credit shall permit partial draws and, in the event you elect to draw upon less than the full stated amount hereof, the stated amount of this Irrevocable Standby Letter of Credit shall be automatically reduced by the amount of such partial draw; and (c) you shall be entitled to transfer your interest in this Irrevocable Standby Letter of Credit from time to time and more than one time without our approval and without charge. In the event of a transfer, we reserve the right to require reasonable evidence of such transfer as a condition to any draw hereunder.

This Irrevocable Standby Letter of Credit is subject to the International Standby Practices (ISP98) ICC Publication No. 590.

Exhibit F-1

We hereby engage with you to honor drafts and documents drawn under and in compliance with the terms of this Irrevocable Standby Letter of Credit.

All communications to us with respect to this Irrevocable Standby Letter of Credit must be addressed to our office located at ____ to the attention of __________________________________.

Very truly yours,

____

___[name]

___[title]

EXHIBIT F-2

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

SUITE 200 POTENTIAL OFFERING SPACE

EXHIBIT F-3

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

SUITE 220 POTENTIAL OFFERING SPACE

EXHIBIT F-4

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

SUITE 230 POTENTIAL OFFERING SPACE

EXHIBIT F-5

METRO CENTER
989 EAST HILLSDALE BOULEVARD
FOSTER CITY, CALIFORNIA

SUITE 250 POTENTIAL OFFERING SPACE

MIRUM PHARMACEUTICALS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Mirum Pharmaceuticals, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service upon and following the date of the underwriting agreement between the Company and the underwriters managing the initial public offering of the Company's common stock (the "***Common Stock***"), pursuant to which the Common Stock is priced in such initial public offering (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $45,000
    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $60,000
    c. Lead Independent Director Service Retainer (in addition to Eligible Director Service Retainer), if applicable: $10,000
2. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
    a. Chair of the Audit Committee: $20,000
    b. Chair of the Compensation Committee: $20,000
    c. Chair of the Nominating and Corporate Governance Committee: $10,000

3. Annual Committee Member Service Retainer:
    a. Member of the Audit Committee: $10,000
    b. Member of the Compensation Committee: $10,000
    c. Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2019 Equity Incentive Plan (the "***Plan***"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be three months from the date of termination).

1. <u>Initial Grant</u>: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board, granted a stock option to purchase 34,000 shares of Common Stock (the "***Initial Grant***"). Each person who, after the Effective Date, served as an employee of, or consultant to, the Company and as a member of the Board, but who later ceases to provide such employment or consulting services shall not be entitled to an Initial Grant. The shares subject to each Initial Grant will vest in equal annual installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. <u>Annual Grant</u>: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board, granted a stock option to purchase 17,000 shares of Common Stock (the "***Annual Grant***"); *provided, however*, that if the Eligible Director has not served as member of the Board for 12 months prior to the applicable annual stockholder meeting, the number of shares subject to such individual's Annual Grant will be pro-rated based on the number of full months served on the Board, rounded to the nearest whole share. The shares subject to the Annual Grant will vest on the first anniversary of the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

THIRD AMENDMENT

THIS THIRD AMENDMENT (this "**Amendment**") is made and entered into as of ___January 17_____, 2024, by and between **HUDSON METRO CENTER, LLC, a Delaware limited liability company** ("**Landlord**"), and **MIRUM PHARMACEUTICALS, INC., a Delaware corporation** ("**Tenant**").

RECITALS

A. Landlord and Tenant are parties to that certain Office Lease dated January 22, 2019 (as confirmed by that certain Confirmation Letter dated August 21, 2019), that certain First Amendment dated June 1, 2019 and that certain Second Amendment dated November 22, 2019 (as amended, the "**Lease**"). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **11,154** rentable square feet (the "**Premises**") at the building commonly known as Metro Center Tower located at 950 Tower Lane, Foster City, California (the "**Building**"); and described as Suite 1025 consisting of approximately 5,555 rentable square feet on the 10^{th} floor of the Building and Suite 1050 consisting of approximately 5,599 rentable square feet on the 10^{th} floor of the Building.

B. The Lease will expire by its terms on March 31, 2025 (the "**Extended Expiration Date**"). The parties wish to accelerate the expiration date of the Lease on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. <u>**Acceleration of Expiration Date**</u>.

1.1. **Accelerated Expiration Date.** Subject to the provisions hereof, the term of the Lease shall expire five days (5) days after the Commencement Date (as defined in the New Lease)of the New Lease (as defined in <u>Section 6.1</u> below) (the "**Accelerated Expiration Date**") with the same force and effect as if such term were, by the provisions of the Lease, fixed to expire on the Accelerated Expiration Date (the "**Acceleration**"). Without limiting the foregoing:

A. Subject to <u>Section 1.1.C</u> below, Tenant shall surrender the Premises to Landlord in accordance with the terms of the Lease on or before the Accelerated Expiration Date.

B. Tenant shall remain liable for all Rent and other amounts payable under the Lease for the period up to and including the Accelerated Expiration Date, even though billings for such amounts may occur after the Accelerated Expiration Date; provided, however, for the period beginning on the Commencement Date (as defined in Section 1.3.2 of the New Lease) of the New Lease and ending five (5) days thereafter, Base Rent shall be abated.

C. Tenant's restoration obligations shall be as set forth in the Lease; provided, however, that Landlord acknowledges and agrees that, for purposes of <u>Sections 8</u> and <u>15</u> of the Lease, all Leasehold Improvements, Alterations and Tenant-Requested Improvements existing in the Premises as of the date hereof are Building-standard and, as a result thereof, Tenant shall have no obligation at the expiration of the Lease to remove (nor pay for the removal of) the same or repair (nor pay for the repair of) any damage resulting from such removal.

D. If Tenant fails to surrender any portion of the Premises on or before the Accelerated Expiration Date, Tenant's tenancy shall be subject to Section 16 of the Lease.

E. Any other rights or obligations of Landlord or Tenant under the Lease that, in the absence of the Acceleration, would have survived the Existing Expiration Date shall survive the Accelerated Expiration Date.

1.2. [Intentionally Omitted].

1.3. **Limitations on Tenant's Rights.** Notwithstanding any contrary provision of the Lease, any unexercised right or option of Tenant to renew or extend the term of the Lease or to expand the Premises (whether in the form of an expansion option, right of first offer or refusal, or any other similar right), and any outstanding tenant improvement allowance or other allowance not claimed and properly used by Tenant in accordance with the Lease as of such date, shall be deemed terminated and no longer available or of any further force or effect.

2. **<u>Representations</u>.** Tenant represents and warrants that, as of the date hereof and the Accelerated Expiration Date: (a) Tenant is the rightful owner of all of the Tenant's interest in the Lease; (b) Tenant has not made any disposition, assignment, sublease, or conveyance of the Lease or Tenant's interest therein; (c) Tenant has no knowledge of any fact or circumstance which would give rise to any claim, demand, obligation, liability, action or cause of action arising out of or in connection with Tenant's occupancy of the Premises; (d) no other person or entity has an interest in the Lease, collateral or otherwise; and (e) there are no outstanding contracts for the supply of labor or material and no work has been done or is being done in, to or about the Premises which has not been fully paid for and for which appropriate waivers of mechanic's liens have not been obtained. Landlord represents and warrants that, as of the date hereof, Landlord is the rightful owner of all of the Landlord's interest in the Lease.

3. [Intentionally Omitted].

4. [Intentionally Omitted].

5. [Intentionally Omitted].

6. **<u>Other Pertinent Provisions</u>.** Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

6.1. **Contingency.** This Amendment is expressly contingent upon Landlord, as landlord, and Tenant, as tenant, entering into a new lease (the "**New Lease**") for space described as Suite 300 consisting of approximately 36,318 rentable square feet located at 989 E. Hillsdale Boulevard, Foster City, California. If this Amendment has not been executed and delivered by Landlord and Tenant (in each parties' sole and absolute discretion) on or before February 29, 2024, then this Amendment shall be null and void and of no force or effect and the Lease shall continue in full force and effect.

7. **<u>Miscellaneous</u>.**

7.1. This Amendment sets forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Tenant shall not be entitled, in connection with entering into this Amendment, to any free rent, allowance, alteration, improvement or similar economic incentive to which Tenant may have been entitled in connection with entering into the Lease, except as may be otherwise expressly provided in this Amendment.

7.2. Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect (including, without limitation, <u>Sections 1.8</u> and <u>21</u> of the Lease (governing the amount, application and return of the Security Deposit), <u>Section 25.6</u> of the Lease (entitled, Attorneys' Fees), <u>Section 25.8</u> of the Lease (entitled, Governing Law; WAIVER OF TRIAL BY JURY) and <u>Section 25.10</u> (entitled, Interpretation)).

7.3. In the case of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall govern and control.

7.4. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered it to Tenant.

7.5. Each party hereto, and their respective successors and assigns shall be authorized to rely upon the signatures of all of the parties hereto which are delivered by facsimile, PDF or DocuSign (or the like) as constituting a duly authorized, irrevocable, actual, current delivery hereof with original ink signatures of each person and entity. This Amendment may be executed in counterparts, each of which shall be deemed an original part and all of which together shall constitute a single agreement.

7.6. Capitalized terms used but not defined in this Amendment shall have the meanings given in the Lease.

[SIGNATURES ARE ON FOLLOWING PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

LANDLORD:

HUDSON METRO CENTER, LLC, a Delaware limited liability company

By: Hudson Pacific Properties, L.P.,
a Maryland limited partnership,
its sole member

By: Hudson Pacific Properties, Inc.,
a Maryland corporation,
its general partner

By: _/s/ Mark Lammas__________________

Name: _Mark Lammas____________________

Title: _President________________________

TENANT:

MIRUM PHARMACEUTICALS, INC., a Delaware corporation

By: _/s/ Chris Peetz__________________________

Name: _Chris Peetz____________________________

Title: _President & CEO_______________________

By: _/s/ Eric Bjerkholt_______________________

Name: _Eric Bjerkholt__________________________

Title: _CFO___________________________________

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-267357) of Mirum Pharmaceuticals, Inc.;
(2) Registration Statement (Form S-3 No. 333-265210) of Mirum Pharmaceuticals, Inc.;
(3) Registration Statement (Form S-3 No. 333-274973) of Mirum Pharmaceuticals, Inc.;
(4) Registration Statement (Form S-8 No. 333-233502) pertaining to the 2018 Equity Incentive Plan, 2019 Equity Incentive Plan, and 2019 Employee Stock Purchase Plan of Mirum Pharmaceuticals, Inc.;
(5) Registration Statements (Form S-8 Nos. 333-238086, 333-254043 and 333-263397) pertaining to the 2019 Equity Incentive Plan, 2019 Employee Stock Purchase Plan, and 2020 Inducement Plan of Mirum Pharmaceuticals, Inc.;
(6) Registration Statement (Form S-8 No. 333-270399) pertaining to the 2019 Equity Incentive Plan and the 2019 Employee Stock Purchase Plan of Mirum Pharmaceuticals, Inc; and
(7) Registration Statement (Form S-8 No. 333-275283) pertaining to the 2020 Inducement Plan of Mirum Pharmaceuticals, Inc.;

of our reports dated March 15, 2024, with respect to the consolidated financial statements of Mirum Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Mirum Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Mirum Pharmaceuticals, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Mateo, California
March 15, 2024

Exhibit 31.1

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

I, Christopher Peetz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Mirum Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2024	By:	/s/ Christopher Peetz
		Christopher Peetz
		Chief Executive Officer
		(Principal Executive Officer)

Exhibit 31.2

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

I, Erik Bjerkholt, certify that:

1. I have reviewed this Annual Report on Form 10-K of Mirum Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2024

By: /s/ Eric Bjerkholt
Eric Bjerkholt
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Mirum Pharmaceuticals, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 15, 2024

By: /s/ Christopher Peetz

Christopher Peetz
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Mirum Pharmaceuticals, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 15, 2024

By: /s/ Eric Bjerkholt
Eric Bjerkholt
Chief Financial Officer
(Principal Financial Officer)

MIRUM PHARMACEUTICALS, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Mirum Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an

Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the

Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX 304") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

MIRUM PHARMACEUTICALS, INC.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Mirum Pharmaceuticals, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Mirum Pharmaceuticals, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

Name:

Title:

Date: