UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2022

☐ **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 001-38709

RVL Pharmaceuticals plc

(Exact name of registrant as specified in its charter)

Ireland	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

400 Crossing Boulevard
Bridgewater, NJ 08807
(Address of principal executive offices)
(Zip Code)

(908) 809-1300
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, $0.01 nominal value per share	RVLP	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange 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, a smaller reporting company, or an emerging growth company. See 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 voting and non-voting shares held by non-affiliates of the registrant on June 30, 2022, based upon the closing price of $1.36 of the registrant's ordinary shares as reported on the Nasdaq Global Select Market, was approximately $44.9 million.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding at March 17, 2023
Ordinary shares, $0.01 nominal value per share	99,349,814 shares

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2023 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III items 10-14 of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "should," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives and financial needs. Examples of forward-looking statements include, among others, statements we make regarding: our intentions, beliefs or current expectations concerning, among other things, future operations; future financial performance, trends and events, particularly relating to Upneeq; U.S. Food and Drug Administration, or the FDA, and other regulatory applications, approvals and actions; the continuation of historical trends; our ability to manage costs and service our debt; and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs.

We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make.

The forward-looking statements included in this Annual Report on Form 10-K are made only as of the date hereof. You should not rely upon forward-looking statements as predictions of future events. We cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by applicable law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date hereof to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

TRADEMARKS AND TRADE NAMES

We own or have rights to trademarks or trade names that we use in conjunction with the operation of our business. In addition, our name, logo and website name and address are our service marks or trademarks. Each trademark, trade name or service mark by any other company appearing in this Annual Report on Form 10-K belongs to its holder. The trade names and trademarks that we use include Upneeq®. We also own or have the rights to copyrights that protect the content of our products. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K are listed without the ™, SM, ® and © symbols, but we will assert, to the fullest extent under applicable law, our rights to these trademarks, service marks, trade names and copyrights.

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our ordinary shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary and other risks that we face can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our ordinary shares.

- Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed or discontinued if we are unable to obtain the additional funding as or when needed.
- Due to our dependence on one product, Upneeq, our business could be materially adversely affected if Upneeq does not perform as well as expected.

- Upneeq may fail to achieve sufficient market acceptance by clinicians and patients, or others in the medical community, and the market opportunity for Upneeq may be smaller than we estimate.
- If we are unable to successfully commercialize Upneeq, or develop new products, on a timely or cost effective basis, our operating results will suffer.
- Our profitability depends on our customers' willingness to pay the price we charge for Upneeq. If we decide to lower the price we charge for Upneeq our profitability could materially suffer.
- Our marketing and sales expenditures may not result in the commercial successful of Upneeq.
- We expend a significant amount of resources on research and development, including milestones on in licensed products, which may not lead to successful product introductions.
- If we are unable to maintain our sales, marketing and distribution capabilities, or establish additional capabilities if and when necessary, we may not be successful in commercializing Upneeq.
- We depend to a large extent on third-party suppliers and distributors for Upneeq, including Nephron Pharmaceuticals, and if such suppliers and distributors are unable to supply raw materials for manufacture and deliver Upneeq in a timely manner, or are unable to manufacture Upneeq at a scale sufficient to meet demand, it could have a material adverse effect on our business, financial position and results of operations.
- Manufacturing or quality control problems at our or our third-party manufacturing facility operated by Nephron Pharmaceuticals may damage our reputation for quality production, require costly remedial activities, delay or interrupt the supply of Upneeq, and negatively impact our business, results of operations and financial condition.
- If Upneeq does not produce the intended effects, our business may suffer.
- The terms of the documentation governing our indebtedness restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.
- Our business may be adversely affected by the ongoing coronavirus outbreak.
- There is no certainty that we will be able to get FDA approval of arbaclofen ER and no certainty that we will be able to realize any value for arbaclofen ER if we license or divest the product.
- The drug regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products that target markets with underserved patient populations in the ocular medicine and medical aesthetics therapeutic areas. In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or droopy or low-lying eyelids in adults. We believe Upneeq is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis. We launched Upneeq in September 2020 to a limited number of eye care professionals with commercial operations expanded in 2021 among ophthalmology, optometry and oculoplastic specialties. In February 2022, Upneeq was commercially expanded into the medical aesthetics market in the United States. Patients may purchase Upneeq either from eye care or medical aesthetic professionals, or exclusively through RVL Pharmacy, LLC, our wholly-owned pharmacy.

We acquired the worldwide rights to RVL-1201 in 2017 in exchange for an upfront cash payment plus the obligation to make additional payments consisting of future earn-out payments to the sellers of RevitaLid based on net sales of Upneeq. In addition, we are required to make milestone payments based on regulatory and sales milestones and to pay royalties to VOOM, LLC in connection with the license for Upneeq that we acquired as part of the acquisition of RVL-1201.

Upneeq is manufactured and supplied to us by Nephron Pharmaceuticals Corporation under an exclusive supply agreement that has a term of five years from the production of the initial commercial batches, which occurred in July 2020 and automatically renews for additional one-year periods unless either party provides at least 90 days advance written notice of non-renewal.

On July 28, 2020, we entered into a license agreement with Santen Pharmaceutical Co. Ltd ("Santen"), granting Santen exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as Europe, the Middle East and Africa ("EMEA") countries (the "License Agreement"). Santen is responsible for further development of RVL-1201 in the licensed territories. Under the License Agreement, we have received an upfront payment of $25.0 million in 2020 and a license milestone payment of $10.0 million in 2021. On March 29, 2022, we amended the License Agreement, effective March 31, 2022 (as amended, the "Amended License Agreement"), and received $15.5 million to expand the licensed territories to include certain additional EMEA countries and Canada and remove certain regulatory approval milestones from the License Agreement. Under the Amended License Agreement, we may receive additional payments of up to $31.0 million based on development, regulatory and sales milestone payments in Santen's territories. We are also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories. See Note 5, "*Revenues*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our License Agreement with Santen.

On August 27, 2021, we announced the closing of the divestiture of our portfolio of branded and non-promoted products and our Marietta, Georgia, manufacturing facility (collectively, the "Legacy Business"), to certain affiliates of Alora Pharmaceuticals, LLC ("Alora") for $111 million in cash upon closing, subject to certain post-closing adjustments, and up to $60 million in contingent milestone payments. Pursuant to the divestiture, we retained the rights to Upneeq and to arbaclofen extended release ("ER") tablets, which is under development for the treatment of spasticity in multiple sclerosis. During the year ended December 31, 2022, we received an aggregate of $5.0 million in cash from Alora related to contingent milestone payments earned in connection with the sale of the Legacy Business.

With the divestiture of the Legacy Business, our commercial operations are conducted by our wholly-owned subsidiary, RVL Pharmaceuticals, Inc. and its subsidiary RVL Pharmacy, LLC ("RVL Pharmacy"). RVL Pharmacy exclusively conducts pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

Following the divestiture of the Legacy Business, we are exploring opportunities to sell or out-license our late-stage product candidate arbaclofen ER tablets designed for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis for which we have completed Phase III clinical trials. In June 2020, we resubmitted our NDA for arbaclofen ER tablets to the FDA. On July 17, 2020, we received notice from the FDA that it considered the resubmission a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020. On December 28, 2020, we received a complete response letter ("CRL") indicating the FDA could not approve the NDA in its then current form. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in the Total Numeric-transformed Ashworth Scale in the most affected limb ("TNmAS-MAL") scores comparing arbaclofen ER 40 mg to placebo, one of the co-primary endpoints. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL's recommendations and obtain advice on a path forward for the NDA. The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a special protocol assessment ("SPA") to the FDA proposing an additional clinical study for arbaclofen ER. The FDA responded in a letter dated October 15, 2021, indicating that they are unable to issue an agreement on the submitted protocol. On October 10, 2022, we resubmitted a SPA and on November 24, 2022, we received a letter from the FDA indicating that they were unable to issue an agreement on the SPA. On February 8, 2023, we resubmitted a SPA with a revised study protocol and statistical analysis.

Our Market

Our healthcare provider customers include optometrists, ophthalmologists, oculoplastic surgeons, facial plastic surgeons, dermatologists, and practitioners qualified to diagnose and treat acquired blepharoptosis, or droopy or low-lying eyelids, in adults. Our target patient population comprises adults with droopy or low-lying eyelids or acquired ptosis, the majority of which are female. While the exact prevalence of acquired ptosis is unknown, we believe it to be a common age-related condition. A survey of eye care providers and medical aesthetics specialists suggests that approximately half of adult patients visiting these specialties may be affected by droopy or low-lying eyelids. Further, we estimate that approximately 60% of adult women self-identify as having some degree of droopy or low-lying eyelids and a majority of those women indicate that they are bothered by the position of their eyelids.

The global medical aesthetics market is expected to grow at a compound annual growth rate of over 10% and reach $18 billion in 2027, with North America representing the largest share of the global market. Similarly, the global eye care market is expected to grow at a compound annual growth rate of over 6% through 2026 and reach $86 billion. An estimated 100 million adults visit an eye care provider each year in the United States alone.

We believe the growth in medical aesthetics and eye care markets will be driven by a number of factors, including:

- an aging population together with an increasing life expectancy, which is resulting in more consumers with a desire for improved appearance and well-being over a longer period of time;
- rising disposable income, with the U.S. Bureau of Economic Analysis reporting that real disposable income in the United States increased approximately 21% from December 2012 to December 2020;
- growing awareness, utilization and acceptance of elective or minimally invasive and non-invasive interventions; and
- continued innovation and improved accessibility to treatments due to an increase in the number of physicians who offer eye care and medical aesthetics services.

Our Strategy

Our goal is to become a growth company in the fields of ocular medicine and medical aesthetics. To accomplish this goal, we intend to:

Establish Upneeq as the First-line Treatment Option for Acquired Ptosis and Continue to Grow Sales. Upneeq is the first and only non-surgical FDA-approved treatment option for acquired ptosis in adults. We believe that there is a significant commercial opportunity for Upneeq given the meaningful unmet need for a non-invasive treatment across millions of acquired ptosis patients in the United States. Our near-term focus is to continue the rollout of Upneeq into the medical aesthetics market through our dedicated aesthetics sales force, while continuing to support ongoing utilization and expanded penetration of Upneeq in ocular medicine markets. While promotion of the product currently relies heavily on our sales force engaging medical aesthetic practices, we continue to raise patient and physician awareness of acquired ptosis and Upneeq through traditional advertising, medical conferences, social media (e.g., Facebook and Instagram) and marketing partnerships.

Broaden Distribution Channels for Upneeq. Following FDA approval in July 2020, we launched Upneeq in eye care specialties and made the product exclusively available through prescription at our wholly-owned and operated pharmacy, RVL Pharmacy. While RVL Pharmacy remains the exclusive point of pharmacy fulfillment for Upneeq, we have also added additional means of access to the product for patients. In September 2021, we initiated the Direct Dispense program to eye care professionals and in early 2022 to medical aesthetics professionals. Under the program we sell Upneeq directly to eye care professionals and medical aesthetics practices where the practice is then able to resell and dispense Upneeq to appropriate patients. To address certain instances where an eye care professional or medical aesthetics practice may be unable to dispense a pharmaceutical product from his or her practice, in January 2022, we initiated the Virtual Inventory program where Upneeq is dispensed and furnished to patients by RVL Pharmacy pursuant to a prescription, after the product is sold to eye care professionals or medical aesthetics practices for resale to patients.

In 2022 we started supplying Upneeq to certain telemedicine providers with established channels to diagnose patients online and prescribe and ship directly to appropriate patients.

Continue to Divest Non-Core Assets. Following the sale of our Legacy Business in 2021, the Company is looking to continue monetizing non-core assets to fully focus resources on growing Upneeq. We consider our late stage product candidate, arbaclofen ER, a treatment for spasticity associated with multiple sclerosis, to be a non-strategic asset and the Company is seeking to either sell the asset or find a license partner to complete development and commercialize the product.

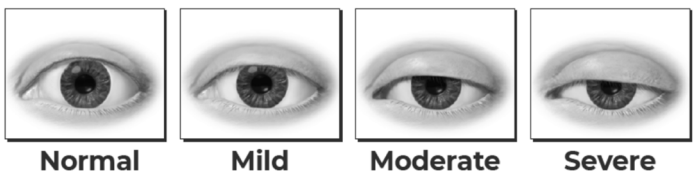
Leverage our pharmacy infrastructure. We consider RVL's pharmacy operations to be a key strategic asset for the Company where we may look to opportunistically acquire or in-license rights to clinically differentiated products or product candidates suitable to our unique pharmacy distribution channel and self-pay healthcare marketplace. Our management team has a history of successfully executing and integrating product and company acquisitions, which we believe positions us to capitalize on these opportunities.

Our Portfolio

Upneeq (RVL-1201) for Acquired Blepharoptosis in Adults

We are focused on growing Upneeq with eye care and medical aesthetic professionals and providing a convenient prescription experience for patients through our pharmacy. RVL Pharmacy dispenses Upneeq only and operates only on a cash basis (i.e., it does not submit any claims to third party payors for prescriptions filled). As the first pharmacological treatment for acquired blepharoptosis approved by the FDA in the United States, we believe Upneeq represents an important therapy in the continuum of care for adult patients with acquired blepharoptosis.

Blepharoptosis, or ptosis, may be present at birth, called congenital blepharoptosis, or acquired over time due to age or illness, called acquired blepharoptosis. Ptosis manifests itself as mild, moderate or severe and can look like the following:



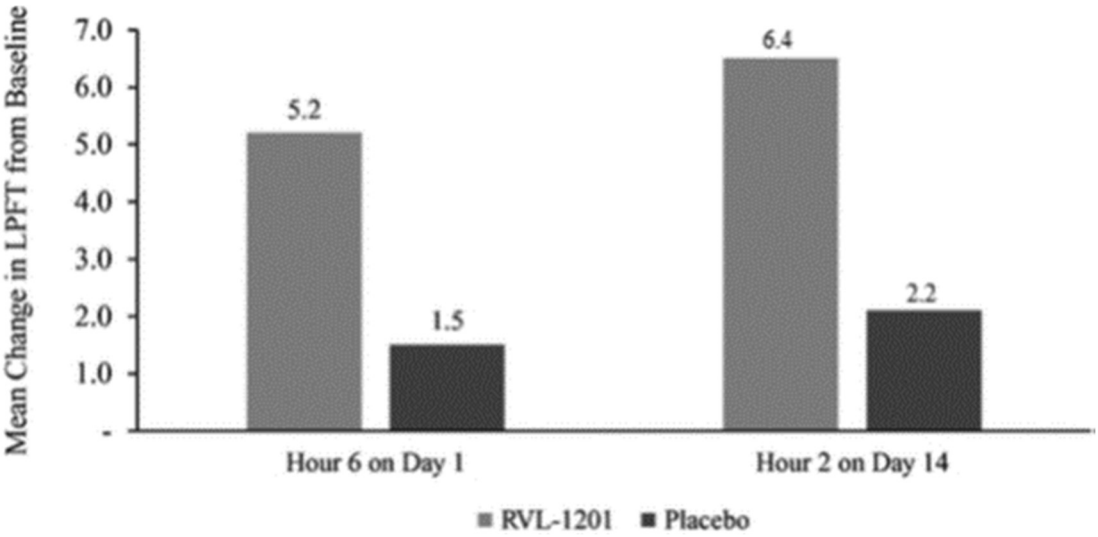
According to a 2018 survey of U.S. optometrists, ophthalmologists and surgeons, approximately 38% of blepharoptosis cases were mild and 48% were moderate. While no robust epidemiological studies exploring the prevalence of blepharoptosis exist, we believe it is a condition affecting millions of Americans. A study conducted in 1995 in the United Kingdom found some level of blepharoptosis in 12% of a sample set of adults age 50 years and older and that 90% of the sample had acquired blepharoptosis after birth.

Medical research has shown that eyelid droop can cause pupil obstruction and deficits in patients' superior visual field. Additionally, blepharoptosis can lead to an asymmetric eye appearance or sleepy look which in turn can lead to increased appearance related distress, anxiety and depression, similar to patients with other appearance-altering ocular conditions. A Company sponsored survey conducted in 2021 (n=149) indicated health care providers estimate prevalence of blepharoptosis among their patient population to range from 42% to 62%. Additionally, consumer interest in eyelid position is high. In a market research report we commissioned in 2021 among 10,000 women aged 20-70 with household incomes greater than $50,000, more than 60% of participants identified as having at least one droopy or low-lying eyelid. Of those who identified as having droopy or low-lying eyelid(s), approximately 29% indicated an interest in purchasing Upneeq, if prescribed.

We acquired the worldwide rights to RVL-1201 in 2017 in exchange for an upfront cash payment plus the obligation to make additional payments based on our net sales of the product. RVL-1201 is manufactured and supplied to us by Nephron Pharmaceuticals Corporation under an exclusive supply agreement that has a term of five years from the production of the initial commercial batches, which occurred in July 2020 and automatically renews for additional one-year periods unless either party provides at least 90 days advance written notice of non-renewal. Remaining milestone payments in an aggregate amount of up to $0.8 million could become payable by us upon the achievement of certain regulatory and sales milestones.

Results from the first Phase III clinical trial of RVL-1201 demonstrated that the formulation met its primary efficacy endpoint and was well-tolerated. The 2:1 randomized, double-masked, placebo-controlled study comprised 140 patients with blepharoptosis in two treatment groups for 42 days. Patients treated with RVL-1201 received one full drop in each eye each morning while patients treated with the placebo also received one full drop in each eye each morning. The primary efficacy endpoints were change in baseline visual field using the Leicester Peripheral Field Test or LPFT, on Hour 6 Day 1 ($p=0.0003$) and Hour 2 on Day 14 ($p< 0.0001$). As shown below, patients who received RVL-1201 once-daily experienced a statistically significant improvement in visual field when compared to the placebo group.

RVL-1201 Phase III Clinical Trial Efficacy: Leicester Peripheral Field Test (LPFT)
(Intent-to-Treat Population)



RVL-1201 was generally well tolerated by patients in this clinical trial when administered once daily over a 6-week period. There were no serious adverse events identified from treatment with RVL-1201 in this Phase III clinical trial.

The second Phase III trial was a six-week randomized, multicenter, double-masked, placebo-controlled study to evaluate the safety and efficacy of once-daily treatment of RVL-1201 compared with placebo for the treatment of acquired blepharoptosis. The primary endpoint was a measurement of the mean change from baseline of the number of points seen out of a total of 35 in the top four rows of the LPFT as measured in two time points: hour 6 on day 1 and hour two on day 14. The secondary endpoint was a measurement of the distance between the center of the pupillary light reflex and the upper eyelid margin, or MRD-1. Topline results from the second Phase III trial showed that the trial met both the primary and secondary endpoints. The mean change from baseline on the LPFT on hour 6, day 1 was 6.3 for RVL-1201 versus 2.1 for vehicle ($p < 0.0001$) and on hour two, day 14 was 7.7 for RVL-1201 versus 2.4 for vehicle ($p < 0.0001$). The results also showed a statistically significant improvement in MRD-1 at 5 and 15 minutes, and 2 and 6 hours post dose on days 1 and 14. We also completed a 12-week randomized, multicenter, double-masked, placebo-controlled safety study to evaluate the safety of RVL-1201 compared with vehicle for the treatment of acquired blepharoptosis. Results of the safety study showed RVL-1201 was well tolerated when administered once daily over a 12-week period

where the majority of adverse events were mild and did not require treatment. On July 8, 2020, the FDA approved Upneeq for the treatment of acquired blepharoptosis, or droopy or low-lying eyelids, in adults.

Arbaclofen ER for the Alleviation of Spasticity in Multiple Sclerosis Patients

We are also developing arbaclofen ER tablets. Baclofen is the only FDA-approved product that targets the GABA b receptor to treat spasticity. Baclofen is a racemic mixture comprised of an R and an S-isomer. The R-isomer of baclofen, or arbaclofen, has been shown in vivo to be up to 100 times more effective at targeting the GABA b receptor than the S-isomer. We developed our product candidate arbaclofen ER using our proprietary Osmodex drug delivery system for the treatment of spasticity in multiple sclerosis patients. Arbaclofen ER has received orphan drug designation by the FDA in this indication, and we have patent coverage for arbaclofen ER extending to 2036.

In June 2020, we amended our NDA, which had been previously submitted in 2015, for arbaclofen ER tablets for the alleviation of spasticity in multiple sclerosis to the FDA. On July 17, 2020, we received notice from the FDA that it considered the amendment a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020. On December 28, 2020, we received a CRL indicating the FDA could not approve the NDA in its then current form. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen ER 40 mg to placebo, one of the co-primary endpoints. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL's recommendations and obtain advice on a path forward for the NDA. The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a SPA to the FDA proposing an additional clinical study for arbaclofen ER. FDA responded in a letter dated October 15, 2021, indicating that they are unable to issue an agreement on the submitted protocol. On October 10, 2022, we resubmitted a SPA and on November 24, 2022, we received a letter from the FDA indicating that they were unable to issue an agreement on the SPA. On February 8, 2023, we resubmitted a SPA with a revised study protocol and statistical analysis. If we are required to conduct any additional clinical trials for arbaclofen ER, our development costs will increase, our regulatory approval process could be delayed or denied and we may not be able to find a third party to license or acquire arbaclofen ER in the timeframe currently contemplated, if at all.

Intellectual Property

We have built and continue to develop our intellectual property portfolio for Upneeq and arbaclofen ER. We rely on our substantial know-how, technological innovation, patents, trademarks, trade secrets, other intellectual property and in-licensing opportunities to maintain and develop our competitive position. We pursue patent protection in the United States and selected international markets. As of December 31, 2022, we owned or had license rights to 25 U.S. patents, 50 patents outside the United States and 28 pending patent applications, the last of which expires in 2039.

Upneeq benefits from substantial intellectual property. Upon approval, Upneeq received three years of data exclusivity from the FDA that expires on July 8, 2023. Additionally, the patent portfolio protecting Upneeq consists of both issued method of use patents expiring in 2031 and formulation patents expiring in 2039. Internationally, Upneeq has intellectual property protection granted or pending in most major markets in North and South America, Asia and Europe.

Competition

We believe Upneeq enjoys certain market benefits including the distribution channels through which patients access the product. Unlike most other pharmaceutical products, Upneeq is not distributed and dispensed by national pharmacy chains but is sold and dispensed directly to patients through our wholly owned pharmacy. Accordingly, in the event a generic equivalent to Upneeq were to be approved by the FDA, there is no retail pharmacy where the drug can be automatically substituted for a generic equivalent. Nevertheless, the pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We may face competition from various eye care, medical aesthetics and generic drug companies that engage in drug development activities. Many of our competitors have greater financial flexibility to deploy capital in certain areas as well as more commercial and other resources, marketing and manufacturing organizations, and larger research and development staff. As a result, these companies may be able to

pursue strategies or approvals that we are not able to finance or otherwise pursue and may receive FDA, European Medicines Agency or other applicable regulatory approvals more efficiently or rapidly than us. Also, our competitors may have more experience in marketing and selling their products post approval and gaining market acceptance more quickly. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Upneeq could become less competitive if our competitors are able to license or acquire technology that is more effective or less costly and thereby offer an improved or a cheaper alternative to Upneeq. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize Upneeq in our target commercial markets.

Government Regulation and Approval Process

Government authorities in the United States at the federal, state and local level, including the FDA, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of drug products such as Upneeq and arbaclofen ER. Failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of operations.

Additionally, future healthcare legislation or other legislative proposals at the federal and state levels could bring about major changes in the affected health care systems. We cannot predict the outcome of such initiatives, but such initiatives, if passed, could result in significant costs to us in terms of costs of compliance and penalties associated with failure to comply.

Pharmaceutical Regulation in the United States

In the United States, the FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing 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. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, Warning Letters, product recalls, 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.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- approval by an institutional review board, or IRB, before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA;

- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's Current Good Manufacturing Practice, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and

- FDA review and approval of the NDA.

Once a product candidate is identified for development, the first step in proceeding to clinical studies is preclinical testing. Preclinical tests include laboratory study evaluations of the product to determine its chemistry, formulation and stability, as well as animal studies to evaluate the potential for efficacy and toxicity. Toxicology studies are also performed to assess the potential safety of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of these studies are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials, including concerns that human research subjects are or would be exposed to an unreasonable and significant risk of illness or injury, and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent IRB must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences and it must monitor the study until completed.

Clinical trials involve the administration of a drug product candidate to human subjects under the supervision of qualified medical investigators. Clinical trials are conducted according to study protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety, and these study protocols must be submitted to the FDA as part of the IND. Clinical trials must also comply with extensive GCP requirements, including requirements related to informed consent.

The FDA, the IRB or the sponsor may suspend or terminate a clinical trial or impose other conditions at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with GCP or the IRB's requirements. Human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase I: In Phase I, through the initial introduction of the drug into healthy human volunteers or patients, the drug is tested to assess absorption, distribution, metabolism, elimination, pharmacokinetics and safety.

- Phase II: Phase II usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks.

- Phase III: Phase III clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the drug. A single Phase III clinical trial with other confirmatory evidence may be sufficient in rare instances, for example, where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer or sponsor of an approved NDA is also subject to annual program fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, as amended, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that are intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapies. The FDA endeavors to review most applications subject to Standard Review within ten months whereas the FDA's goal is to review most Priority Review applications within six months.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the NDA unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective for the labeled indication.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter, which authorizes commercial marketing of the drug with specific prescribing information for specific indications, or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or certain problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on www.ClinicalTrials.gov. Information related to the product, subject population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss certain results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs such as Upneeq may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If a company, including any agent of the company or anyone speaking on behalf of the company, is found to have improperly promoted off-label uses, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Adverse event reporting and submission of periodic reports and promotional material is also required following FDA approval of an NDA. Additionally, the FDA may require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to comply with cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments and list their marketed products with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls based on the discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or the failure to comply with regulatory standards. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, Warning Letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, clinical trial holds, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The Hatch-Waxman Amendments

505(b)(2) NDAs

We submitted our NDA for arbaclofen ER under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant's drug and the reference drug. Additionally, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in the 505(b)(2) NDA. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval of a Section 505(b)(2) NDA.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Upneeq, for example, as of December 31, 2022, had ten patents listed in the FDA Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (i) that there is no patent listed with the FDA as covering the relevant branded product, (ii) that any patent listed as covering the branded product has expired, (iii) that the patent listed as covering the branded product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent or (iv) that any patent listed as covering the branded drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the Paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

For example, for listed drugs that were considered new chemical entities at the time of approval, an ANDA or 505(b)(2) application referencing that drug may not be filed with the FDA until the expiration of five years after approval of that drug, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if

one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Upneeq, for example, was afforded three years of exclusivity through July 8, 2023. In addition, drugs approved for diseases for which the patient population is sufficiently small, or orphan indications, are entitled to a seven-year data exclusivity period.

Orphan Drugs

Arbaclofen ER has received Orphan Drug Designation for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which means a disease or condition that affects fewer than 200,000 individuals in the United States, or affects more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from domestic sales of the product. Orphan drug designation must be requested before submitting an NDA, and both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act and FDA's implementing regulations at 21 C.F.R. Part 316. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

Orphan drug designation entitles the applicant to incentives such as grant funding towards clinical study costs, tax advantages, and waivers of FDA user fees. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is also entitled to seven years of orphan drug exclusivity. During the seven-year marketing exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process and a subsequent grant of orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Healthcare Reform

In the United States, federal and state governments continue to propose and pass legislation or take administrative action designed to reform the health care system, which include initiatives to reduce the cost of health care. Pharmaceutical pricing and reimbursement has been a focus of such efforts. Continued health care reform efforts are likely. The nature and scope of such efforts cannot be predicted. Additionally, although Upneeq is not currently covered by any private or government insurance, we cannot predict if Upneeq may be covered in the future, or the future effect such reforms may have on our business. No assurance can therefore be given that any such reforms will not have a material adverse effect. See "Risk Factors – Risks related to our industry."

Healthcare Regulations

In the United States, our business activities are subject to numerous other federal, state and local laws designed to, for example, prevent fraud and abuse; promote transparency in interactions with others in the healthcare industry; and protect the privacy of individual information. These laws are enforced by various federal and state enforcement authorities, including but not limited to, the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, the U.S. Department of Health and Human Services, or HHS, HHS' various divisions, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, and the Office of Inspector General, and state boards of pharmacy.

We may be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws, and false claims laws, for activities related to past and future sales of any products reimbursable by third party payors such as federal health care programs (including Medicare and Medicaid) or, in some cases, commercial health plans. Anti-kickback laws generally prohibit a pharmaceutical manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase, prescription or use of a particular drug. False

claims laws generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third-party payors that are false or fraudulent. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such laws.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require manufacturers to adopt certain compliance standard; require disclosure to the government and public of such interactions; require disclosure of marketing expenditures or pricing information; regulate drug pricing and/or require the registration of pharmaceutical sales representatives. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to challenge.

The FDA regulates the sale and marketing of prescription drug products and, among other things, prohibits pharmaceutical manufacturers from making false or misleading statements and from promoting products for unapproved uses.

We may be subject to data privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. Numerous U.S. federal and state laws govern the collection, use, disclosure and storage of personal information. Various foreign countries also have, or are developing, laws governing the collection, use, disclosure and storage of personal information. Globally, there has been an increasing focus on privacy and data protection issues that may affect our business. See “Risk Factors - Risks related to our industry.”

If our operations are found to be in violation of any of the health regulatory laws described above, or any other laws that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

State Price Reporting

Several states have implemented regulations around price transparency and are requiring pharmaceutical manufacturers to register and report a drug’s wholesale acquisition cost, or WAC, and any increase in a drug’s WAC price. We may or may not be subject to these regulations and cannot predict how many additional states will enact similar regulations or how these regulations will change in the future. If we are required to register and submit information and fail to do so, we may be subject to fines and other penalties for non-compliance.

Drug Pedigree Laws

State and federal governments have proposed or passed various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, companies are required to file with the Federal Trade Commission, or FTC, and DOJ certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC also enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Information about our Executive Officers

Brian Markison, 63, became a director and our Chief Executive Officer in 2016. Mr. Markison has been a healthcare industry advisor to Avista since September 2012 and has more than 30 years of operational, marketing, commercial development and sales experience with international pharmaceutical companies. From July 2011 to July 2012, he served as the President and Chief Executive Officer and member of the board of directors of Fougera Pharmaceuticals Inc., a specialty pharmaceutical company in dermatology that was sold to Sandoz Ltd., the generics division of Novartis AG. Before leading Fougera, Mr. Markison was Chairman and Chief Executive Officer of King Pharmaceuticals, Inc., which he joined as Chief Operating Officer in March 2004. He was promoted to President and Chief Executive Officer later that year and elected Chairman in 2007. Prior to joining King Pharmaceuticals, Inc., Mr. Markison held various senior leadership positions at Bristol-Myers Squibb Company, including President of Oncology, Virology and Oncology Therapeutics Network; President of Neuroscience, Infectious Disease and Dermatology; and Senior Vice President, Operational Excellence and Productivity. He serves as Chairman of the board of Lantheus Holdings, Inc. and is on the board of directors of Cosette Pharmaceuticals, Inc. He is also a Director of the College of New Jersey. Mr. Markison received a B.S. degree from Iona College.

James Schaub, 41, has served as our Executive Vice President and Chief Operating Officer since 2016. Prior to that he served as Chief Operating Officer of Trigen Laboratories beginning in December 2013. Mr. Schaub previously served as Vice President, M&A of Fougera Pharmaceuticals, Inc. from August 2011 to September 2012. Prior to that, Mr. Schaub spent five years with King Pharmaceuticals, Inc., where he held several commercial roles of increasing responsibility.

He joined our company in December 2013. Mr. Schaub holds a B.A. in Economics from Middlebury College and an M.B.A. from Rutgers Business School.

Christopher Klein, 59, became our General Counsel and Secretary in December 2013. Mr. Klein previously served as the General Counsel of Fougera Pharmaceuticals Inc. from August 2011 to September 2012. Prior to his time at Fougera Pharmaceuticals Inc., Mr. Klein spent six years with King Pharmaceuticals, Inc. where he held the position of Deputy General Counsel prior to King Pharmaceuticals, Inc.'s acquisition by Pfizer, Inc. Prior to that, Mr. Klein spent six years in senior legal roles with Bristol-Myers Squibb Company. Mr. Klein holds a B.A. in Biology from Adelphi University, an M.A. in Education from Columbia University and a J.D. from Fordham University.

Employees

As of December 31, 2022, we had a total of 125 full time employees (including two employees in Hungary). We have no collective bargaining agreements with our employees and none are represented by labor unions. We consider our current relations with our employees to be good.

Corporate Information

Our principal executive offices are located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807, and our registered office in Ireland is 3 Dublin Landings, North Wall Quay, Dublin 1, D01 C4E0, Ireland and our telephone number is (908) 809-1300. Our website address is www.rvlpharma.com.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, or the Exchange Act. We file periodic reports, current reports, proxy statements, and other information with the Securities and Exchange Commission, or SEC. The SEC maintains a website at http://www.sec.gov that contains all of our information that has been filed or furnished electronically with the SEC. We make available free of charge on our website a link to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable, after such material is electronically filed with, or furnished to, the SEC.

ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our Consolidated Financial Statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. We have presented the below risks as "Risks related to our business," "Risks related to the development and commercialization of products," "Risks related to our intellectual property rights," "Risks related to our industry," "Risks related to our indebtedness," "Risks related to our ordinary shares," "Risks related to being an Irish corporation listing ordinary shares," "Risks related to taxation" and "General risk factors." If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially and adversely affect our business, prospects, operating results or financial condition.

Risks related to our business

Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed or discontinued if we are unable to obtain the additional funding as or when needed.

The divestiture of the Legacy Business in 2021 resulted in the loss of substantially all of our revenue generating assets. Our current business plan is focused on the continued commercialization and growth of Upneeq, which has and will continue to diminish our cash flows in at least the near term. We will require additional capital to fund our operating needs, including the expanded commercialization and growth of Upneeq and other activities. Accordingly, we expect to incur significant expenditures and sustain operating losses in the future.

In addition, the documentation governing our primary indebtedness contains various restrictive covenants including minimum liquidity and minimum quarterly product sales requirements. See the risk factor titled "The terms of the Note Purchase Agreement restrict our current and future operations, particularly our ability to respond to changes or to take certain actions."

These conditions give rise to a substantial doubt as to our ability to operate as a going concern as our current sources of liquidity will not be sufficient to allow us to meet our obligations, including the minimum liquidity covenant, for at least 12 months following the date the Consolidated Financial Statements contained in this Annual Report on Form 10-K are issued without raising additional funding. If we are not successful in executing our strategic plans described below, we expect that our current cash on hand, together with the net proceeds of anticipated sales of Upneeq, may not be sufficient to meet the minimum liquidity covenant through the end of the third quarter of 2023.

Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets. We are exploring options to raise additional funding and may seek to raise additional capital through product collaborations or sales of our ordinary shares, including through equity sales agreements with broker/dealers or other public or private equity financings, convertible debt or through a sale of a portion or all rights to any of our assets. We cannot provide assurance that we will receive cash proceeds from any of these potential sources or to the extent cash proceeds are received, that such proceeds would be sufficient to support our current operating plan or allow us to continue as a going concern. Additional funds may not be available when we need them on terms that are acceptable to us or at all and the terms of any such financings may impose operating restrictions on us that limit or restrict our ability to operate our business, which could adversely affect our ability to continue and grow the commercialization of Upneeq and other activities on our intended timeline or at all.

To the extent that we raise additional capital through the sale of convertible debt securities or equity, including through our existing at-the-market equity facility, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our ordinary shareholders. In addition, under U.S. securities laws, a company with a public float of less than $75 million measured at certain time periods may not issue securities under Registration Statements on Form S-3 in excess of one-third of its public float in a 12-month period, which may limit the amount of funds we can raise using Registration Statements on Form S-3. For purposes of the prior sentence, "public float" means the aggregate market value of a company's shares held by non-affiliates.

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. In addition, debt financing would result in increased fixed payment obligations. For information about our current outstanding debt, see Note 12 in the accompanying notes to our Consolidated Financial Statements appearing elsewhere in this Annual Report on Form 10-K and the risk factor titled "The terms of the Note Purchase Agreement restrict our current and future operations, particularly our ability to respond to changes or to take certain actions." 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 or product candidates or grant licenses on terms that may not be favorable to us. 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 product

development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Due to our dependence on Upneeq, our business would be materially adversely affected if this product does not perform as well as expected.

On June 24, 2021, we and certain of our wholly-owned subsidiaries entered into a purchase and sale agreement with Acella Holdings, LLC, or Acella, and Alora Pharmaceuticals, LLC, an affiliate of Acella, pursuant to which we agreed to divest our Legacy Business to Acella through the sale of the equity interests of certain of our indirect subsidiaries and other assets. Following the closing of this transaction on August 27, 2021, and the divestiture of our Legacy Business, we retained the RVL Pharmaceuticals business focused on eye care and medical aesthetics, led by Upneeq. We do not currently commercialize any product other than Upneeq.

Any material adverse developments, including an inability of our sales force to effectively market and sell Upneeq, new competition from generic or other brand products, supply shortages with respect to the manufacture, sale, distribution or use of Upneeq, the unwillingness of patients or healthcare providers to pay the price at which we offer Upneeq, or our failure to successfully introduce Upneeq into the medical aesthetics market, could have a material adverse effect on our revenues and gross profit.

Upneeq may fail to achieve market acceptance by clinicians and patients, or others in the medical community, and the market opportunity for Upneeq may be smaller than we estimate.

Upneeq may fail to gain market acceptance by clinicians, patients, and others in the medical community. While there are no drugs other than Upneeq currently approved in the United States for the treatment of acquired blepharoptosis, or droopy eye lids, in adults, some clinicians may treat blepharoptosis with off-label use of other products or with surgery, or they may not treat the condition at all. Additionally, as the first drug approved for blepharoptosis, we spend significant resources on educating clinicians about the disorder and the impact on patients' lives. Our education efforts may not be sufficient to convince clinicians to prescribe Upneeq for their patients suffering from blepharoptosis.

If Upneeq does not achieve adequate levels of acceptance by clinicians or patients, we will not generate significant product revenues. The degree of market acceptance of Upneeq will depend on a number of factors, including:

- the efficacy and potential advantages of Upneeq compared to alternative treatments, including surgery;
- the timing of market introduction of competitive products;
- the price at which we offer Upneeq;
- the clinical indication for which Upneeq is approved;
- the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies; and
- the effectiveness of our marketing and distribution support, and our available resources to support adequate marketing efforts.

Our assessment of the potential market opportunity for Upneeq is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of acquired blepharoptosis, or droopy eye lid, is difficult to estimate precisely. The results from our physician and patient

surveys may be less reflective of the acquired blepharoptosis population as a whole than a survey conducted with a larger sample size. Our estimates of the potential market opportunities for our product include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size or otherwise fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for Upneeq may be smaller than we expect, and as a result our product revenue may be less than expected. The uncertainty with respect to the long-term effects of the COVID-19 pandemic may also adversely impact the accuracy of such estimates and our potential market opportunity for Upneeq. Upneeq is available directly from a patient's healthcare provider or through our pharmacy, RVL Pharmacy, and is a cash-only product not covered by any private or government insurance. We control the price for Upneeq at our pharmacy which is consistent for all patients. Although we believe this cash-only model with consistent pricing is a benefit to patients, the price or distribution model may not be accepted by clinicians or patients and may negatively impact filled prescriptions and sales of Upneeq.

If we are found to have improperly promoted Upneeq, we may be subject to restrictions on the sale or marketing of our product and significant fines, penalties and sanctions, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, promotion for a product must be balanced, truthful, not misleading and consistent with the labeling approved by the FDA. Upneeq has been approved by the FDA for the treatment of acquired blepharoptosis, or droopy eye lid, in adults. Acquired blepharoptosis may be caused by a variety of factors and may negatively impact the vision and appearance of a patient. Although we cannot legally promote Upneeq for uses inconsistent with its FDA-approved labeling, we cannot control how prescribers choose to use the product. We have policies, procedures, and controls in place to address off-label promotion, but there remains a risk that the FDA or other regulatory agencies could view our promotional practices in eye care and/or medical aesthetics as improper. If we are found to have promoted such unapproved uses prior to the FDA's approval for an additional indication, we may, among other consequences, receive Untitled or Warning Letters and become subject to significant liability, which would materially harm our business. The U.S. federal government has levied significant civil and criminal fines against companies and individuals for alleged improper promotion and has entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. Violation of the Federal Food, Drug and Cosmetic Act, or the FDCA, and other statutes, including the False Claims Act, and other legislation relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws. 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 reputation could be damaged.

If our product or our current or future product candidates do not produce the intended effects, our business may suffer.

If our product or our current and future product candidates do not produce the effects intended our business may suffer. For example, in July 2020, we received regulatory approval from the FDA for Upneeq, the first approved non-surgical treatment for acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 to a limited number of eye care professionals and expanded our commercialization efforts in 2021 among ophthalmology, optometry and oculoplastic specialties. In January 2022, we began the launch of Upneeq into medical aesthetics practices in select markets in the United States. Despite these efforts, Upneeq may not produce sufficient treatment results such that patients, eye care specialists and other healthcare professionals deem it an effective treatment for acquired blepharoptosis. Upneeq and any products we may develop in the future may not have the effect intended if they are not taken in accordance with applicable instructions. Even when used as directed, there can be no assurance that Upneeq or any products we may develop in the future will not experience an actual or perceived lack of efficacy or increase in side effects.

If we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell Upneeq or any other products we may develop.

We face a number of additional risks in developing or maintaining internal sales and marketing capabilities, including:

- not being able to attract talented and qualified personnel to build an effective marketing or sales force capability, or not being able to attract personnel with sufficient experience in selling and marketing to the physicians in eye care and medical aesthetics;

- the cost of establishing or maintaining a marketing and sales force capability may not be justified by the total revenues generated from our product; and

- our direct sales and marketing efforts for Upneeq may not be successful.

If we are unable to establish or maintain adequate sales and marketing capabilities or are unable to do so in a timely manner, our ability to generate revenues and profits from our product will be limited and this could have a material adverse effect on our business, financial position and results of operations.

As we expand our marketing efforts for Upneeq, we are investing in expanding our sales and marketing organization into new areas such as medical aesthetics. In 2020, we established our sales and marketing infrastructure for the commercial launch of Upneeq to eye care professionals and the distribution of Upneeq directly to patients through RVL Pharmacy. As a company we have limited experience in the sales, marketing and distribution of ophthalmic products. In 2022, we continued expanding our sales force and increasing the number of managers and sales people with medical aesthetics experience.

There are risks involved with establishing, maintaining and expanding our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any future product launch. Further, we may underestimate the size of the sales force required for successful commercialization of Upneeq and may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial success of Upneeq is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize Upneeq on our own include:

- our inability to recruit, train and retain adequate numbers of effective eye care and medical aesthetics sales and marketing personnel;

- the inability of sales personnel to obtain access to clinicians, including as a result of limitation on office visits as a result of COVID-19 or other health concerns, or persuade adequate numbers of clinicians to prescribe Upneeq; and

- unforeseen costs and expenses associated with maintaining and expanding an independent sales, marketing and pharmacy organization.

Our decision to establish and dispense Upneeq exclusively through a wholly-owned mail order pharmacy represents a new distribution model for us and has expanded the scope of applicable government regulation and may provoke government scrutiny.

We have made the decision to dispense Upneeq solely through a mail order pharmacy operated by RVL Pharmacy, LLC. RVL Pharmacy LLC was established as a wholly-owned subsidiary of RVL Pharmaceuticals, Inc. (formerly RevitaLid, Inc. and the New Drug Application, or NDA, holder of Upneeq), which is our wholly-owned subsidiary commercializing Upneeq. The pharmacy dispenses only Upneeq and operates only on a cash basis (i.e., it does not submit any claims to

third party payors for prescriptions filled). We cannot be certain that this business model will be successful. As a pharmacy, RVL Pharmacy is subject to certain regulations that have not historically applied to our operations, including state pharmacy licensure requirements and certain privacy and data security laws applicable only to health care providers. In the United States, our companies may be subject to federal and state privacy laws generally applicable to business entities. There are, however, numerous other federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information that could apply to our pharmacy operations. For example, pharmacies licensed under California law are subject to California's Confidentiality of Medical Information Act, CMIA, which places restrictions on the use and disclosure of medical information by providers of health care, including pharmacies, and can impose a significant compliance obligation on such providers. Violations of the CMIA can result in criminal, civil and administrative sanctions, and the CMIA also provides individuals a private right of action with respect to disclosures of their health information that violate CMIA.

Despite our status as a pharmacy, we are not currently subject to the federal health information privacy law known as the Health Insurance Portability and Accountability Act, or HIPAA. If our business model changes and RVL Pharmaceuticals or RVL Pharmacy engages in certain activities that would make RVL a business associate or covered entity under HIPAA, such as processing financial transactions for a healthcare professional who is a covered entity or processing electronic standard transactions involving individually identifiable information, such as submission of claims to third party payors, RVL Pharmaceuticals or RVL Pharmacy could become subject to HIPAA as could other companies that had access to individually identifiable information about pharmacy patients in connection with activities supporting the pharmacy. HIPAA covered entities and business associates are subject to comprehensive data privacy, security and breach notification obligations and non-compliance may result in civil money penalties as well as criminal fines and imprisonment.

Compliance with data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, and restrict our ability to collect, use and disclose data. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Also, certain pharmacies owned by or closely affiliated with pharmaceutical manufacturers have been subject to government scrutiny in the past. Although we do not expect the pharmacy to submit claims to third party payors and anticipate that patients will be responsible for the costs associated with the product, there can be no assurance that RVL Pharmacy and its relationship to RVL Pharmaceuticals, Inc. will not be subject to government scrutiny. Such scrutiny could result in increased regulatory costs to us or cause us to be the subject of a regulatory investigation or sanctions, which could adversely affect our business, results of operations or financial condition, which would materially harm our business.

Our Direct Dispense and Virtual Inventory programs pursuant to which practitioners sell Upneeq directly to patients may increase scrutiny by state regulators.

Upneeq is currently marketed to eye care professionals who submit prescriptions for Upneeq directly to RVL Pharmacy for processing and dispensing. In September 2021, we introduced the Direct Dispense model to eye care practices. Pursuant to this model, eye care practices can purchase case quantities of Upneeq directly from RVL and then charge and dispense Upneeq directly from the practitioner's office to patients who are diagnosed with acquired blepharoptosis and prescribed Upneeq by the practitioner. In January 2022, we introduced the Virtual Inventory program for practitioners who are unable to provide Upneeq directly from their offices. This program allows practitioners to purchase case quantities of Upneeq from RVL and charge their patients for the product, but the prescriptions for Upneeq are processed by and dispensed from RVL Pharmacy without the practitioner holding physical inventory even though title passes to the practitioner before passing to the patient. Under either the Direct Dispense or Virtual Model, state attorneys

general or state regulatory agencies such as boards of ophthalmology, optometry or pharmacy may challenge the ability of practitioners to charge for and/or dispense Upneeq directly from a practitioner's office or the financial arrangements underlying the models. We are developing a connected account program for healthcare professionals that we intend to offer in the second half of 2023, pursuant to which RVL would provide financial transaction processing services for healthcare professionals who prescribe and sell Upneeq directly to patients. The connected account program will offer practitioners a way to prescribe and sell Upneeq to a patient, submit the prescription to RVL Pharmacy for processing and dispensing, and have RVL handle the financial processing to charge the patient's credit card. At the time of sale, the practitioner will send to RVL its cost of goods and send to the physician's connected account the difference between his or her cost of Upneeq and the charge to the patient. If practitioners are unwilling to purchase Upneeq as part of the Direct Dispense or Virtual Inventory programs, or are unwilling to participate in the connected account program, or if one or more states prohibit implementation of the models or take enforcement action against us or the practitioners, we may not be successful with the Direct Dispense, Virtual Inventory and/or connected account programs, which would adversely affect our business, results of operations or financial condition.

We may incur operating losses in the future.

Our net loss was $51.7 million for the year ended December 31, 2022. Our operating results may fluctuate significantly from quarter to quarter and year to year.

We devote significant amounts of financial resources to the marketing, sale and commercialization of Upneeq, and support of our research and development of our clinical and preclinical programs. We expect to incur significant expenses in the future. These expenses include those related to ongoing activities, as we:

- add personnel to support our marketing, commercialization and sales of Upneeq and continue clinical and preclinical product development efforts;
- launch new products into the marketplace;
- potentially conduct clinical trials and seek regulatory approval for additional indications for Upneeq;
- continue development of arbaclofen ER;
- continue our efforts for identifying new product opportunities, including business development and acquisitions; and
- operate as a public company.

To become profitable, we must succeed in developing or acquiring products, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. Even if we achieve profitability for any period in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other products or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Our business may be adversely affected by the ongoing coronavirus outbreak.

The economic impact of the spread of COVID-19, which has caused a broad impact globally, has and may in the future adversely affect us. In particular, we launched our commercial activities for Upneeq and began engaging with eye care providers to promote Upneeq in September 2020, and since that time have expanded our field sales force into medical aesthetics. In some instances, our sales force has encountered challenges engaging with healthcare providers during this on-going pandemic.

Additionally, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the pandemic has resulted in and could continue to result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity and our ability to execute on our strategic plans.

In addition, the disruptions caused by the COVID-19 pandemic could divert healthcare resources away from, or materially delay the FDA approval with respect to, our clinical trials and marketing applications for our current and future product candidates. It is unknown how long these disruptions could continue.

The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted. We cannot reasonably estimate the length or severity of the COVID-19 pandemic or the related mitigation efforts, including the length of time it may take for normal economic and operating conditions to resume or the extent to which the disruption may materially impact our business, financial position, results of operations or cash flows.

If we determine that our goodwill or indefinite-lived intangible assets have become impaired, we may record significant impairment charges, which would adversely affect our results of operations.

Goodwill and indefinite-lived intangible assets represent a significant portion of our total assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. Our indefinite-lived intangible assets relate to in-process research and development assets representing the value assigned to acquired research & development projects that principally represent rights to develop and sell a product that the Company has acquired which have not yet been completed or approved. In the future, goodwill and indefinite-lived intangible assets may increase as a result of future acquisitions. We review our goodwill and indefinite lived intangible assets at least annually for impairment. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business. Any impairment of goodwill or indefinite-lived intangible assets, although a non-cash charge against earnings, could have a material adverse effect on our business, consolidated financial condition and results of operations. For example, we recognized impairment charges of $13.3 million and $7.9 million for the years ended December 31, 2022 and 2021, respectively, related to write downs to fair value of arbaclofen ER due to delays in anticipated commercialization of the product candidate, if approved. The extent to which we may record additional impairment charges in the future, in particular with respect to the commercialization of Upneeq or the development and regulatory approval of arbaclofen ER, remains uncertain. Any significant further impairment charges may adversely affect our results of operations.

We may not enter into any additional license agreements, and any license agreement that we may enter into in the future may not be successful, which could adversely affect our ability to continue to grow or sustain our product or current and future product candidates.

We may seek license agreements with pharmaceutical and healthcare companies in order to grow or sustain our product or current or future product candidates. To the extent that we decide to enter into license agreements, we will face significant competition in seeking appropriate licensees. Moreover, license agreements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement license agreements or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we enter into license agreements with third parties for development and commercialization of a product or current or future product candidate, we can expect to relinquish some or all of the control over the future success of such product or current or future product candidate to the third party. The success of any license agreements we may enter into will depend heavily on the efforts and activities of our future licensees. Licensees generally have significant discretion in determining the efforts and resources that they will apply to a product or product candidate.

Disagreements between parties to a license arrangement can lead to delays in developing or commercializing the applicable product or product candidate and can be difficult to resolve in a mutually beneficial manner.

We may face competition, including from other drug manufacturers and compounding pharmacies, which could significantly limit our growth and materially adversely affect our financial results.

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical industry include:

- introduction of other drug manufacturers' products in direct competition with Upneeq;
- introduction of authorized generic products in direct competition with Upneeq, particularly during exclusivity periods;
- the willingness of our customers to switch among products;
- pricing pressures by competitors and customers;
- a company's reputation as a manufacturer and distributor of quality products;
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries); and
- product appearance and labeling.

Currently our commercial product, Upneeq, is the only FDA approved pharmaceutical agent to treat blepharoptosis in adults. That may change in the future, and we may face competition from other pharmaceutical and biopharmaceutical companies developing similar products and technologies. Our competitors may have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products or processes competitive with, or superior to, our own. Furthermore, we may not be able to differentiate our product from those of our competitors, to successfully develop or introduce new products, on a timely basis or at all, that are less costly than those of our competitors, or to offer payment and other commercial terms to customers as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technological advances and consolidations continue. New developments by other manufacturers and distributors could render our product uncompetitive or obsolete.

We may also face price competition generally as other manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower than our production costs (sometimes significantly), especially lower-cost non-U.S. jurisdictions. Any of these factors, in turn, could result in reductions in our sales prices and gross profit. There can be no assurance that we will be able to compete successfully in the industry or that we will be able to develop and implement any new or additional strategies successfully.

Our product Upneeq is a reference listed drug. After the regulatory exclusivity period expires for Upneeq in July 2023, manufacturers may gain approval of generic versions of Upneeq through the submission of Abbreviated New Drug Applications, or ANDAs. In order to obtain approval of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use and labeling as the reference listed drug, and that the generic version is bioequivalent to the reference listed drug, meaning that it is chemically identical and is absorbed in the body at the same rate and to the same extent. Ordinarily a generic drug developer will obtain samples of a reference listed drug on the open market. However, in cases where a reference listed drug is not available because of, for example, limited distribution, a generic company may request samples of the reference listed drug from the NDA holder under the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act established a process that requires brand-name companies to provide generic companies with needed samples if the product is not generally available. The CREATES Act imposes substantial penalties if a branded company does not follow timing or other requirements set out in the law or otherwise acts in bad

faith with respect to the sample request. As of December 31, 2022, we have received two requests for samples of Upneeq from generic companies pursuant to the CREATES Act. We have provided samples in response to each request.

An ANDA applicant need not conduct its own clinical trials to demonstrate the safety or effectiveness of its generic product, but instead may rely on the prior findings of safety and effectiveness for the reference listed drug. As a result, generic products may be significantly less costly to bring to market than reference listed drugs, and companies that produce generic products are generally able to offer them at lower prices. Moreover, many states allow or require substitution of a therapeutically equivalent generic drug at the pharmacy level even if a reference listed drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the market share of a reference listed drug may be lost to the generic product. Competition from generic versions of Upneeq could negatively impact our future total revenues, profitability and cash flows.

A business interruption at our pharmacy in Sayreville, New Jersey or at facilities operated by third parties that we rely on, could have a material adverse effect on our business, financial condition and results of operations.

Upneeq prescriptions are distributed to patients through our pharmacy, RVL Pharmacy, in Sayreville, New Jersey and through a contract pharmacy, KnippeRx, in Charlestown, Indiana. Under our Direct Dispense program Upneeq is shipped directly to healthcare practices from Eversana Life Science Services, in Memphis Tennessee. These facilities, or the facilities of third parties that we rely on for the development, supply, marketing or distribution of raw materials or finished products, including Nephron Pharmaceuticals' facility in South Carolina, which we rely upon for the manufacture of Upneeq, could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. For example, the ongoing COVID-19 outbreak has resulted in increased travel restrictions and may result in extended shutdown of our facilities or certain of our suppliers' businesses, which may negatively affect our suppliers' operations. These or any further political or governmental developments or health concerns in countries in which we or our suppliers operate could result in social, economic and labor instability, which could have a material adverse effect on the continuity of our business, including with respect to the availability of raw materials for production. A significant disruption at any of these facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial condition and results of operations.

We depend to a large extent on third-party suppliers and distributors for the raw materials for Upneeq, particularly the chemical compounds comprising the API used in Upneeq, as well as suppliers and distributors for certain finished goods. A prolonged interruption in the supply of such products could have a material adverse effect on our business, financial position and results of operations.

We purchase raw materials, including API, and finished goods from both U.S. and non-U.S. companies. If we experience supply interruptions or delays, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. We may source finished goods, raw materials or API from a single source, which increases the risk to our business if supply from that source is interrupted. For example, Nephron Pharmaceuticals Corporation is our only supplier of Upneeq. If Nephron is unable to manufacture and deliver Upneeq in a timely manner, or is unable to manufacture Upneeq at a scale sufficient to meet demand or in compliance with FDA requirements, it could have a material adverse effect on our business, financial position and results of operations.

Further, third parties with whom we have agreements may allege that we have failed to perform our obligations under such agreements and we may become involved in lawsuits or other proceedings related to such agreements. If any dispute with a third-party supplier or distributor were determined adversely to us, it could have a material adverse effect on our business, financial position and results of operations.

In addition, changes in our suppliers, including suppliers of finished goods, raw materials or API, could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption could have a material adverse effect on our business, research and development programs,

financial condition, prospects and results of operations. Because the federal drug approval application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier may be required. A delay in the manufacture and marketing of the drug involved while a new supplier becomes approved by the FDA and its manufacturing process is determined to meet FDA standards could have a material adverse effect on our results of operations and financial condition. Generally, we attempt to mitigate the potential effects of any such situation by providing for, where economically and otherwise feasible, two or more suppliers of raw materials for the drugs that we manufacture. In addition, we may attempt to enter into a contract with a raw material supplier in an effort to ensure adequate supply for our product.

Our future success depends on our ability to attract and retain key employees and consultants.

Our future success depends, to a substantial degree, upon the continued service of the key members of our management team. The loss of the services of key members of our management team, including Brian Markison and James Schaub, or their inability to perform services on our behalf could have a material adverse effect on our business, financial condition, prospects and results of operations. Our success also depends, to a large extent, upon the contributions of our sales, marketing, scientific and quality assurance staff. We compete for qualified personnel against other brand and generic pharmaceutical manufacturers that may offer more favorable employment opportunities. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we could experience constraints that would adversely affect our ability to sell and market Upneeq and any other products we may develop effectively and to support our research and development programs. In particular, sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales, marketing and quality assurance representatives. Although we believe that we have been successful in attracting and retaining skilled personnel in all areas of our business, we cannot provide assurance that we can continue to attract, train and retain such personnel. Any failure in this regard could limit our ability to generate sales and develop or acquire new products.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. We experienced a ransomware attack in the past and there is no guarantee that we will not experience future attacks or breaches.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. Our systems are subject to frequent attacks. For example, we were recently subject to an attack involving the Conti ransomware strain. We were able to restore our systems, and although forensic investigators determined that no RVL data was impacted during the incident, there is no guarantee that future attempts will not be successful. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. Service interruptions could also result from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

Risks related to the development and commercialization of products

If we are unable to successfully develop or commercialize new products, or to do so on a timely or cost-effective basis, or to extend life cycles of our existing product, our operating results will suffer.

Developing and commercializing a new product is time consuming and costly and is subject to numerous factors that may delay or prevent development and commercialization. Our future results of operations will depend upon our ability to successfully gain FDA approval of and commercialize new, including in-licensed, products in a timely and cost-effective manner. There are numerous difficulties in developing and commercializing new products, including:

- the ability to develop products in a timely and cost-effective manner and in compliance with regulatory requirements;
- the success of the pre-clinical and clinical testing processes to assure that new products are safe and effective;
- the risk that any of our current and future product candidates, if and when fully developed and tested, will not perform as expected;
- the ability to acquire or in-license new products that can be successfully commercialized by our existing marketing and sales team;
- delays or unanticipated costs, including delays associated with the completion of clinical trials for our branded products;
- delays associated with FDA registration, listing and approval processes and the ability to obtain in a timely manner, and maintain, required regulatory approvals;
- legal challenges to our branded product or branded product intellectual property;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;
- our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of products in compliance with regulatory requirements; and
- acceptance of our current and future products by physicians, patients, payors and the healthcare community.

As a result of these and other difficulties, products currently in development or that we may seek to develop or acquire may not receive necessary regulatory approvals on a timely basis or at all and we may not succeed in effectively managing our development costs. Further, if we are required by the FDA or any equivalent foreign regulatory authority to complete clinical trials in addition to those we currently expect to conduct, or to repeat a clinical trial that has already been completed, or if there are any delays in completing preclinical studies, filing an Investigational New Drug Application, or IND, or completing clinical trials, our expenses could increase.

NDAs are subject to uncertainties, high costs and lengthy time frames associated with research and development of such products and the inherent unproven market acceptance of such products. For example, in December 2020 we received a complete response letter, or CRL, from the FDA in connection with our NDA for arbaclofen ER for the treatment of multiple sclerosis patients with spasticity. A CRL indicates that FDA will not approve an NDA or ANDA in its present form due to certain deficiencies. In the CRL, FDA recommended that we conduct a new study in order to provide substantial evidence of efficacy of arbaclofen ER. On March 4, 2021, we participated in a meeting with the FDA during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a Special Protocol Assessment, or SPA, to the FDA proposing an additional clinical study for arbaclofen ER. The FDA responded in a letter dated October 15, 2021, indicating that they are unable to issue an agreement on the submitted protocol. On October 10, 2022, we

resubmitted a SPA and on November 24, 2022, we received a letter from the FDA indicating that they were unable to issue an agreement on the SPA. On February 8, 2023, we resubmitted a SPA with a revised study protocol and statistical analysis. The FDA's review of arbaclofen ER, as well as any required subsequent clinical testing, has delayed and may prevent the commercial launch of, or ability to divest or partner, arbaclofen ER and increase our operating expenses, including the expenses associated with any additional clinical trials for arbaclofen ER, which could have a material adverse effect on our business, financial position and results of operations. If we are unable to develop and commercialize branded products successfully or are delayed in our attempts to do so, we may have to rely primarily on revenue from Upneeq to support research and development efforts.

If any of our current and future product candidates, when acquired or developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

We may expend a significant amount of resources on research and development, including milestones on in-licensed products, which may not lead to successful product introductions.

We expend resources on research and development primarily to enable us to manufacture and market FDA-approved products in accordance with FDA regulations. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various research and development events and regulatory approvals. As we continue to develop new products, we may incur increased research, development and licensing expenses. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of new FDA-approved products. Also, after we or our development partners submit an NDA, the FDA may request that we conduct additional clinical trials for an NDA, as the FDA did in December 2020 in its CRL in connection with our NDA for arbaclofen ER. In the CRL FDA indicated we would need to conduct a new study in order to provide substantial evidence of efficacy of arbaclofen ER given that the primary endpoint for Study OS440-3004, change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen ER 40 mg to placebo, was not met and the co-primary endpoint, results from the clinical global impression of change on Day 84, did not support a treatment benefit. Any additional clinical studies required for arbaclofen ER as a result of our discussions with the FDA regarding the CRL may result in substantial additional research and development costs.

We may be unable to reasonably determine the total research and development costs required to develop a particular product. As a result, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercializing the product. To the extent that we expend significant resources on research and development efforts and are not ultimately able to introduce successful new products as a result of those efforts or cost-effectively commercialize new products, our business, financial position and results of operations may be materially adversely affected.

If the FDA does not conclude that arbaclofen ER satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for arbaclofen ER will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

FDA approval of arbaclofen ER could potentially be available through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for arbaclofen ER or any future product

candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our current and future product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that arbaclofen ER or any future product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our current or future product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

The testing required for the regulatory approval and maintenance of our product and our current and future product candidates is conducted primarily by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications seeking regulatory approval of our products and our current and future product candidates, including both internally developed and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations, or CROs, or independent research facilities). Our ability to obtain and maintain regulatory approval of our product and our current and future product candidates is dependent, in part, upon the quality of the work performed by these third parties, the quality of the third parties' facilities and the accuracy of the information provided by third parties. Our control over any of these factors may be limited. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of all of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding good clinical practices, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our current and future product candidates. Regulatory authorities enforce GCP through periodic inspections of clinical trial sponsors, principal investigators and trial sites.

We have in the past been subject to audits by the FDA that have identified irregularities and deviations from GCP. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all.

We also rely on contract laboratories and other third parties, such as CROs, to conduct or otherwise support our preclinical studies properly and on time, which are subject to good laboratory practices, or GLP, requirements. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies comply with applicable GCP and GLP regulations. In addition, our clinical trials must be conducted with products produced under the FDA's current good manufacturing practices, or cGMP, regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our current and future product candidates may be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP and GLP requirements.

If testing of our current or future product candidates is not performed properly, or if the FDA or any equivalent foreign regulatory authority finds that the clinical trials are deficient, we may be required to repeat the clinical trials or to conduct additional clinical trials, which would result in additional expenses and may adversely affect our ability to obtain or maintain regulatory approvals. As a result, our ability to launch or continue selling products could be denied, restricted or delayed.

Although we have received Orphan Drug Designation for arbaclofen ER, we may not obtain or maintain the benefits associated with Orphan Drug Designation, including market exclusivity for arbaclofen ER.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs intended 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 a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Although we have received Orphan Drug Designation for arbaclofen ER for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, we may not receive the full set of benefits potentially associated with Orphan Drug Designation. The FDA has previously approved baclofen, a racemic mixture comprised of an R- and an S-isomer, for the treatment of intractable muscle spasticity in multiple sclerosis patients. If the FDA determines that our product, arbaclofen ER, which is the R-isomer of baclofen, contains the same active ingredient and is indicated for the same use as the approved product, we could be precluded from obtaining orphan drug exclusivity for our product unless we are able to demonstrate that our product is clinically superior to the approved product, which could potentially require a head-to-head study. Moreover, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same 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. Additionally, orphan drug exclusivity may be lost if the FDA 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. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Our product or our current and future product candidates may cause undesirable side effects or have other adverse properties that could delay or prevent their regulatory approval or limit the scope of any approved package insert or market acceptance, or result in significant negative consequences following marketing approval.

Treatment with our product or our current and future product candidates may produce undesirable side effects or adverse reactions or events. Although arbaclofen ER contains active ingredients that have already been approved, meaning that the side effects arising from the use of the active ingredient or class of drug in our product candidate is generally known, our product candidate may still cause undesirable or unknown side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such product candidate, or other potentially harmful characteristics. Such characteristics could cause us, our institutional review boards, or IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

If any of our products or product candidates cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result. If side effects are identified with Upneeq, or if manufacturing problems occur, changes in labeling of our product may be required, which could have a material adverse effect on our sales. Label changes may be necessary for a number of reasons, including the identification of actual or potential safety or efficacy concerns by regulatory agencies or the discovery of significant problems with a similar product that implicates an entire class of products. Any significant concerns raised about the safety or efficacy of Upneeq could also result in the need to reformulate our product, to conduct additional clinical trials, to make changes to the manufacturing process, or to seek re-approval of the relevant manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. Our product and our current and future product candidates may become subject to additional safety labeling changes in the future. New safety issues may require us to, among other things, provide additional warnings or restrictions on product package inserts, even including boxed warnings in the United States or similar warnings outside of the United States, directly alert healthcare providers of new safety information, narrow our approved indications, conduct additional clinical studies, alter or terminate current or planned trials for additional uses of products, impose restrictions on distribution, require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, or even remove a product from the market, any of which could have a significant adverse impact on potential sales or require us to expend significant additional funds. The revision of product labeling or the regulatory actions described above could have a material adverse effect on our sales of the affected products and on our business and results of operations. Additionally, we could be sued and held liable for harm caused to patients, which may result in significant legal expenses and our reputation may suffer.

If Upneeq or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived lack of effect or harmful effects, our business, financial condition, results of operations and prospects could be harmed significantly.

Risks related to our intellectual property rights

We depend on our ability to protect our intellectual property and proprietary rights. We may not be able to keep our intellectual property and proprietary rights confidential and protect such rights.

Our success depends on our ability to protect and defend the intellectual property rights associated with Upneeq and any products we may develop in the future. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that may be confused with, Upneeq or any products we may develop in the future, and our generic competitors may obtain regulatory approval to make and distribute generic versions of Upneeq or any future branded products. We cannot be certain that patents will be issued with respect to any of our patent applications or that any existing or future patents issued to or licensed by us will provide competitive advantages for Upneeq or any products we may develop in the future or will not be challenged, invalidated, circumvented or held unenforceable in proceedings commenced by our competitors or other third parties. Furthermore, our patent rights may not prevent or limit our present and future competitors from developing, making, importing, using or commercializing products that are functionally similar to Upneeq or any products we may develop in the future.

The patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of significant litigation in recent years. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. For example, Upneeq is protected by three years of new product data exclusivity that expires July 8, 2023, and eleven patents listed in the FDA Orange Book, three of which expire August 26, 2031 and eight of which expire December 16, 2039. A competitor that develops a generic version of Upneeq can submit an ANDA at any time, and that ANDA may include a Paragraph IV certification alleging that our Orange Book-listed patents are invalid, unenforceable or not infringed. If that were to occur, we would need to assert one or more of our patents. Litigation in which generic companies challenge Orange Book listed patents tends to be lengthy and expensive, and may result in one or more of our patents being held invalid, unenforceable or not infringed and, may expose us to generic competition sooner than we otherwise expect. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. 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.

In addition to the above limitations, our patent protection outside the United States may be further limited. Filing, prosecuting and defending patents on our current and future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. We generally select to pursue patent protection in only a limited number of jurisdictions outside of the United States. Even where we wish to pursue protection, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. The laws of certain non-U.S. jurisdictions do not protect proprietary rights to the same extent or in the same manner as the U.S., and therefore we may encounter additional problems in protecting and defending our intellectual property in certain non-U.S. jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions.

Proceedings to enforce patent rights, whether in the United States or in non-U.S. jurisdictions, could: result in substantial costs and divert our efforts and attention from other aspects of our business; put our patents at risk of being invalidated or interpreted narrowly; put our patent applications at risk of not issuing; and 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 to us, 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.

We also rely particularly on trade secrets, unpatented know-how and proprietary expertise and continuing innovation to develop and maintain our competitive position. We generally enter into confidentiality agreements with licensees, suppliers, employees, consultants and other parties. We cannot provide assurance that these agreements will not be breached. We also cannot be certain that we will have recourse to adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not be independently developed or otherwise become known by our competitors or, if patents are not issued with respect to internally developed products, that we will be able to maintain the confidentiality of information relating to these products. Efforts to enforce our intellectual property rights can be costly, time-consuming and ultimately unsuccessful. Any failure to adequately prevent disclosure of our know-how, trade secrets and other propriety information could have a material adverse impact on our business and our prospects.

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.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trademark office, or the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and

other similar provisions during the patent application process. While an inadvertent lapse may, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly prepare and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product or our current or future product candidates, our competitors might be able to enter the market, which would harm our business, prospects and financial position.

Our competitors or other third parties may allege that we, our suppliers or partners are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial position and results of operations.

Companies that produce branded products routinely bring litigation against entities selling or seeking regulatory approval to manufacture and market products related to their branded products or technologies. These companies or other patent holders, including patent holders who do not have related products, may allege patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling an approved product. Litigation often involves significant expense and can delay or prevent introduction or sale of a product. For example, a certain period of delay may be statutorily prescribed, or a court could grant a patent holder injunctive relief for the period of the litigation. If third party patents are held valid, enforceable and infringed by our product, we may, unless we could obtain a license from the patent holder, need to delay selling our corresponding product, pay damages, and, if we are already selling our product, cease selling and potentially destroy existing product stock. Third parties, including our competitors, may allege that our product violates their patent rights, which would expose us to the same risks. A license may not be available from the patent holder on commercially reasonable terms, or at all. If available, we may choose to take a license under a third party's patent rights to resolve a dispute, even in the absence of a finding by a court that a patent is valid, enforceable and infringed.

There may be situations in which we may make business and legal judgments to manufacture, market or sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon our belief that such patents are invalid, unenforceable, or are not infringed by our manufacturing, marketing and sale of such products. This is referred to in the pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, permanent injunctive relief preventing the sale of the product and damages measured as a reasonable royalty or by the profits lost by the patent holder, which can be significantly higher than the profits we make from selling our product. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such inventory that we are unable to market or sell.

Litigation concerning intellectual property rights in the pharmaceutical industry is commonplace and can be protracted and expensive. Competing pharmaceutical companies may file lawsuits against us alleging patent infringement or other violations of intellectual property rights or may file declaratory judgment actions against us alleging non-infringement, invalidity, or unenforceability of our own patents. The threat of intellectual property litigation, the outcome of which is inherently uncertain, is always present. Such litigation is often costly and time consuming and could result in a substantial delay in, or prevent, the introduction or marketing of our new products, or result in the loss of our intellectual property rights, which could have a material adverse effect on our business, financial condition, prospects and results of operations. For more information on our material pending litigation, see "Legal Proceedings."

If we fail to comply with our obligations in the agreements under which we license rights from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to certain licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements, for example our License Agreement with VOOM, LLC pursuant to which we have license rights to certain patents covering Upneeq, impose, and we expect that future license agreements will impose, on us various development, regulatory and commercial diligence obligations, payment of milestones or royalties

and other obligations. Additionally, existing or future license agreements may include a sublicense from a third party that is not the original licensor of the intellectual property at issue. Under such an agreement, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost, on reasonable terms or at all, and this may impact our ability to continue to develop or commercialize our product incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our existing or future important licenses were to be terminated by the licensor, we would likely need to cease further development and commercialization of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license. In the case of marketed products that depend upon a license agreement, we could be required to cease our commercialization activities, including sale of the affected product.

Disputes may arise between us and any of our licensors regarding intellectual property subject to such agreements, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our right to transfer or assign the license; and
- the effects of termination.

These or other disputes over intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms or may impair the value of the arrangement to us. Any such dispute, or termination of a necessary license, could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

We may be subject to claims that our employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our product if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to our management team. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service

providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our product.

We may be subject to claims challenging the inventorship or ownership of our owned or in-licensed patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees and consultants. However, these agreements may be breached and may not effectively assign intellectual property rights to us. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of inventions. The owners of intellectual property in-licensed to us could also face such claims. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish our product and our current and future product candidates from the products of our competitors. Our trademark applications may not result in registered trademarks. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in substantial cost, loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. Even if we are successful in defending the use of our trademarks or preventing third parties from infringing our trademarks, resolution of such disputes may result in substantial costs.

Risks related to our industry

Our profitability may depend on coverage and reimbursement by governmental authorities, private health plans and other third-party payors; healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels.

Currently RVL Pharmaceuticals, Inc. does not participate in any federal or state healthcare programs or submit any claims to third party payors. Upneeq is a cash-pay only product not covered by any government healthcare program or private health insurance plan that is dispensed exclusively through RVL Pharmacy or sold directly to healthcare practices. However, this may change for Upneeq in the future, or products we may develop or acquire in the future that we commercialize may be covered under public and/or private insurance. There is no assurance that any drug that we market will be covered by any third-party payor, or that, once a coverage determination has been made, the third-party payor will offer an adequate reimbursement level for that product. Third-party payors may limit coverage to specific products on an approved formulary, which might not include all of the approved products for a particular indication or implement other measures (such as requiring prior authorization) to manage utilization of covered drugs. In determining whether to approve reimbursement for our product and at what level, we expect that third-party payors will consider factors that include the efficacy, cost effectiveness and safety of our product, as well as the availability of other treatments including other generic prescription drugs and over-the-counter alternatives. Further, in order to obtain and maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we may face mounting pressure to offer new or enhanced discounts or rebates from list prices or to implement other unfavorable pricing modifications. Obtaining and maintaining favorable coverage and reimbursement can be a time consuming and expensive process, and there is no guarantee that we will be able to negotiate or continue to negotiate pricing terms with third-party payors at levels that are profitable to us, or at all. Additionally, any reimbursement granted may not be maintained and any limits on reimbursement available from third-party payors may reduce the demand for, or negatively affect the price of those products, and could significantly harm our business, results of operations, financial condition and cash flows.

Within the United States, federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended, the Health Care and Education Reconciliation Act, or the Affordable Care Act, which among other things, expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included a number of changes to the coverage and reimbursement of drug products under government healthcare programs.

Beyond the Affordable Care Act, there have been ongoing health care reform efforts. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes, which have varying implementation dates, include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program and a drug price negotiation program for certain high spend Medicare Part B and D drugs.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenges. For example, with respect to the Affordable Care Act tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2031 (Except May 1, 2020 to March 31, 2022) unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the Affordable Care Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

There has been heightened public pressure and government scrutiny over pharmaceutical pricing practices, which may negatively impact our ability to generate revenues from our product, which could result in material adverse effects to our business, financial position and results of operations.

There has been heightened federal and state governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs. At the federal level, such scrutiny has resulted in several Congressional inquiries in recent years 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 assistance programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have become increasingly active in passing, or seeking to pass, legislation

and regulations designed to control pharmaceutical and biological product pricing, including laws establishing maximum drug reimbursement rates for governmental or other payors within a state, laws limiting consumer copayment obligations, transparency and disclosure measures related to drug price increases and laws seeking to encourage drug importation from other countries and bulk purchasing. If it is determined that we are subject to certain state regulations related to, for example, price reporting and we fail to submit such reports we may be subject to state scrutiny, investigations or fines. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our product is prescribed or administered. Any downward pricing pressure on the price of our product arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition.

There has also been increasing U.S. federal and state enforcement interest with respect to drug pricing. In addition to the effects of any investigations or claims brought against us, our business, results of operations and financial condition could also be adversely affected if any such inquiries, of us or of other pharmaceutical companies or the industry more generally, were to result in legislative or regulatory proposals that limit our ability to increase the price of our product.

We are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations. Any non-compliance may result in fines or other sanctions, including debarment, product seizures, product recalls, injunctive actions and criminal prosecutions, which could result in material adverse effects to our business, financial position and results of operations.

The pharmaceutical industry operates in a highly regulated environment and the operations of a pharmaceutical company are subject to regulation by various governmental authorities at the federal, state and local levels with respect to the development, manufacture, labeling, sale, distribution, marketing, advertising and promotion of pharmaceutical products. Such regulation may restrict our operations. As a pharmaceutical distributor, we are subject to extensive regulation by the federal government, principally the FDA, FTC and the Drug Enforcement Administration, or DEA, as well as by state governments.

The FDCA, the Controlled Substances Act, the Generic Drug Enforcement Act of 1992, or the Generic Drug Act, and other federal, state and local statutes and regulations govern the testing, manufacture, safety, labeling, storage, disposal, tracking, recordkeeping, approval, advertising and promotion (including to the healthcare community) of our product and our current and future product candidates. If we fail, or if the manufacturing facilities for our products, our CROs, or other persons or entities working on our behalf fail, to comply with applicable regulatory requirements either before or after marketing approval, a regulatory agency, such as the FDA, may, depending on the stage of product development and approval, revoke, withdraw, or suspend approvals of previously approved products for cause, debar companies and individuals from participating in the drug-approval process, request or in certain circumstances mandate recalls of allegedly violative products, seize allegedly violative products, issue Warning Letters or Untitled Letters, mandate modifications to promotional materials or require the provision of corrective information to healthcare practitioners, amend and update labels or package inserts, suspend or terminate any ongoing clinical trials, refuse to approve pending applications or supplements to applications filed, refuse to allow entry into government contracts, obtain injunctions to close manufacturing plants allegedly not operating in conformity with FDA's cGMP requirements, stop shipments of allegedly violative products, impose fines perhaps significant in amount, require entry into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance and other sanctions imposed by courts or regulatory bodies, including criminal prosecutions. We have in the past received Warning Letters from the FDA regarding certain operations and the FDA may in the future issue a Warning Letter for violation of post-marketing adverse drug experience reporting requirements. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to us, that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. From time to time, we have voluntarily recalled our legacy products and may be required to voluntarily recall our products in the future.

Because of the chemical ingredients of pharmaceutical products and the nature of the manufacturing process, the pharmaceutical industry is subject to extensive environmental laws and regulation and the risk of incurring liability for

damages and the costs of remedying environmental problems. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of hazardous materials and pollutants into the environment. We do not currently own a manufacturing facility and instead use third parties to manufacture for us. Our previous ownership of a manufacturing facility in Marietta, GA, or the acquisition of a manufacturing facility in the future, may expose us to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could result in (i) our noncompliance with such environmental and occupational health and safety laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an unapproved or illegal environmental discharge or accident occurred or if we were to discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, then we could be liable for cleanup, damages or fines, which could have a material adverse effect on our business, financial position, results of operations and cash flow. In the future, we may be required to increase expenditures in order to remedy environmental problems or comply with changes in applicable environmental laws and regulations. We could also become a party to environmental remediation investigations and activities. These obligations may relate to sites that we currently or in the future may own or lease, sites that we formerly owned or operated, or sites where waste from our operations was disposed. Additionally, if we fail to comply with environmental regulations to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the provisions of our operating licenses, the licenses could be revoked, and we could be subject to criminal sanctions or substantial civil liability or be required to suspend or modify our manufacturing operations. We currently operate in New Jersey, and overseas in Hungary, and we are required to comply with the laws and regulations of those states or overseas jurisdictions in addition to any federal laws and regulations. We may in the future establish or acquire operations in other jurisdictions subject to equally or more stringent laws and regulations. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to us, and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures, as well as other costs and liabilities, which could materially adversely affect us.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are now required to file with the FTC, and the DOJ certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The potential for FTC investigations and litigation and private-party lawsuits associated with arrangements between brand and generic drug manufacturers could adversely affect our business. In recent years, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged payment from the brand company to the generic company (so-called “pay for delay” patent litigation settlements) and to call on legislators to pass stronger laws prohibiting such settlements. In 2013, the U.S. Supreme Court held that certain of such settlements could violate anti-trust laws and must be evaluated under a “rule of reason” standard of review.

We are subject to the effects of changes in statutes, regulations and interpretative guidance that may adversely affect our business and that could require us to devote increased time and resources to our compliance efforts, which may not be successful. Any changes in statutes, regulations or interpretative guidance could have a material adverse effect on our business, financial condition, prospects and results of operations.

We also cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If any legislative or administrative actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted, and if we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product, which would adversely affect our ability to generate revenues and achieve or maintain profitability.

These risks, along with others, have the potential to materially and adversely affect our business, financial position, results of operations and prospects. Although we have developed compliance programs to address the regulatory environment, there is no guarantee that these programs will meet regulatory agency standards now or in the future.

Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we are deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected.

Our business operations and interactions with third parties in the health care industry, including healthcare professionals, other healthcare providers, third-party payors, patient organizations and patients, are or may be subject to a wide range of healthcare and other regulatory laws and any failure to comply with such laws could expose us to penalties and other sanctions.

Our business operations and interactions with third parties in the healthcare industry, including healthcare professionals, other healthcare providers, third-party payors and patient organizations, are or may be subject to a wide range of healthcare and other regulatory laws. These laws constrain the business or financial arrangements through which we conduct our operations, including how we research, market, sell and distribute Upneeq and any products we may develop in the future. In particular, although currently Upneeq is not reimbursed by any government or private health plan, if this changes or if we market future products reimbursed by government healthcare programs and private health plans, additional laws designed to prevent fraud and abuse in the healthcare industry may apply. Healthcare and other regulatory laws applicable to our activities or activities related to any products we may develop in the future may include:

- U.S. federal anti-kickback or similar fraud and abuse laws which prohibit the offer, solicitation, payment or receipt of value in order to generate business reimbursable under government healthcare programs and/or private health plans;

- U.S. federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;

- the U.S. federal law HIPAA, as amended, which imposes certain privacy, security and breach reporting obligations, with respect to individually identifiable health information upon covered entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates which perform certain services that involve creating, using, maintaining or transmitting individually identifiable health information;

- the U.S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the so-called federal “Sunshine” or Open Payments law, which requires pharmaceutical and medical device companies to report certain financial interactions with teaching hospitals, physicians and certain non-physician practitioners as well as ownership and investment interests held by physicians and their immediate family members to the federal government for re-disclosure to the public;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws that require pharmaceutical companies to comply with specific compliance standards; state laws that require pharmaceutical companies to report certain financial interactions with healthcare providers; state laws that require drug manufacturers to file reports relating to pricing sales, shipping and marketing information; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the

privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- similar healthcare laws and regulations in the European Union, or the EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers have not or do not comply with past, current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our operations in non-U.S. jurisdictions subject us to increased regulatory oversight and regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position and results of operations.

We are subject to certain risks associated with our operations in non-U.S. jurisdictions, including Hungary, and with having assets and operations located in non-U.S. jurisdictions. Our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies and increased government regulation. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations there to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, we operate in countries, including Argentina and Hungary, where there have been reported instances of government corruption and there are circumstances in which anti-bribery laws may conflict with some local customs and practices.

Our international operations may subject us to heightened scrutiny under the U.S. Foreign Corrupt Practices Act, or FCPA, other federal statutes and regulations, including those established by the Office of Foreign Assets Control, the Irish Criminal Justice (Money Laundering and Terrorist Financing) Acts 2010-2018, or the Irish Money Laundering Acts, the Irish Criminal Justice (Corruption Offences) Act 2018, the U.K. Bribery Act, anti-corruption provisions in the Hungarian Criminal Code, Argentina's recently enacted Law 27.401 and other similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws and regulations. The FCPA prohibits any U.S. individual or business from paying, offering, 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 Irish Criminal Justice (Corruption Offences) Act 2018 renders a company liable for prosecution where any of its officers, managers, employees, agents or subsidiaries are found to be involved in corruption. The only defense is for the company to show that it took all reasonable steps and exercised all due diligence to prevent such corruption from taking place. The legislation also applies to certain international activities. The Irish Money Laundering Acts provide for criminal sanctions for engaging in "money laundering offences," which are offenses committed where a person knows or believes that (or is reckless as to whether or not) the property represents the proceeds of criminal conduct and the party is involved in concealing or disguising the true nature, source, location, disposition, movement or ownership of property, or in converting, transferring, handling, acquiring possession or using the property, or removing the property from, or bringing the property into, Ireland. In addition, the U.K. Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the U.K. Bribery Act unless the organization can establish the

defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to our business practices, including the cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase our compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition. As a result of our policy to comply with the FCPA, the Irish Money Laundering Acts, the Irish Criminal Justice (Corruption Offences) Act 2018, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws and regulations.

We are subject to various laws protecting the confidentiality of certain patient health information, and other personal information, and our failure to comply could result in penalties and reputational damage.

Numerous U.S. states and countries in which we operate, manufacture and sell our product have, or are developing, laws protecting data privacy and the confidentiality of certain personal data, including not only patient health information but also data on employees, customers, contractors and other types of individuals with whom we interact. The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations, and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. One example of such a law is the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to receive certain details regarding the processing of their data by covered companies, the right to request deletion of their data, and the right to opt out of sales of their data. The CCPA additionally imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities. The CCPA provides for imposition of substantial fines on companies that violate the law and also confers a private right of action on data subjects to seek statutory or actual damages for breaches of their personal information. On November 3, 2020, California voters passed a ballot initiative approving the California Privacy Rights Act (CPRA), which will significantly expand the CCPA to incorporate additional provisions, including a requirement that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions took effect on January 1, 2023, though the obligations apply to any personal information collected after January 1, 2022. Other states are also enacting comprehensive privacy legislation, including Virginia and Colorado, both of which passed expansive privacy laws in 2021 that take effect in 2023.

In Europe, the EU General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Economic Area (EEA) and substantial fines for breaches of the data protection rules. The GDPR expanded the territorial scope of European data privacy legislation to include not only entities that are established in the EEA, but also entities that are not established in the EEA but that offer goods or services to individuals located in the EEA or monitor the behavior of individuals located in the EEA. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, introduced mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition. The GDPR also provides for the assessment of fines on entities that violate the regulation of up to 20 million Euros or four percent of annual turnover and provides data subjects a private right of action to seek compensation for damages suffered as a result of violations of the regulation.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the EEA, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data and the processing of personal data for research purposes), meaning that inconsistencies between different member states will still arise. EEA member states have their own regimes on medical confidentiality and national and EU-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the EEA.

European data protection law generally prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, unless there are specific frameworks or mechanisms in place, such as the European Commission approved standard contractual clauses, or if very narrow legal exceptions (such as data subject consent) apply. The July 2020 invalidation by the Court of Justice of the European Union of the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S., has led to increased scrutiny on data transfers from the EEA to the U.S. generally and may increase our costs of compliance with data privacy legislation. Our ability to receive data from the EEA could be affected by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as challenges to these mechanisms in the European courts. Following "Brexit," the United Kingdom has adopted legislation substantially similar to the GDPR and thus the requirements of the GDPR, including restrictions on cross-border transfer to the U.S., apply with respect to data collected in the United Kingdom.

In recent years, U.S. and European regulators have expressed concern over electronic marketing and the use of third-party cookies, web beacons and similar technology for online behavioral advertising. In the EEA, informed consent is required for the placement of many types of cookies on a user's device, such as cookies used for online behavioral advertising, as well as for the sending of many types of electronic marketing communications. The current EU laws that cover the use of cookies and similar technology and marketing online or by electronic means are under reform. A draft of the new ePrivacy Regulation is currently going through the European legislative process. Unlike the current ePrivacy Directive, the draft ePrivacy Regulation will be directly implemented into the laws of each of the EU member states, without the need for further enactment. When implemented, it is expected to alter rules on third-party cookies, web beacons and similar technology for online behavioral advertising and to impose stricter requirements on companies using these tools. The current provisions of the draft ePrivacy Regulation also significantly increase penalties.

We expect to be subject to additional privacy at both the U.S. state level and abroad as many jurisdictions worldwide in addition to those examples discussed above have either recently passed data privacy legislation or are considering enacting such legislation. Failure to comply with data protection laws and regulations could result in government enforcement actions, which may involve civil and criminal penalties, private litigation and/or adverse publicity and could negatively affect our business, financial condition and results of operations. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business, financial condition and results of operations.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. Persons who are not subject to HIPAA as a covered entity or business associate may nonetheless be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information that we receive throughout the clinical trial process or in the course of our research collaborations. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR. Also, our status for HIPAA purposes may change in the future

as we implement a connected account program and process financial transactions for healthcare providers who are covered entities, in which case we may be considered a business associate under HIPAA.

Even if we are not subject to HIPAA, we may maintain sensitive personally identifiable information, including health information that we receive throughout the clinical trial process or in the course of our research collaborations. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws and consumer protection laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. If we or third-party CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our current and future product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our product. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Increased scrutiny around the abuse of opioids, including law enforcement concerns over diversion and legislative and regulatory efforts to combat abuse, could impact some of our legacy pharmaceutical products, and could subject us to litigation costs for a period of time.

Aggressive enforcement by federal and state regulators, unfavorable publicity regarding, for example, the use or misuse of opioid drugs or the limitations of abuse-deterrent formulations, litigation, public inquiries or investigations related to the abuse, sales, marketing, distribution or storage of our legacy products could harm our reputation and result in financial consequences in the form of, for example, litigation costs.

The attorneys general from nearly every state have also either opened an investigation into or filed a lawsuit against pharmaceutical manufacturers and distributors of opioid products. At the state and local level, a number of states, cities, counties, Native American tribes, third party payors, hospitals and other health service providers, schools, individuals and guardians of children diagnosed with neonatal abstinence syndrome have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. Over 2,500 of these lawsuits have been consolidated in multi-district litigation in the Northern District of Ohio in *In re: National Prescription Opiate Litigation*, 1:17md2804, or Federal Opioid MDL. The Legacy Business was not named in any of the cases pending in the multi-district litigation, but cases continue to be filed in federal courts across the country and continue to be consolidated into the Federal Opioid MDL. Cases against pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioids drugs, also continue to be separately litigated in state courts across the country. If similar federal or state lawsuits are filed against the Legacy Business in the future, we may be subject to litigation costs or negative publicity, which could have a material adverse effect on our business, results of operations and financial condition.

We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums.

Like all pharmaceutical companies, we face the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We likely cannot avoid such claims. Unanticipated side effects or unfavorable publicity concerning our product would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, customers, patients and clinical trial participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management's time, damage our reputation and impair the marketability of our product. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. In addition, insurance coverage for product liability may become prohibitively expensive in the future or, with respect to certain high-risk products, may not be available at all.

Manufacturing or quality control problems at our or our third-party manufacturing facility operated by Nephron Pharmaceuticals may damage our reputation for quality production, require costly remedial activities delay or interrupt the supply of Upneeq and negatively impact our business, results of operations and financial condition.

As a pharmaceutical company, we and our third-party suppliers are subject to substantial regulation by various governmental authorities. For instance, we and our third-party suppliers must comply with requirements of the FDA and other healthcare regulators with respect to the manufacture of pharmaceutical products. Our product, including our investigational products, must be made in a manner consistent with applicable cGMP regulations, or similar standards in each territory in which we or our third-party suppliers manufacture. The failure of one of our facilities, or a facility of one of our third-party suppliers such as Nephron Pharmaceuticals, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility. In addition, the FDA and other agencies periodically inspect our facilities, and the facilities of our third-party suppliers, for compliance with, among other requirements, adverse event reporting and employee training on applicable regulations and requirements. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or a Warning Letter for violations of "regulatory significance" that may result in enforcement action if not promptly and adequately corrected. We have in the past received Warning Letters from the FDA regarding certain operations and the FDA may in the future issue a Warning Letter for violation of post-marketing adverse drug experience reporting requirements. In addition, on October 11, 2022, the FDA sent a Warning Letter to Nephron citing several cGMP violations in their pharmaceutical manufacturing facility observed by the FDA during an inspection from March 28 through April 20, 2022. Nephron responded to the Warning Letter on November 1, 2022. Failure to comply strictly with these regulations and requirements may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production or distribution, withdrawal or suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions and criminal prosecution. The delay and cost of remedial actions, or obtaining approval to manufacture at a different facility, could negatively impact our business. Any failure by us to comply with applicable laws and regulations or any actions by the FDA and other agencies as described above could have a material adverse effect on our business, financial position and results of operations.

The illegal distribution and sale by third parties of counterfeit versions of our product or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition.

Third parties could illegally distribute and sell counterfeit versions of our product, which do not meet the rigorous manufacturing and testing standards that our product undergo. Counterfeit products are frequently unsafe or ineffective and can be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation and our business.

Public loss of confidence in the integrity of our pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our reputation, business, results of operations and financial condition.

Our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy and security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, off-label promotion, 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 programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and results of operations.

Risks related to our indebtedness

The terms of the Note Purchase Agreement restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.

The note purchase agreement, dated October 1, 2021 (as amended on August 4, 2022 and March 8, 2023, the "Note Purchase Agreement"), with Athyrium Opportunities IV Acquisition LP, as the administrative agent (the "Administrative Agent"), contains a number of restrictive covenants that impose significant operating and financial restrictions on our operating subsidiaries and may limit our ability to engage in acts that may be in our long-term best interest, including restrictions on our ability to:

- incur additional indebtedness;
- pay dividends or make other distributions or repurchase or redeem our share capital;
- prepay, redeem or repurchase certain debt;
- consolidate, merge or sell all or substantially all of our assets;
- amend or modify the organizational documents of our operating subsidiaries;

- amend or modify certain indebtedness of our operating subsidiaries;
- change our fiscal year; and
- enter into certain derivative transactions.

In addition, the restrictive covenants in the Note Purchase Agreement require us to comply with certain minimum liquidity requirements and minimum quarterly product sales requirements. Under the terms of the Note Purchase Agreement, we are required to maintain unrestricted cash and cash equivalents greater than or equal to $12.5 million, as further described in the Note Purchase Agreement, and, as of the end of each fiscal quarter, we are required to maintain Consolidated Upneeq Net Product Sales (as defined in the Note Purchase Agreement) greater than or equal to specified quarterly thresholds (currently at $7 million for the quarter ending March 31, 2023, and increasing in $1 million increments each quarter thereafter until the quarter ending June 30, 2024, for which quarter and all subsequent quarters the threshold is $12 million). Our ability to meet these restrictive covenants can be affected by events beyond our control.

A breach of the covenants under the Note Purchase Agreement (subject to any applicable grace periods) would result in an event of default under the Note Purchase Agreement. Such an event of default would allow the noteholders to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies which could have a material adverse effect on our business, operations and financial results. Furthermore, if we were unable to repay our obligations in respect of the senior secured notes issued pursuant to the Note Purchase Agreement (the "Senior Secured Notes"), the noteholders could proceed against the collateral granted to them to secure the Senior Secured Notes which could force us into bankruptcy or liquidation. In the event the noteholders accelerate the repayment of the Senior Secured Notes, we and our subsidiaries may not have sufficient assets to repay such Senior Secured Notes. Any acceleration of amounts due under the Note Purchase Agreement or the exercise by the applicable lenders of their rights under the related security documents would likely have a material adverse effect on us. As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively or to take advantage of new business opportunities. These restrictions may affect our ability to grow in accordance with our strategy.

Our substantial indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting obligations on our indebtedness.

Subject to the limits contained in our Note Purchase Agreement, we may incur substantial additional indebtedness from time to time to finance working capital, capital expenditures, investments or acquisitions, or for other purposes. If we do so, the risks related to this high level of debt could intensify. Specifically, the high level of debt could have important consequences, including, but not limited to:

- increasing our vulnerability to general adverse economic and industry conditions;
- exposing us to the risk of increased interest rates as certain of our indebtedness, including the Senior Secured Notes, are at variable rates of interest;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete;
- placing us at a disadvantage compared to other, less leveraged competitors; and

- increasing our cost of borrowing.

We are a holding company with nominal net worth and will depend on dividends and distributions from our subsidiaries, which are restricted from paying dividends and distributions to us pursuant to the terms of our existing indebtedness and may be restricted pursuant to the terms of future indebtedness, which as a result may restrict us from paying dividends to you.

We are a holding company with nominal net worth. We do not have any material assets or conduct any business operations other than our investments in our subsidiaries. Our business operations are conducted primarily out of our indirect operating subsidiary, RVL Pharmaceuticals, Inc. As a result, notwithstanding any restrictions on payment of dividends under our existing indebtedness or under Irish law, our ability to pay dividends, if any, will be dependent upon cash dividends and distributions or other transfers from our subsidiaries. Payments to us by our subsidiaries will be contingent upon their respective earnings and subject to any limitations on the ability of such entities to make payments or other distributions to us. The Note Purchase Agreement restricts our subsidiaries from paying dividends and making distributions to its direct or indirect equity holders unless there are available exceptions thereunder. If we are not able to meet such available exceptions that would allow our subsidiaries to pay a dividend or make a distribution to us, and which would then allow us to pay a dividend to you, then we will need to obtain a waiver from the noteholders under the Note Purchase Agreement.

We may incur significant indebtedness in the future.

We and our subsidiaries may have to incur significant additional indebtedness in the future. Although the Note Purchase Agreement contains restrictions on the incurrence of additional indebtedness, these restrictions, and restrictions contained in any future debt agreement, are subject to a number of qualifications and exceptions, and the additional indebtedness incurred in compliance with these restrictions could be substantial. These restrictions also will not prevent us from incurring obligations that do not constitute indebtedness. If new debt is added to our current debt levels, the related risks that we and the guarantors now face could intensify. In addition, the restrictions in the Note Purchase Agreement will no longer apply following our repayment of the Senior Secured Notes. At that time, we will be able to incur new indebtedness without regard to the restrictions in the Note Purchase Agreement, which could result in similar, or more severe, risks than those described above.

Our variable rate indebtedness subjects us to interest rate risk, which could cause our obligations under the Senior Secured Notes to increase significantly.

The Senior Secured Notes accrue interest at a variable rate, which exposes us to interest rate risk. Specifically, the Senior Secured Notes bear interest at a rate per annum equal to the sum of 9.00% plus the adjusted three-month term Secured Overnight Financing Rate, or Term SOFR. The Note Purchase Agreement includes a Term SOFR floor of 1.50% with a cap of 3.00%. An increase in Term SOFR could result in a substantial increase in our annual interest expense associated with the Note Purchase Agreement.

Risks related to our ordinary shares

We qualify both as an "emerging growth company" and as a "smaller reporting company," and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation.

We could be an emerging growth company until the end of 2023, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenues of $1.235 billion or more during any fiscal year before that time, in which cases, we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. In addition, we qualify as a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding financial statements, executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them, and we cannot predict or estimate the amount or timing of such additional costs.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Investment funds affiliated with Avista Capital Partners, or Avista, and affiliates of Altchem Limited, or Altchem, have significant influence over us, including control over decisions that require the approval of shareholders, which could limit your ability to influence the outcome of matters submitted to shareholders for a vote.

We are currently controlled by Avista and Altchem, who we refer to as our Sponsors. At December 31, 2022, investment funds affiliated with the Sponsors beneficially owned approximately 47.8% of our outstanding ordinary shares. For as long as the Sponsors own or control a significant portion of our outstanding voting power, they will have the ability to strongly influence or effectively control corporate actions requiring shareholder approval, including over the election and removal of directors, any amendment to our Constitution, the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. In addition, each of the Sponsors has a contractual right to nominate two directors for so long as such Sponsor owns at least 20% of our outstanding ordinary shares, and one director for so long as such Sponsor owns less than 20% but more than 10% of our outstanding ordinary shares.

Additionally, the Sponsors' interests may not align with the interests of our other shareholders. Avista and Altchem are in the business of making investments in companies and may acquire and hold interests in businesses that compete directly or indirectly with us. The Sponsors may also pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us.

Our directors who have relationships with Avista or Altchem may have conflicts of interest with respect to matters involving our company.

Two of our seven directors are affiliated with Avista and two directors are affiliated with Altchem. In addition, our Chief Executive Officer, Brian Markison, serves as an operating executive at Avista Capital Partners. Our directors have fiduciary duties to us and, in addition, may have duties to Avista or Altchem, as applicable. As a result, these directors may face real or apparent conflicts of interest with respect to matters affecting both us and Avista or Altchem, as applicable, whose interests, in some circumstances, may be adverse to ours.

Your percentage ownership in us may be diluted in the future, which could reduce your influence over matters on which shareholders vote.

In the future, your percentage ownership in us may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we have granted or may grant in the future to directors, officers and employees and the exercise of our outstanding warrants for ordinary shares. From time to time, we may issue additional options or other share-based awards to our directors, officers and employees under our benefits plans.

Pursuant to our Constitution, our board of directors has the authority, without action or vote of our shareholders and on a non-pre-emptive basis, to issue all or any part of our authorized but unissued ordinary shares, and one or more classes or series of preferred shares having such powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. For example, our board of directors could grant the holders of preferred shares the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences our board of directors could assign to holders of preferred shares could affect the residual value of our ordinary shares.

Issuances of ordinary shares or voting preferred shares in the manner outlined above or the exercise of our outstanding warrants for ordinary shares may reduce your influence over matters on which our shareholders vote.

Currently there is a limited public market for our securities, which may limit your ability to sell your shares.

Although our ordinary shares are listed on the Nasdaq Global Select Market under the symbol ‘‘RVLP,’’ our shares have been thinly traded, and there may not be an active trading market for our shares. A public trading market having the desirable characteristics of depth, liquidity and orderliness depends upon the existence of willing buyers and sellers at any given time, such existence being dependent upon the individual decisions of buyers and sellers over which neither we nor any market maker has control. The failure of an active and liquid trading market to continue would likely have a material adverse effect on the value of our ordinary shares. The market price of our ordinary shares may decline and you may not be able to sell our ordinary shares at or above the price you paid for them, or at all. An inactive market may also impair our ability to raise capital to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Registration of the beneficial interests in our shares subjects us and the holders of such beneficial interests to certain risks.

We entered into a Depository Agreement, or DTC Agreement, with the Depository Trust Company, or DTC, in connection with the listing and trading of our shares on the Nasdaq Global Select Market. In accordance with the DTC Agreement, following completion of the initial public offering of our shares, DTC’s nominee, Cede & Co., was registered as the legal owner of certain of our ordinary shares in the Irish shareholder register that we are required to maintain pursuant to the Companies Act 2014 of Ireland, or the Irish Companies Act. Under the DTC Agreement, DTC credited the beneficial interests in those ordinary shares in book entry form to its participants. Accordingly, while the ordinary shares issued in accordance with Irish law are listed and traded on the Nasdaq Global Select Market, it is the beneficial interests in such ordinary shares that are settled and held in DTC. In accordance with market practice and system requirements of the Nasdaq Global Select Market, the ordinary shares are listed and traded on the Nasdaq Global Select Market under the category of “Common Share.” In respect of beneficial interests in ordinary shares held in DTC, such beneficial ownership would not necessarily be recognized by an Irish court. As such, investors holding beneficial interests in our ordinary shares within DTC may have no direct rights against us and our officers and directors and may be required to obtain the cooperation of DTC in order to assert claims against us and our officers and directors, and to look solely to DTC for the payment of any dividends, for exercise of voting rights attaching to the underlying ordinary shares and for all other rights arising in respect of the underlying ordinary shares. We cannot guarantee that DTC will be able to continue to execute its obligations under the DTC Agreement, including that the beneficial owners of the ordinary shares within DTC will receive notice of general meetings in time to instruct DTC to either effect registration of their ordinary shares or otherwise vote their ordinary shares in the manner desired by such beneficial owners. Any such failure may, inter alia, limit the access for, delay or prevent, such beneficial shareholders from being able to exercise the rights attaching to the underlying ordinary shares.

DTC has certain termination rights under the DTC Agreement. In the event that the DTC Agreement is terminated, we will use our reasonable best efforts to enter into a replacement agreement for purposes of permitting the uninterrupted listing of our ordinary shares on the Nasdaq Global Select Market. There can be no assurance, however, that it would be possible to enter into such a new agreement on substantially the same terms as the DTC Agreement or at all. A termination of the DTC Agreement could, therefore, have a material and adverse effect on us and the beneficial

shareholders holding their ordinary shares within DTC. The DTC Agreement limits DTC's liability for any loss suffered by us. DTC disclaims any liability for any loss attributable to circumstances beyond DTC's control, including, but not limited to, errors committed by others. DTC is only liable for direct losses incurred as a result of events within DTC's control. Thus, we may not be able to recover our entire loss if DTC does not perform its obligations under the DTC Agreement.

Our share price may be volatile, and the market price of our ordinary shares may drop below the price you pay.

Our share price has been and may continue to be volatile. Since our initial public offering in October 2018, the closing price of our ordinary shares as reported on the Nasdaq Global Select Market has ranged from a low of $0.98 on December 17, 2021 to a high of $9.20 on October 22, 2018. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could subject the market price of our shares to wide price fluctuations regardless of our operating performance. The trading price of our shares may fluctuate in response to various factors, including:

- market conditions in the broader stock market;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- market conditions in the broader stock market;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- introduction of new products or services by us or our competitors;
- issuance of new or changed securities analysts' reports or recommendations;
- results of operations that vary from expectations of securities analysts and investors;
- results of operations that vary from those of our competitors;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- strategic actions by us or our competitors;
- announcement by us, our competitors or our vendors of significant contracts or acquisitions;
- sales, or anticipated sales, of large blocks of our shares;
- additions or departures of key personnel;
- regulatory, legal or political developments;
- public response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- litigation and governmental investigations; and
- changing economic conditions.

These and other factors, many of which are beyond our control, may cause our market price and demand for our shares to fluctuate substantially. Fluctuations in our share price could limit or prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of shares has been volatile, holders of those shares have sometimes instituted securities class action litigation against the company that issued the shares. For example, on April 30, 2019 we were served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*, and on May 10, 2019, a complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints named us, certain of our directors and officers and the underwriters of our initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for our initial public offering of ordinary shares. The parties negotiated a settlement, which called for a payment by the Company of $5.25 million (a portion of which was covered by applicable insurance). On November 9, 2021, the Court held a hearing with the Parties and on November 10, 2021, entered a Judgment and Order Granting Final Approval of Class Action Settlement.

In general, we intend to continue to vigorously prosecute and defend these proceedings, as appropriate; however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations and legal proceedings, individually or in the aggregate, could have a material adverse effect on our business, results of operations and cash flows in any given accounting period or on our overall financial condition.

Since we have no current plans to pay regular cash dividends on our ordinary shares, you may not receive any return on investment unless you sell your ordinary shares for a price greater than that which you paid for it.

We do not anticipate paying any regular cash dividends on our ordinary shares for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. Our ability to pay dividends is, and may be, limited by covenants of existing and any future outstanding indebtedness we or our subsidiaries incur. In addition, our ability to pay cash dividends may be limited by Irish law, as discussed under the risk factor titled "The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our ordinary shares less attractive to investors." Therefore, any return on investment in our ordinary shares is solely dependent upon the appreciation of the price of our ordinary shares on the open market, which may not occur.

Risks related to being an Irish corporation listing ordinary shares

Provisions contained in our Constitution, as well as provisions of Irish law, could impair a takeover attempt, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

Our Constitution, together with certain provisions of the Irish Companies Act could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors.

There are a number of approaches for acquiring an Irish public limited company, including a court-approved scheme of arrangement under the Irish Companies Act, through a tender offer by a third party, by way of a merger with a company incorporated in the European Economic Area, or EEA, under the EU Cross-Border Mergers Directive (EU) 2017/1132 as implemented in Ireland by the European Communities (Cross-Border Mergers) Regulations 2008 (as amended) and by way of a merger with a company incorporated in Ireland under the Irish Companies Act. Each method requires shareholder approval or acceptance and different thresholds apply.

The Irish Takeover Panel Act 1997 and the Irish Takeover Rules 2013 made thereunder, or the Irish Takeover Rules, govern a takeover or attempted takeover of our company by means of a court-approved scheme of arrangement or a tender offer. The Irish Takeover Rules contain detailed provisions for takeovers, including as to disclosure, process,

dealing and timetable. The Irish Takeover Rules could discourage an investor from acquiring 30% or more of our outstanding ordinary shares unless such investor was prepared to make a bid to acquire all outstanding ordinary shares.

Our Constitution contains provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting and other rights of the holders of our ordinary shares. These provisions include:

- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions that allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before shareholder meetings, including proposed nominations of persons for election to our board of directors;
- the ability of our board of directors to fill vacancies on our board in certain circumstances; and
- imposing particular approval and other requirements in relation to certain business combinations.

These provisions do not make us immune from takeovers. However, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our board of directors may be limited by the Irish Takeover Rules in its ability to defend an unsolicited takeover attempt.

We are subject to the Irish Takeover Panel Act 1997 and the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions, such as (i) the issue of shares, options, restricted share units or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in a jurisdiction of the United States.

The operation of the Irish Takeover Rules may affect the ability of certain parties to acquire our ordinary shares.

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of a company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. Under the Irish Takeover Rules, certain separate concert parties are presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of the company. The application of these presumptions resulted and may continue to result in restrictions upon the ability of certain concert parties and members of our board of directors to acquire more of our securities,

including under the terms of any executive incentive arrangements. We have consulted and may consult again in the future with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities, although we are unable to provide any assurance as to whether the Irish Takeover Panel will overrule this presumption in the future.

Our Constitution designates the courts of Ireland for all actions and proceedings, other than those relating to U.S. securities law, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees and require shareholders to pursue certain claims outside the United States.

Our Constitution provides that, unless our board of directors or one of its duly authorized committees approves the selection of an alternate forum and to the fullest extent permitted by applicable law, the courts of Ireland shall be the exclusive forum for all actions or proceedings, other than those related to U.S. securities law, but including (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to us or our shareholders, (iii) any action asserting a claim against us arising pursuant to any provision of Irish law or our Constitution and (iv) any action to interpret, apply, enforce or determine the validity of our Constitution. Any person or entity purchasing or otherwise acquiring any interest in our shares shall be deemed to have notice of and to have consented to the provisions of our Constitution and waived any argument relating to the inconvenience of the forums described above. As a result, certain shareholder actions and proceedings may only be brought in Ireland and our shareholders would not have access to any U.S. courts with respect to such actions. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Constitution inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Irish law differs from the laws in effect in the United States and U.S. shareholders may have difficulty enforcing civil liabilities against us, our directors or members of senior management.

A number of our directors are non-residents of the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may not be possible to serve process on these directors, or us, in the United States or to enforce court judgments obtained in the United States against these individuals or us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. The United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland. A judgment obtained against us will be enforced by the courts of Ireland if the following general requirements are met:

- U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule); and

- the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it.

A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. But where the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether a final judgment given in default of appearance is final and conclusive. Irish courts may also refuse to enforce a judgment of the U.S. courts that meets the above requirements for one of the following reasons:

- the judgment is not for a definite sum of money;

- the judgment was obtained by fraud;

- the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice;

- the judgment is contrary to Irish public policy or involves certain U.S. laws that will not be enforced in Ireland; or

- jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Irish Superior Courts Rules.

As an Irish company, we are principally governed by Irish law, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or other officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our ordinary shares may have more difficulty protecting their interests than would holders of shares of a corporation incorporated in a jurisdiction of the United States.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our ordinary shares less attractive to investors.

We are incorporated under Irish law and, therefore, certain of the rights of holders of our shares are governed by Irish law, including the provisions of the Irish Companies Act, and by our Constitution. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations and these differences may make our ordinary shares less attractive to investors. The principal differences include the following:

- under Irish law, dividends may only be declared if we have, on an individual entity basis, profits available for distribution, within the meaning of the Irish Companies Act. In addition, no distribution or dividend may be paid or made by us unless our net assets are equal to, or exceed, the aggregate of our called up share capital plus non-distributable reserves and the distribution does not reduce our net assets below such aggregate;

- under Irish law, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of shares. Preemption rights may be disapplied under Irish law for renewable five-year periods by Irish companies by way of a provision in such companies' constitution or a special resolution of their shareholders. We have opted out of these preemption rights in our Constitution as permitted under Irish law for the maximum period permitted of five years from the date of adoption of the Constitution;

- under Irish law, certain matters require the approval of holders of 75% of the votes cast at a general meeting of our shareholders, including amendments to our Constitution, which may limit our flexibility to manage our capital structure;

- under Irish law, a bidder seeking to acquire us would need, on a tender offer, to receive shareholder acceptance in respect of 80% of our outstanding shares. If this 80% threshold is not achieved in the offer, under Irish law, the bidder cannot complete a "second step merger" to obtain 100% control of us. Accordingly, tender of 80% of our outstanding shares will likely be a condition in a tender offer to acquire us, not 50% as is more common in tender offers for corporations organized under U.S. law; and

- under Irish law, shareholders may be required to disclose information regarding their equity interests upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on the transfer of the shares, as well as restrictions on voting, dividends and other payments.

Risks related to taxation

Changes in our effective tax rate may reduce our earnings in future periods.

We cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions in which we operate and the varying applications of statutes, regulations and related interpretations.

A number of factors may increase our future effective tax rates, including: the jurisdictions in which profits are determined to be earned and taxed (which may vary depending on our taxable presence in such jurisdictions as may be determined by tax authorities in such jurisdictions); the resolution of issues arising from tax audits that may be undertaken by various tax authorities; changes in the valuation of our deferred tax assets and liabilities due to changes in applicable tax legislation; increases in expenses that are not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; changes in available tax credits; changes in share-based compensation; changes in tax laws or the interpretation of such tax laws (including U.S. tax legislation enacted in 2017 or 2022 and current U.S. legislative proposals); changes to currently applicable tax treaties, including those resulting in a loss of treaty benefits; changes in GAAP; and challenges to the transfer pricing policies related to our structure undertaken by various tax authorities. Currently, jurisdictions within the Organization for Economic Co-Operation and Development, or the OECD, are reviewing OECD proposals relating to base erosion and profit shifting, or BEPS, including minimum tax proposals. Jurisdictions within the OECD and other countries have implemented or begun to implement OECD proposals related to BEPS. Our effective tax rate could be adversely affected by such OECD proposals or corresponding European Union directives (and the implementation of such proposals and directives).

It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become a resident for tax purposes in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a higher rate of tax in another jurisdiction and/or be subject to an exit tax charge on ceasing to be an Irish tax resident. Additionally, the tax laws of Ireland and other jurisdictions in which we operate could change in the future, and such changes could cause a material adverse change in our effective tax rate.

If our tax rates or tax expenses were to increase as described above, such increases could cause a material and adverse change in our worldwide effective tax rate and we may have to take action, at potentially significant expense, to seek to mitigate the effect of such changes. In addition, any amendments to the current double taxation treaties between Ireland and other jurisdictions could subject us to increased taxation. Any such amendments to double taxation treaties or increases in taxation based on examinations by taxing authorities, if such increases are ultimately sustained, could result in increased charges, financial loss, including penalties, and reputational damage and materially and adversely affect our results, financial condition and prospects.

If we are a passive foreign investment company, U.S. investors in our ordinary shares could be subject to adverse U.S. federal income tax consequences.

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. federal income tax purposes. We would be classified as a PFIC for any taxable year in which either: (i) at least 75% of our gross income is classified as ‘‘passive income’’ for purposes of the PFIC rules, or (ii) at least 50% of the fair market value of our assets (determined on the basis of a quarterly average) is attributable to assets that produce or are held for the production of ‘‘passive income.’’ For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation we own, directly or indirectly, 25% or more (by value) of its stock.

We do not believe that we were a PFIC for the 2022 taxable year, and, based upon our current and projected income and assets, and projections as to the value of our assets, we do not anticipate becoming a PFIC for the 2023 taxable year. However, no assurance can be given in this regard. In general, the application of the PFIC rules depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets, and the composition of our income) and the application of the PFIC rules (including the classification of assets and

income), which are subject to differing interpretations. Moreover, with respect to the current tax year a determination is only made annually after the end of the taxable year. In addition, the value of our assets for purposes of the asset test, including the value of our goodwill and other intangibles, may be determined by reference to the market price of our ordinary shares. Furthermore, the composition of our income and assets may also be affected by how quickly we spend any cash that is raised in any financing transaction or offering. If our ordinary shares are not treated as "publicly traded" within the meaning of applicable U.S. Treasury Regulations, our risk of becoming classified as a PFIC may increase. In light of the foregoing, no assurance can be provided that we have not been and will not be a PFIC for the current taxable year or that we will not become a PFIC for any future taxable year.

A U.S. Holder may be able to mitigate some of the adverse U.S. federal income tax consequences described above with respect to owning our ordinary shares if we are classified as a PFIC, provided that such U.S. Holder is eligible to make, and validly makes a "mark-to-market" election. In certain circumstances a U.S. Holder may be able to make a "qualified electing fund" or "QEF" election to mitigate some of the adverse tax consequences described below with respect to an ownership interest in a PFIC by including in income its share of the PFIC's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a qualified electing fund election. In any event, the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and any distributions such U.S. holders may be affected by making a timely qualified electing fund election if we provide the necessary information to such U.S. holders to make such election, or to a U.S. holder that makes a mark-to-market election

Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

U.S. holders of 10% or more of the voting power or value of our ordinary shares may be subject to U.S. federal income taxation at ordinary income tax rates on undistributed earnings and profits.

There is a risk that we will be classified as a ''controlled foreign corporation,'' or CFC, for U.S. federal income tax purposes. We will generally be classified as a CFC if more than 50% of our outstanding shares, measured by reference to voting power or value, are owned (directly, indirectly or by attribution) by ''U.S. Shareholders.'' For this purpose, a ''U.S. Shareholder'' is any U.S. person that owns directly, indirectly or by attribution, 10% or more of the total voting power or total value of our outstanding shares. If we are classified as a CFC, a U.S. Shareholder may be subject to U.S. income taxation at ordinary income tax rates on its proportionate share of our undistributed earnings and profits attributable to ''subpart F income'' or undistributed earnings and profits invested in certain U.S. property and may also be subject to tax at ordinary income tax rates on any gain realized on the sale of our ordinary shares, to the extent of our current and accumulated earnings and profits attributable to such shares. A U.S. Shareholder of a CFC is also required to include in gross income for a taxable year, at a reduced effective tax rate, its proportionate share of certain non-U.S. active business income of a CFC not included in a CFC's ''subpart F income,'' or ''global intangible low-taxed income,'' to the extent such CFC's ''tested income'' is in excess of 10% of the adjusted U.S. federal income tax basis of depreciable tangible assets used in the CFC's trade or business (reduced by a U.S. Shareholder's allocable net interest expense) and is not otherwise offset by any ''tested loss'' attributable to other CFCs owned by such U.S. Shareholder. Foreign taxes paid by a CFC attributable to the CFC's ''subpart F income'' and ''global intangible low-taxed income'' and any corresponding foreign tax credits may affect the amount of income includible in a U.S. Shareholder's gross income for U.S. tax purposes. Even if we are not classified as a CFC, certain of our non-U.S. subsidiaries are treated as (or could be treated) as CFCs due to the application of certain attribution rules that currently apply in determining CFC status. Any U.S. Shareholder of such non-U.S. subsidiaries may be required to report annually and include in its U.S. taxable income its pro rata share of ''subpart F income,'' ''global intangible low-taxed income'' and investments in U.S. property attributable to those non-U.S. subsidiaries. While we do not currently expect any such non-U.S. subsidiary that is currently treated as a CFC to generate material "subpart F income" or "global intangible low-taxed income," no assurance can be given in this regard. The CFC rules are complex and U.S. Shareholders and U.S. holders of our ordinary shares are urged to consult their own tax advisors regarding the possible application of the CFC, ''subpart F income,'' and ''global intangible low-taxed income'' rules (including applicable direct and indirect attribution rules) to them based on their particular circumstances.

A future transfer of your ordinary shares, other than one effected by means of the transfer of book entry interests in DTC, may be subject to Irish stamp duty.

Transfers of ordinary shares effected by means of the transfer of book entry interests in the DTC should not be subject to Irish stamp duty where ordinary shares are traded through DTC, either directly or through brokers that hold such shares on behalf of customers through DTC. However, if you hold your ordinary shares as of record rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty to arise could adversely affect the price of our ordinary shares.

General risk factors

We are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes.

We may be a party to legal proceedings, including matters involving securities liability, personnel and employment issues, intellectual property claims and other proceedings arising in the ordinary course of business. In addition, there are an increasing number of investigations and proceedings in the health care industry generally that seek recovery under the statutes and regulations identified in the section entitled "Business—Government Regulation and Approval Process." We evaluate our exposure to these legal proceedings and establish reserves for the estimated liabilities in accordance with generally accepted accounting principles, or GAAP. Assessing and predicting the outcome of these matters involves substantial uncertainties. Unexpected outcomes in these legal proceedings, or changes in our evaluation or predictions and accompanying changes in established reserves, could have a material adverse impact on our financial results. For more information on our material pending litigation, see the risk factor titled "Our competitors or other third parties may allege that we, our suppliers or partners are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial position and results of operations" and the section entitled "Legal Proceedings" herein.

Material weaknesses in our internal control over financial reporting have occurred in the past and could occur in the future.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting.

Maintaining effective internal control over financial reporting is necessary for us to produce reliable financial reports and is important to help prevent financial fraud. We have in the past and may in the future identify material weaknesses in our internal control over financial reporting. If we are unable to maintain adequate internal controls, our business and operating results could be harmed, we could be subjected to regulatory scrutiny, civil or criminal penalties or shareholder litigation, the defense of any of which could cause the diversion of management's attention and resources, we could incur significant legal and other expenses, and we could be required to pay damages as a result of such actions if any such actions were not resolved in our favor. Moreover, we may be the subject of negative publicity focusing on a material weakness and we may be subject to negative reactions from shareholders and others with whom we do business. Further, we may not be able to remediate a future material weakness in a timely manner and our management may be required to devote significant time and expense to remediate any such material weakness. Failure to maintain adequate internal control over financial reporting could also result in financial statements that do not accurately reflect our financial condition or results of operations, which could result in the need to restate previously issued financial statements. There can be no assurance that we will not identify any significant deficiencies or other material weaknesses in the future that will impair our ability to report our financial condition and results of operations accurately or on a timely basis. In addition, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting in future periods, investors may lose confidence in the accuracy and completeness of our financial reports.

We have in the past identified errors in our financial statements, which required us to restate those financial statements. If we identify errors in our financial reporting in the future, we may be required to restate previously issued financial statements and any such restatement may subject us to regulatory penalties and could cause investors to lose confidence in the accuracy and completeness of our financial statements.

In connection with the preparation of the prospectus for our initial public offering, we identified errors in our financial statements for the years ended December 31, 2016 and 2017 related to our accounting for certain aspects of a business combination. The required adjustments to address these errors led to restatements of those financial statements. In addition, we had to correct certain misstatements in our annual and interim financial statements for 2018 and 2019 related to misstatements associated with the tax treatment of certain intercompany transactions at the time of the business combination. Additionally, as previously reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2019, revisions were necessary to correct misstatements related to uncertain tax positions and prepaid taxes and certain other previously identified immaterial misstatements. If we are required to restate any of our financial statements in the future due to our inability to adequately remedy the issues that gave rise to these restatements or for any other reason, we may be subject to regulatory penalties and investors could lose confidence in the accuracy and completeness of our financial statements, which could cause our share price to decline.

Our operating results are affected by many factors and may fluctuate significantly on a quarterly basis.

Our operating results may vary substantially from quarter to quarter and may be greater or less than those achieved in the immediately preceding period or in the comparable period of the prior year. Factors that may cause quarterly results to vary include, but are not limited to, the following:

- our ability to create demand in the marketplace for Upneeq;
- losses related to inventory write-offs;
- marketing exclusivity, if any, for Upneeq;
- the level of competition in the marketplace;
- the likelihood or ability of customers to pay the price at which we offer Upneeq;
- availability of raw materials and finished products from suppliers;
- the ability of our third party contract manufacturers to produce Upneeq in a timely and cGMP compliant manner;
- the scope and outcome of governmental regulatory actions;
- our dependence on Upneeq for a significant portion of total revenues or income; and
- legal actions asserting intellectual property rights against our product brought by competitors and legal challenges to our intellectual property rights brought against us by our competitors; price erosion and customer consolidation; and significant payments (such as milestones) payable by us under licensing and development agreements to our partners before the related product has received FDA approval.

The profitability of our product sales is also dependent upon the prices we are able to charge for our product, the costs to purchase products from third parties and our ability to have our product manufactured in a cost-effective manner. If our total revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of total revenues could, therefore, significantly harm our business and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located in Bridgewater, New Jersey, where we lease approximately 7,300 square feet of office space pursuant to a sub-lease that expires in November 2023. We also lease approximately 5,200 square feet of space in Sayreville, New Jersey, from which we operate RVL Pharmacy, pursuant to a lease that expires in December 2026. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to various legal proceedings. In addition, we have in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which exposes us to greater risks associated with litigation, regulatory or other proceedings, including significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us.

In general, we intend to continue to vigorously prosecute and defend any proceedings, as appropriate; however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations and legal proceedings, individually or in the aggregate, could have a material adverse effect on our business, results of operations and cash flows in any given accounting period or on our overall financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our ordinary shares began trading October 18, 2018. Our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "RVLP."

As of March 20, 2023, there were three registered holders of record of our ordinary shares.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Dividend Policy

We have never declared nor paid cash dividends on our ordinary shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our ordinary shares in the foreseeable future. Any future determination to pay cash dividends will be made at the discretion of our board of directors and will depend on restrictions and other factors our board of directors may deem relevant. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

No ordinary shares were purchased by or on behalf of RVL Pharmaceuticals plc or any "affiliated purchaser," as defined by Rule 10b-18(a)(3) of the Securities Exchange Act of 1934 during the year ended December 31, 2022.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The statements in the discussion and analysis regarding industry outlook, our expectations regarding the performance of our business and the forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." Our actual results may differ materially from those contained in or implied by any forward-looking statements. You should read the following discussion together with the sections entitled "Risk Factors," "Business" and the audited Consolidated Financial Statements, including the related notes, appearing elsewhere in this Annual Report on Form 10-K. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. As used in this Annual Report on Form 10-K, unless the context suggests otherwise, "we," "us," "our," "the Company" or "RVL" refer to RVL Pharmaceuticals plc (formerly Osmotica Pharmaceuticals plc) and subsidiaries. This discussion and analysis is based upon the historical financial statements of RVL Pharmaceuticals plc and subsidiaries appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products that target markets with underserved patient populations in the ocular medicine and medical aesthetics therapeutic areas.

In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or droopy or low-lying eyelids in adults. We believe Upneeq is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis. We launched Upneeq in September 2020 to a limited number of eye care professionals with commercialization operations expanded in 2021 among ophthalmology, optometry and oculoplastic specialties. In February 2022, Upneeq was commercially expanded into the medical aesthetics market in the United States. Patients may purchase Upneeq either from eye care or medical aesthetic professionals, or exclusively through RVL Pharmacy, LLC, our wholly-owned pharmacy.

We acquired Upneeq as part of our asset acquisition of RevitaLid, Inc., now known as RVL Pharmaceuticals, Inc., in 2017. As part of the acquisition, we agreed to make future earn-out, milestone and royalty payments based on net sales and regulatory developments with respect to Upneeq. Upneeq is manufactured and supplied to us by Nephron Pharmaceuticals Corporation under an exclusive supply agreement that has a term of five years from the production of the initial commercial batches, and automatically renews for additional one-year periods unless either party provides at least 90 days' advance written notice of non-renewal.

On July 28, 2020, we entered into a license agreement with Santen Pharmaceutical Co. Ltd ("Santen"), granting Santen exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as Europe, the Middle East and Africa ("EMEA") countries (the "License Agreement"). Santen is responsible for further development of RVL-1201 in the licensed territories. Under the License Agreement, we have received an upfront payment of $25.0 million in 2020 and a license milestone payment of $10.0 million in 2021. On March 29, 2022, we amended the License Agreement, effective March 31, 2022 (as amended, the "Amended License Agreement"), and received $15.5 million to expand the licensed territories to include certain additional EMEA countries and Canada and remove certain regulatory approval milestones from the License Agreement. Under the Amended License Agreement, we may receive additional payments of up to $31.0 million based on development, regulatory and sales milestone payments in Santen's territories. In addition, during the first five years following the effective date of the Amended License Agreement, Santen was granted an option to expand the territories to include Russia, subject to additional upfront and milestone payments of $2.0 million and $1.0 million, respectively. Further, under the terms of the Amended License Agreement, if we desire to enter into an agreement to license certain rights related to the Amended License Agreement to a third party in Russia, then Santen will have a right to exercise an option to expand the territories to include Russia or to match the terms of the agreement with the third party. We are also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories. See Note 5, "*Revenues*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our License Agreement with Santen.

On August 27, 2021, we announced the closing of the divestiture of our portfolio of branded and non-promoted products and our Marietta, Georgia, manufacturing facility (collectively, the "Legacy Business"), to certain affiliates of Alora Pharmaceuticals, LLC ("Alora") for $111.0 million in cash upon closing, subject to certain post-closing adjustments, and up to $60.0 million in contingent milestone payments. Pursuant to the divestiture, we retained the rights to Upneeq and to arbaclofen ER tablets, which is under development for the treatment of spasticity in multiple sclerosis. During the year ended December 31, 2022, we received an aggregate of $5.0 million in cash from Alora related to contingent milestone payments earned in connection with the sale of the Legacy Business.

With the divestiture of the Legacy Business, our commercial operations are conducted by our wholly-owned subsidiary, RVL Pharmaceuticals, Inc. and its subsidiary RVL Pharmacy, LLC ("RVL Pharmacy"). RVL Pharmacy exclusively conducts pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

Following the divestiture of the Legacy Business, we are exploring opportunities to sell or out-license our late-stage product candidate arbaclofen ER tablets designed for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis for which we have completed Phase III clinical trials. In June 2020, we resubmitted our NDA for arbaclofen ER tablets to the FDA. On July 17, 2020, we received notice from the FDA that it considered the resubmission a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020. On December 28, 2020, we received a complete response letter ("CRL") indicating the FDA could not approve the NDA in its then current form. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in the Total

Numeric-transformed Ashworth Scale in the most affected limb ("TNmAS-MAL") scores comparing arbaclofen ER 40 mg to placebo, one of the co-primary endpoints. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL's recommendations and obtain advice on a path forward for the NDA. The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a special protocol assessment ("SPA"), to the FDA proposing an additional clinical study for arbaclofen ER. The FDA responded in a letter dated October 15, 2021, indicating that they are unable to issue an agreement on the submitted protocol. On October 10, 2022, we resubmitted a SPA and on November 24, 2022, we received a letter from the FDA indicating that they were unable to issue an agreement on the SPA. On February 8, 2023, we resubmitted a SPA with a revised study protocol and statistical analysis.

Business Update Regarding COVID-19

The COVID-19 pandemic presented a substantial public health and economic challenge around the world. We launched our commercial activities for Upneeq and began engaging with eye care providers to promote Upneeq in September 2020 and have since expanded our field sales force into the medical aesthetics market. In some instances our sales force encountered challenges engaging with healthcare professionals during the pandemic. Although most areas of the United States have re-opened, restrictions on access to offices and other commercial facilities may be reinstated as a result of concerns about the spread of new variants, which may have the potential to affect our ability to conduct our business and the ability of patients to visit their eye care providers and medical aesthetics clinics.

To date, we have been able to continue to supply Upneeq to patients and healthcare professionals without significant disruption, and we do not currently anticipate significant interruption in the near term. Additionally, our third-party contract manufacturing partner for Upneeq has been able to operate its manufacturing facility at or near normal levels. We currently do not anticipate significant interruptions in our manufacturing supply chain due to COVID-19.

In the U.S., our office-based employees have been permitted to work from home since mid-March 2020. During this time, we are ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our pharmacy.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in this Annual Report on Form 10-K.

Financial Operations Overview

Segment Information

We currently operate in one business segment focused on the commercialization and development of specialty pharmaceutical products that target markets with underserved patient populations. We are not organized by market and are managed and operated as one business. We also do not operate any separate lines of business or separate business entities with respect to Upneeq. A single management team reports to our chief operating decision maker who comprehensively manages our entire business. Accordingly, we do not accumulate discrete financial information with respect to separate product lines and do not have separately reportable segments. See Note 2, "*Summary of Significant Accounting Policies,*" to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Components of Results of Operations

Revenues

Our revenues consist of product sales, royalty revenues and licensing revenue.

Net product sales—Our net product revenues consist of sales of Upneeq. RVL Pharmacy ships Upneeq to our customers pursuant to prescriptions; however, in certain cases where our state pharmacy licenses are pending prescriptions are fulfilled by a third-party pharmacy partner. We refer to these sales as Pharmacy Sales. Additionally, Upneeq is sold directly to physician practices in certain states which permit physicians to dispense Upneeq in their offices or directly to telemedicine partners. We refer to these sales as Direct Dispense sales. Predominately, we collect payment in advance from our customers. From time to time, we may invoice a customer after the products have been delivered in which case payments are typically due within 30 days. We recognize revenue when control has transferred to the customer, which is typically upon delivery to the customer, the physician or the partner as the case may be. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which largely consists of discounts and disputed chargebacks, at the time revenues are recognized.

Royalty revenue—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

Licensing revenue—For license arrangements with commercial partners that include payments based on the achievement of regulatory approvals or other non-sales milestone, revenue is recognized when the performance obligation identified in the arrangement is completed.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel expenses, including salaries and benefits for employees in executive, sales, marketing, finance, accounting, business development, legal, information technology and human resource functions. General and administrative expenses also include corporate facility costs, including rent, utilities, insurance, legal fees related to corporate matters, share based compensation, fees for accounting and other consulting services, including public company costs associated with the preparation of our SEC filings, legal and accounting costs, investor relations costs, director and officer liability insurance costs, as well as costs related to compliance with laws and regulations, including the Sarbanes-Oxley Act of 2002, and the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Research and Development Expenses

Costs for research and development are charged as incurred and include employee related expenses (including salaries and benefits, share based compensation, travel and expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies), costs associated with preclinical activities and development activities and costs associated with quality and regulatory operations.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in our Consolidated Financial Statements as prepaid expenses or accrued expenses as applicable.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

Financial Operations Overview

The following table presents revenues and expenses from continuing operations for the periods indicated (dollars in thousands):

	Year Ended December 31,		
	2022	2021	% Change
Net product sales	$ 34,221	$ 7,511	356 %
Royalty and licensing revenue	15,500	9,990	55 %
Total revenues	49,721	17,501	184 %
Cost of goods sold	9,456	3,618	161 %
Gross profit	40,265	13,883	190 %
Gross profit percentage	81 %	79 %	
Selling, general and administrative expenses	81,979	87,463	(6)%
Research and development expenses	3,966	6,930	(43)%
Impairments of intangible assets	13,310	7,880	69 %
Total operating expenses	99,255	102,273	(3)%
Gain on sales of product rights, net	—	5,636	(100)%
Operating loss	(58,990)	(82,754)	(29)%
Interest expense and amortization of debt discount	3,110	3,036	2 %
Change in fair value of debt and interest expense	(2,857)	982	391 %
Change in fair value of warrants	(1,269)	(5,571)	(77)%
Other non-operating (income) expense, net	(6,262)	1,333	570 %
Total other non-operating income	(7,278)	(220)	3,208 %
Loss before income taxes	(51,712)	(82,534)	(37)%
Income tax (benefit) expense, continuing operations	(20)	315	106 %
Loss from continuing operations	(51,692)	(82,849)	(38)%
Gain on sales of discontinued operations	—	4,062	(100)%
Income from discontinued operations before income taxes	—	13,570	(100)%
Income tax benefit, discontinued operations	—	297	(100)%
Income from discontinued operations, net of tax	—	17,929	(100)%
Net loss	$ (51,692)	$ (64,920)	(20)%

Revenues

The following table presents total revenues for the periods indicated (dollars in thousands):

	Year Ended December 31,		
	2022	2021	% Change
Net product sales - Upneeq	$ 34,221	$ 7,511	356 %
Royalty and licensing revenue	15,500	9,990	55 %
Total revenues	$ 49,721	$ 17,501	184 %

Total Revenues. Total revenues increased by $32.2 million to $49.7 million for the year ended December 31, 2022, from $17.5 million for the year ended December 31, 2021 primarily due to higher volumes of Upneeq sold and higher licensing revenue from Santen.

Net Product Sales. Net product sales increased by $26.7 million to $34.2 million for the year ended December 31, 2022, as compared to $7.5 million for the year ended December 31, 2021, primarily due to higher volumes of Upneeq sold, reflecting expanded commercialization into eye care markets and, effective February 2022, the medical aesthetics market.

Royalty and Licensing Revenue. Royalty and licensing revenue increased by $5.5 million to $15.5 million for the year ended December 31, 2022, as compared to $10.0 million for the year ended December 31, 2021, primarily due to changes in milestone revenues recognized under our License Agreement with Santen. See Note 5, "*Revenues*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our License Agreement with Santen.

Cost of Goods Sold and Gross Profit Percentage

The following table presents a breakdown of total cost of goods sold for the periods indicated (dollars in thousands):

	Year Ended December 31,		
	2022	2021	% Change
Royalty expense	$ 2,753	$ 487	465 %
Depreciation expense	55	55	— %
Other costs of goods sold	6,648	3,076	116 %
Total costs of goods sold	$ 9,456	$ 3,618	161 %

Total cost of goods sold increased by $5.9 million to $9.5 million for the year ended December 31, 2022, as compared to $3.6 million for the year ended December 31, 2021. The year over year increase in cost of goods sold was primarily driven by $3.7 million in higher product costs for Upneeq due to higher sales volume and by $2.3 million relating to increased royalties and contingent milestone payments due under an intellectual property license agreement, each attributable to sales of Upneeq.

Gross profit percentage was 81% for the year ended December 31, 2022 compared to 79% for the year ended December 31, 2021, primarily due to higher licensing revenues in 2022 compared to 2021. Excluding licensing revenues, gross profit percentage from net product sales was 72% and 52% in the 2022 and 2021 periods, respectively, reflecting improved overhead absorption driven by higher volumes and more favorable average selling prices in the 2022 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $5.5 million to $82.0 million for the year ended December 31, 2022, as compared to $87.5 million for the year ended December 31, 2021. The year over year decrease in selling, general and administrative expenses was primarily influenced by $8.4 million in lower legal and other professional fees, $2.4 million in lower share-based compensation expense, $1.1 million in lower debt and equity issuance and transactional fees and $0.7 million in lower restructuring related expenditures, partially offset by $6.9 million in higher net compensation costs primarily for our expanded salesforce and $0.8 million of higher credit card fees.

Selling, general and administrative expenses for the years ended December 31, 2022 and 2021 include various restructuring-related expenditures, including severance, of $2.9 million and $3.5 million, respectively, and share-based compensation expenses of $3.4 million and $5.8 million, respectively.

See Notes 19, "*Restructuring Expenses*," and 14, "*Share-Based Compensation*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Research and Development Expenses

The following table summarizes our research and development ("R&D") expenses incurred for the periods indicated (dollars in thousands):

	Year Ended December 31,		
	2022	2021	% Change
Arbaclofen ER	$ 177	$ 702	(75)%
RVL-1201 (Upneeq)	513	1,198	(57)%
Other research and development	3,276	5,030	(35)%
Total research and development expenses	$ 3,966	$ 6,930	(43)%

R&D expenses decreased by $2.9 million to $4.0 million for the year ended December 31, 2022, as compared to $6.9 million for the year ended December 31, 2021. The year over year decrease in R&D expenses primarily reflects $1.2 million in lower project spending, $0.3 million in lower share-based compensation expense and $1.2 million in restructuring expenses particular to the 2021 period.

R&D expenses include share-based compensation expenses of $0.6 million and $0.9 million for the years ended December 31, 2022 and 2021, respectively.

Impairments of Intangible Assets

Based on the results of quantitative impairment assessments performed relative to arbaclofen ER, an in-process research and development project-based intangible asset, we recognized impairment charges of $13.3 million and $7.9 million for the years ended December 31, 2022 and 2021, related to delays in anticipated commercialization of the product candidate, if approved.

See Note 9, "*Goodwill and Indefinite-Lived Intangible Assets*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our impairments.

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount increased by less than $0.1 million to $3.1 million in the year ended December 31, 2022, as compared to $3.0 million in the year ended December 31, 2021. The year over year increase was attributable to our recognition of $3.1 million of amortization expense from the second tranche financial commitment asset, particular to the 2022 period, substantially offset by the absence of interest expense in the 2022 period in this caption.

Beginning in the fourth quarter of 2021, our recognition of interest expense on our Senior Secured Notes has been classified within the separate caption titled "Change in fair value of debt and interest expense" pursuant to our elections related to fair value accounting (see "Change in Fair Value of Debt and Interest Expense and Change in Fair Value of Warrants" section below).

See Note 12, "*Financing Arrangements*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our indebtedness.

Change in Fair Value of Debt and Interest Expense and Change in Fair Value of Warrants

Changes in the fair value of our Senior Secured Notes and warrants, each newly issued in October 2021, resulted in gains of $2.9 million and $1.3 million, respectively, for the year ended December 31, 2022 and (losses) gains of $(1.0) million and $5.6 million, respectively, for the year ended December 31, 2021. Changes in the fair value of our Senior Secured Notes includes $7.1 million and $1.3 million of related interest expense for the 2022 and 2021 periods, respectively.

See Note 21, "*Financial Instruments and Fair Value Measurements*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on our recurring fair value measurements.

Other Non-operating (Income) Expense, Net

Other non-operating (income) expense, net was $(6.3) million and $1.3 million for the years ended December 31, 2022 and 2021, respectively. Non-operating income in the 2022 period was primarily attributable to our receipt of an aggregate of $5.0 million in cash from Alora related to contingent milestone payments earned in connection with the sale of the Legacy Business. Non-operating expense in the 2021 period was primarily attributable to $1.3 million of asset disposal costs related to asset disposal costs recognized under a restructuring program.

See Notes 4, "*Discontinued Operations*," and 22, "*Subsequent Events*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on the Alora contingent milestone payments.

Income Tax (Benefit) Expense

The following table summarizes our income tax (benefit) expense and effective tax rate for the periods indicated (dollars in thousands):

	Year Ended December 31,	
	2022	2021
Loss before income taxes, continuing operations	$ (51,712)	$ (82,534)
Income tax (benefit) expense, continuing operations	(20)	315
Effective income tax rate	0.04 %	(0.38)%

Income tax (benefit) expense decreased by $0.3 million to less than $(0.1) million benefit for the year ended December 31, 2022, from $0.3 million expense for the year ended December 31, 2021, primarily related to our recognition of individually minor net income taxes during the respective periods.

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents and borrowings available under our Note Purchase Agreement. Our primary uses of cash are to fund operating expenses, including commercialization costs associated with Upneeq, capital expenditures, and debt service payments.

Our Note Purchase Agreement provides for the issuance of Senior Secured Notes in an aggregate principal amount of up to $100.0 million in three separate tranches. The first tranche of Senior Secured Notes, initially issued by the Company to Athyrium Opportunities IV Acquisition 2 LP and subsequently assigned to Athyrium Opportunities IV Acquisition LP, was in an aggregate principle amount equal to $55.0 million on October 12, 2021. The second tranche of Senior Secured Notes was issued by the Company to Athyrium Opportunities IV Co-Invest 1 LP (the "New Purchaser") in an aggregate principle amount equal to $20.0 million on August 8, 2022. At any time prior to April 15, 2023, upon the satisfaction of certain conditions, including a minimum liquidity requirement and minimum net product sales target for Upneeq, we may request the issuance of the third tranche Senior Secured Notes in an aggregate principal amount of up to $25.0 million.

The Senior Secured Notes bear interest at an annual rate of 9.0% plus adjusted three-month term SOFR, with a floor of 1.50% and a cap of 3.00%, payable in cash quarterly in arrears. At December 31, 2022, the interest rate on our Senior Secured Notes was 12.0%, at the adjusted three-month term SOFR cap. In the year ended December 31, 2022, we obtained waivers from the applicable purchasers under the Note Purchase Agreement of mandatory repayments of an aggregate of $5.0 million in principal of the Senior Secured Notes as otherwise required under the Note Purchase Agreement in exchange for a consent fee of $0.2 million, resulting in net retained proceeds of $4.8 million.

The restrictive covenants in the Note Purchase Agreement require us to comply with certain minimum liquidity requirements and minimum quarterly net product sales requirements. Under the terms of the Note Purchase Agreement, we are required to maintain unrestricted cash and cash equivalents in an amount greater than or equal to $12.5 million and, as of the end of each fiscal quarter, we are required to maintain consolidated Upneeq net product sales greater than or equal to specified quarterly thresholds (currently at $7.0 million for the fiscal quarter ending March 31, 2023, and increasing in $1.0 million increments each quarter thereafter until the quarter ending June 30, 2024, for which quarter and all subsequent quarters the threshold is $12.0 million). At December 31, 2022, we were in compliance with all covenants under the Note Purchase Agreement. See Notes 12, "*Financing Arrangements*," and 22, "*Subsequent Events*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

On August 4, 2022, we entered into a series of share subscription agreements the ("2022 Share Subscription Agreements") with Athyrium Opportunities IV Co-Invest 2 LP, Avista Healthcare Partners, L.P., Brian Markison and James Schaub (together, the "Equity Purchasers"), pursuant to which we agreed to sell and issue to the Equity Purchasers, in a private placement, 15,451,612 ordinary shares in the aggregate (the "2022 PIPE Shares"). On August 8, 2022, we issued and sold to the Equity Purchasers the 2022 PIPE Shares at a purchase price of $1.55 per ordinary share for aggregate gross proceeds to us of approximately $24 million, before deducting offering expenses payable by us.

On October 12, 2021, we completed a follow-on offering and issued and allotted 14,000,000 ordinary shares and warrants to purchase up to 14,000,000 ordinary shares, at a public offering price of $2.50 per share and accompanying warrant. The aggregate net proceeds from the follow-on offering were approximately $32.5 million after deducting underwriting commissions and offering expenses. See Note 20, "*Shareholders' Equity and Warrant Liabilities*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Going Concern

At December 31, 2022, we had cash and cash equivalents of $44.5 million, an accumulated deficit of $569.2 million and total long-term debt with aggregate principal amounts of $75.0 million, with such maturities commencing in March 2024 and extending through October 2026. In addition, our primary indebtedness contains various restrictive covenants including minimum liquidity and minimum quarterly product sales requirements. For the years ended December 31, 2022 and 2021, we incurred net losses from continuing operations of $51.7 million and $82.8 million, respectively, and used $37.8 million and $54.7 million, respectively, in cash from operating activities.

The divestiture of the Legacy Business in 2021 resulted in the loss of substantially all of our revenue generating assets. Our current business plan is focused on the continued commercialization and growth of Upneeq, which has and will continue to diminish our cash flows in at least the near term. We will require additional capital to fund our operating needs, including the expanded commercialization of Upneeq and other activities. We expect to incur significant expenditures and sustain operating losses in the future.

We do not believe that current sources of liquidity will be sufficient to fund our planned expenditures and meet our obligations, including the minimum liquidity covenant, for at least 12 months following the date the Consolidated Financial Statements contained in this Annual Report on Form 10-K are issued without raising additional funding. As a result, there is a substantial doubt as to our ability to operate as a going concern. If we are not successful in executing our strategic plans described below, we expect that our current cash on hand, together with the net proceeds of anticipated sales of Upneeq, may not be sufficient to meet the minimum liquidity covenant through the end of the third quarter of 2023. Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

Our plans to address these conditions include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or is entirely within our control, i) raise funds through additional sales of ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings, ii) raise funds through borrowings under new and/or existing debt facilities and/or convertible debt, and/or iii) raise non-dilutive funds through product collaborations and/or to partner or sell a portion or all rights to any of our assets.

There can be no assurance that we will receive cash proceeds from any of these potential sources or, to the extent cash proceeds are received, such proceeds would be sufficient to support our current operating plan for at least the next 12 months from the date the Consolidated Financial Statements contained in this Annual Report on Form 10-K are issued. The sale of additional equity or convertible debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred shares, these securities could provide for rights senior to those of our ordinary shares and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

The Consolidated Financial Statements contained in this Annual Report on Form 10-K have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business, and therefore do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Cash Flows

The following table provides information regarding our consolidated cash flows, including our continuing operations and discontinued operations, for the periods indicated (dollars in thousands):

	Year Ended December 31,		
	2022	2021	$ Change
Net cash used in operating activities	$ (37,810)	$ (54,732)	$ 16,922
Net cash provided by investing activities	126	116,453	(116,327)
Net cash provided by (used in) financing activities	41,783	(135,330)	177,113
Net increase (decrease) in cash and cash equivalents	$ 4,099	$ (73,609)	$ 77,708

Net cash from operating activities

Cash flows from operating activities are primarily driven by earnings from operations (excluding the impact of non-cash items), the timing of cash receipts and disbursements related to accounts receivable and accounts payable and the timing of inventory transactions and changes in other working capital amounts. Net cash used in operating activities was $37.8 million and $54.7 million for the years ended December 31, 2022 and 2021. The decrease in cash used in operating activities was primarily as a result of lower net loss after considering non-cash adjustments and from a favorable change in net cash used to fund working capital assets and liabilities.

Net cash from investing activities

Net cash provided by investing activities was $0.1 million and $116.5 million for the years ended December 31, 2022 and 2021, respectively. The decrease in cash from investing activities was primarily attributable to proceeds of $110.8 million from the disposition of the Legacy Business in August 2021 and $7.3 million from the sale of Osmolex product rights in January 2021, each particular to the 2021 period, partially offset by lower purchases of property, plant and equipment in the 2022 period.

Net cash from financing activities

Net cash provided by financing activities of $41.8 million for the year ended December 31, 2022, largely reflects financing transactions that raised $43.9 million in proceeds, comprised of $23.9 million in aggregate gross proceeds from the private placement of ordinary shares and, concurrently, $20.0 million from the issuance of second tranche Senior Secured Notes. Net cash used in financing activities of $135.3 million for the year ended December 31, 2021, largely reflected $221.4 million of debt repayments under a prior credit agreement, partially offset by net proceeds from the issuance of first tranche Senior Secured Notes, ordinary shares and warrants and insurance financing loans.

See Notes 12, "*Financing Arrangements*," and 20, "*Shareholders' Equity and Warrant Liabilities*," of our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for additional information on the above referenced financing activities.

Critical Accounting Estimates

The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported throughout the financial statements. Those estimates and assumptions are based on our best estimates and judgment. We evaluate our estimates and assumptions on an ongoing basis using historical experience and known facts and circumstances. We adjust our estimates and assumptions when we believe the facts and circumstances warrant an adjustment. As future events and their effects cannot be determined with precision, actual results could differ significantly from those estimates.

We consider the policies and estimates discussed below to be critical to an understanding of our financial statements because their application places the most significant demands on our judgment. Specific risks for these critical accounting policies are described in the following sections. For all these policies, we caution that future events rarely develop exactly as forecast, and such estimates naturally require adjustment.

Our discussion of critical accounting policies and estimates is intended to supplement, not duplicate, our summary of significant accounting policies so that readers will have greater insight into the uncertainties involved in these areas. For a summary of all our significant accounting policies see Note 2, "*Basis of Presentation and Summary of Significant Accounting Policies*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Testing Goodwill and Indefinite-Lived Intangible Assets for Impairment

Subsequent to the divestiture of the Legacy Business, we continue to carry significant amounts of goodwill from prior acquisitions and substantial value for an indefinite-lived in-process research and development, or IPR&D, intangible asset relating to arbaclofen ER on our balance sheet. At December 31, 2022, the combined carrying value of goodwill and indefinite-lived intangible assets, net of impairment charges, was $69.8 million or 54% of our total assets. See Note 9, "*Goodwill and Other Intangible Assets*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

On October 1 of each year, we perform annual impairment testing of our goodwill and indefinite-lived intangible assets, or more frequently whenever an event or change in circumstance occurs that would require reassessment of the recoverability of those assets. The impairment analysis for goodwill and indefinite-lived intangible assets consists of an optional qualitative test potentially followed by a quantitative analysis. These measurements rely upon significant judgment from management described as follows:

- The qualitative analysis for goodwill and indefinite-lived intangible assets requires us to identify potential factors, including, but not limited to, changes, if any, in our market capitalization, carrying values, the status of regulatory and commercial success risks, competitive trends or related cash flow projections that may result in an impairment and estimate whether such factors would warrant performance of a quantitative test;

- The quantitative goodwill impairment test, when performed, requires us to estimate the fair value of our single reporting unit. We estimate the fair value of our reporting unit using a weighted average of up to three valuation methods based on discounted cash flows, market multiples and/or market references. These valuation methods require management to make various assumptions, including, but not limited to, future profitability, cash flows, discount rates, weighting of valuation methods and the selection of comparable publicly traded companies; and

- The quantitative test for indefinite-lived intangible assets, when performed, is determined using a discounted cash flow model that necessitates the development of estimated net cash flows for each asset, the appropriate discount rate to select for each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. IPR&D assets are also subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development.

Our estimates are based on historical trends, management's knowledge and experience and overall economic factors, including projections of future earnings potential. Developing future cash flows in applying the income approach requires us to evaluate our intermediate to longer-term strategies, including, but not limited to, estimates about sales growth, operating margins, capital requirements, inflation and working capital management. The development of appropriate rates to discount the estimated future cash flows requires the selection of risk premiums, which can materially impact the present value of future cash flows. Selection of an appropriate peer group and/or market reference transactions under the market approach involves judgment, and an alternative selection of guideline companies or market references could yield materially different market multiples. Weighing the different value indications involves judgment about their relative usefulness and comparability to the reporting unit. A variety of the above-referenced valuation assumptions are based on significant inputs not observable in the market and thus our quantitative tests, when performed, represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease the resulting estimated fair values and the amounts of related impairments, if any.

There was no impairment of goodwill during the years ended December 31, 2022 and 2021. Concurrent with the divestiture of our Legacy Business in August 2021, goodwill of $45.0 million was allocated based on relative fair value of the Legacy Business. As a result, $55.8 million in goodwill remains on our balance sheet at December 31, 2022. A sustained decline in our market capitalization, even if due to macroeconomic or industry-wide factors, could put pressure on the carrying value of our goodwill and cause us to conduct additional impairment tests.

Based on the results of IPR&D impairment assessments performed relative to arbaclofen ER, we recognized impairment charges of $13.3 million and $7.9 million during the years ended December 31, 2022 and 2021, respectively, related to delays in anticipated commercialization of the product candidate, if approved. At December 31, 2022, $13.9 million in indefinite-lived IPR&D intangible assets remains on our balance sheet. The use of any different valuation inputs would have increased or decreased our recognized impairment charges. Further delays in the anticipated timing of commercialization of arbaclofen ER and/or material changes in legal, market and/or regulatory risks may cause us to conduct additional impairment tests.

A determination that all or a portion of our goodwill and/or IPR&D asset is impaired, although a non-cash charge to operations, could have a material adverse effect on our business, consolidated financial condition and results of operations.

Calculating Expense for Share-Based Compensation Arrangements

Our employees and directors have received various long-term compensation awards, including from time-to time, stock options, restricted stock units, performance stock units, and other share-based awards. We calculate expense for some of those awards using fair value estimates based on significant unobservable inputs. See Note 14, "*Share-Based Compensation*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

During the year ended December 31, 2022 we recognized $4.0 million of aggregate share compensation expense. During the year ended December 31, 2021 we recognized $7.0 million of aggregate share compensation expense, which included, the acceleration of the vesting of certain stock options and restricted stock units and all performance stock units under our incentive compensation plans in connection with the divestiture of the Legacy Business.

At December 31, 2022, there were approximately:

- 2.5 million stock options outstanding under the 2018 Equity Incentive Plan, with aggregate unrecognized share compensation expense related to unvested awards of $1.2 million, which is expected to be recognized over a weighted-average remaining service period of 1.6 years; and
- 1.0 million restricted stock units outstanding under the 2018 Equity Incentive Plan, with aggregate unrecognized share compensation expense related to unvested awards of $1.9 million, which is expected to be recognized over a weighted-average remaining service period of 1.5 years.

Share compensation expense is measured at the date of grant, based on the fair value of an award and recognized ratably over its vesting term, which is generally the vesting period on a graded vesting basis. We determine the fair value of restricted stock units based on the market price of our ordinary shares at the grant date, which is objectively determinable and not subject to significant unobservable inputs.

We estimate the grant date fair value of stock options and performance stock units using a Black-Scholes Merton option-pricing model and a Monte Carlo simulation model, respectively. The assumptions used in our models represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. The most significant unobservable input is the volatility of our stock price. A public quotation was first established for our ordinary shares in October 2018, which often does not provide us with an adequate historical basis to reasonably estimate the expected volatility of our ordinary shares over the expected life of an award. Accordingly, we generally estimate volatility based on a weighting of our own stock price volatility and/or the historical stock price trends of similar entities within our industry over a period of time commensurate with the expected term.

The fair value of our stock options and performance stock units would have differed had we selected different peers, assigned different weighting assumptions between our own and peer volatility or used different techniques to estimate volatility.

Increasing our estimated volatility assumption by 500 basis points, or 5 percent, for all stock options issued in 2022 at the date of grant would increase our 2022 share compensation expense by an immaterial amount and also increase our aggregate unrecognized share compensation cost related to unvested awards at December 31, 2022 by an immaterial amount.

Estimating the Value of Financial Instruments Remeasured at Fair Value on a Recurring Basis

Our Senior Secured Notes, a material component of long-term debt, and warrants, as reflected within warrant liabilities, a material component of total liabilities, have each been measured and carried at fair value since their issuance in October 2021. Changes in the estimated fair value of such instruments are recognized as a non-cash gain or loss in the consolidated statements of operations and comprehensive loss. Such instruments represent financial liabilities whose

measurement contains significant unobservable inputs, which management considers to be Level 3 measurements under the fair value hierarchy. See Note 21, "*Financial Instruments and Fair Value Measurements*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Changes in the fair value of our Senior Secured Notes and warrants during the year ended December 31, 2022 resulted in gains recognized through earnings of $2.9 million and $1.3 million, respectively, with a resultant fair value at December 31, 2022 of $(55.5) million and $(2.0) million, respectively.

We use a discounted cash flow technique, an income-based approach, to determine the fair value of the Senior Secured Notes. This technique relies upon an assumption of pricing the Senior Secured Notes to their maturity (without mandatory or voluntary prepayments) and incorporates inputs such as contractual repayment terms, maturity, and discount rate. The most significant unobservable input for the Senior Secured Notes is the discount rate which we estimate by performing a yield analysis that relies upon the discount rate observed in the initial issuance of the Senior Secured Notes as well as certain benchmark debt instruments with observable pricing from which we draw conclusions on the change in the discount rate from period to period.

We use the Black-Scholes Merton option-pricing model to value the warrants. This model incorporates transaction details such as our stock price, contractual terms, maturity, risk free rates, and volatility. The most significant unobservable input for the warrant liabilities is volatility. Given the limited trading volume and period of time that our stock has been traded in an active market, the expected volatility is estimated by taking the average historical price volatility for industry peers, consisting of several public companies in our industry that are similar in size, stage, or financial leverage, over a period of time commensurate to the expected term of the warrants.

Remeasuring the fair value of our Senior Secured Notes and warrants on a recurring basis through earnings requires the estimation of significant unobservable inputs, and thereby requires significant demands on our judgment. Using different estimates or assumptions would have materially affected our results in 2022 and subsequent periods. For example, as of December 31, 2022:

- A 100 basis point, or one percent, decrease or increase to the rate we used to discount future cash flows under our Senior Secured Notes would have increased or decreased, respectively, the estimated fair value of our Senior Secured Notes and changed the associated gains or losses recognized through 2022 earnings by $1.4 million; and

- A 1,000 basis point, or ten percent, decrease or increase to the estimated volatility assumption under our warrants would have increased or decreased, respectively, the estimated fair value of our warrants and decreased or increased, respectively, the associated gains recognized through 2022 earnings by $0.9 million.

Estimating Valuation Allowances on Deferred Tax Assets

We are required to estimate the degree to which tax assets and loss carryforwards will result in a future income tax benefit, based on our expectations of future profitability by tax jurisdiction. We provide a valuation allowance for deferred tax assets that we believe will more likely than not go unutilized. If it becomes more likely than not that a deferred tax asset will be realized, we reverse the related valuation allowance and recognize an income tax benefit for the amount of the reversal. See Note 17, "*Income Taxes*," to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

At December 31, 2022, we had federal net operating loss carryforwards of $70.2 million, state net operating loss carryforwards of $139.2 million, net operating loss carryforwards in certain foreign tax jurisdictions of $109.9 million which will begin to expire in 2026 and total tax credit carryforwards of $8.6 million, primarily consisting of Federal Orphan Drug Tax Credits that are expected to be fully realized prior to their expiration, beginning in 2036. We also had federal capital loss carryforwards of $95.8 million at December 31, 2022, which will expire in 2026.

At December 31, 2022, our valuation allowance on deferred tax assets was $64.9 million, which primarily consists of $16.7 million relating to $209.3 million net operating loss carryforwards and $20.1 million relating to $95.8 million of federal capital loss carryforwards, none of which are expected to be realized.

We must make assumptions and judgments to estimate the amount of valuation allowance to be recorded against our deferred tax assets, which take into account current tax laws and estimates of the amount of future taxable income, if any. Realization of the deferred tax assets is dependent on a variety of factors, some of which are subjective in nature, including the generation of future taxable income, the amount and timing of which are uncertain. In evaluating the ability to recover the deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, the forecast of future taxable income exclusive of certain reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, management is responsible for assumptions utilized including, but not limited to, the amount of U.S. federal, state and international pre-tax operating income, the reversal of certain temporary differences, carryforward periods available to us for tax reporting purposes, the implementation of feasible and prudent tax planning strategies and other relevant factors. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying business.

We assess the need for a valuation allowance each reporting period and would record any material changes that may result from such assessment to income tax expense in that period. Changes to any of the assumptions or judgments could cause our actual income tax obligations to differ from our estimates.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes. We do not engage in any hedging activities against changes in interest rates.

At December 31, 2022, we had cash and cash equivalents of $44.5 million. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% change in interest rates would have a significant impact on the realized value of our investments. We do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

We are exposed to fluctuations in interest rates, subject to a designated floor and cap, on our Senior Secured Notes. A change in interest rates could have a material impact on our cash flow. For example, at December 31, 2022, a 100 basis point change in assumed interest rates for our Senior Secured Notes would have an annual impact of approximately $0.8 million on interest expense.

Through the operation of our subsidiary based in Hungary, we are exposed to foreign exchange rate risks. In addition to the operations of our foreign subsidiary, we also contract with vendors that are located outside the United States, and in some cases require payments denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. At December 31, 2022, our liabilities denominated in foreign currencies were not material.

Inflation generally affects us by increasing our cost of labor, API costs and the costs of clinical trials. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2022 and 2021.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of RVL Pharmaceuticals plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of RVL Pharmaceuticals plc (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our 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.

/s/ Ernst & Young LLP

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

Iselin, New Jersey
March 20, 2023

RVL PHARMACEUTICALS PLC
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 44,543	$ 40,444
Accounts receivable and other receivables	3,031	2,133
Inventories, net	784	838
Prepaid expenses and other current assets	8,617	12,901
Financial commitment asset	—	3,063
Total current assets	56,975	59,379
Property, plant and equipment, net	1,276	866
Operating lease assets	512	1,368
Indefinite-lived intangible assets	13,900	27,210
Goodwill	55,847	55,847
Total assets	$ 128,510	$ 144,670
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	$ 2,407	$ 3,777
Accrued liabilities	15,395	13,077
Current portion of debt	1,432	2,409
Current portion of obligations under finance leases	10	5
Current portion of lease liability	435	839
Income taxes payable - current portion	44	1
Total current liabilities	19,723	20,108
Long-term debt (measured at fair value and representing $75,000 and $55,000 of aggregate unpaid principal at December 31, 2022 and December 31, 2021, respectively)	55,500	43,800
Warrant liability	1,951	3,220
Long-term portion of obligations under finance leases	18	—
Long-term portion of lease liability	94	592
Income taxes payable - long term portion	70	66
Deferred taxes	61	151
Total liabilities	77,417	67,937
Commitments and contingencies (see Note 16)		
Shareholders' equity:		
Ordinary shares ($0.01 nominal value, 400,000,000 shares authorized, 99,161,375 and 83,297,567 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively)	992	833
Preferred shares ($0.01 nominal value, 40,000,000 shares authorized, no shares issued and outstanding)	—	—
Euro deferred shares (€1.00 nominal value, 25,000 shares authorized, no shares issued and outstanding)	—	—
Additional paid in capital	619,323	591,730
Accumulated deficit	(569,222)	(517,530)
Accumulated other comprehensive income	—	1,700
Total shareholders' equity	51,093	76,733
Total liabilities and shareholders' equity	$ 128,510	$ 144,670

See accompanying notes to consolidated financial statements.

RVL PHARMACEUTICALS PLC
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Net product sales	$ 34,221	$ 7,511
Royalty and licensing revenue	15,500	9,990
Total revenues	49,721	17,501
Cost of goods sold	9,456	3,618
Gross profit	40,265	13,883
Selling, general and administrative expenses	81,979	87,463
Research and development expenses	3,966	6,930
Impairments of intangible assets	13,310	7,880
Total operating expenses	99,255	102,273
Operating loss before gain on sales of product rights, net	(58,990)	(88,390)
Gain on sales of product rights, net	—	5,636
Operating loss	(58,990)	(82,754)
Interest expense and amortization of debt discount	3,110	3,036
Change in fair value of debt and interest expense	(2,857)	982
Change in fair value of warrants	(1,269)	(5,571)
Other non-operating (income) expense, net	(6,262)	1,333
Total other non-operating income	(7,278)	(220)
Loss before income taxes	(51,712)	(82,534)
Income tax (benefit) expense, continuing operations	(20)	315
Loss from continuing operations	(51,692)	(82,849)
Gain on sales of discontinued operations	—	4,062
Income from discontinued operations before income taxes	—	13,570
Income tax benefit, discontinued operations	—	297
Income from discontinued operations, net of tax	—	17,929
Net loss	$ (51,692)	$ (64,920)
Reclassification adjustment of cumulative foreign currency translation losses, net of tax	—	2,229
Change in fair value of debt due to change in credit risk, net of tax	(1,700)	1,700
Other comprehensive (loss) income	(1,700)	3,929
Comprehensive loss	$ (53,392)	$ (60,991)
(Loss) earnings per ordinary share:		
Basic and diluted, continuing operations	$ (0.58)	$ (1.23)
Basic and diluted, discontinued operations	—	0.27
Basic and diluted	$ (0.58)	$ (0.96)
Weighted average ordinary shares outstanding:		
Basic and diluted	89,797,357	67,354,336

See accompanying notes to consolidated financial statements.

RVL PHARMACEUTICALS PLC
Consolidated Statements of Changes in Shareholders' Equity
(In thousands, except share data)

	Ordinary shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total shareholders' equity
	Shares	Amount				
Balance at January 1, 2021	62,545,832	$ 625	$ 548,070	$ (452,610)	$ (2,229)	$ 93,856
Share compensation	456,741	5	7,818	—	—	7,823
Net loss	—	—	—	(64,920)	—	(64,920)
Payments for taxes related to the net share settlement of equity awards	—	—	(783)	—	—	(783)
Proceeds from issuance of ordinary shares, net of offering costs	20,294,994	203	36,625	—	—	36,828
Reclassification adjustment of cumulative foreign currency translation losses to earnings	—	—	—	—	2,229	2,229
Change in fair value of debt due to change in credit risk	—	—	—	—	1,700	1,700
Balance at December 31, 2021	83,297,567	$ 833	$ 591,730	$ (517,530)	$ 1,700	$ 76,733
Balance at January 1, 2022	83,297,567	$ 833	$ 591,730	$ (517,530)	$ 1,700	$ 76,733
Share compensation	412,196	4	4,257	—	—	4,261
Net loss	—	—	—	(51,692)	—	(51,692)
Payments for taxes related to the net share settlement of equity awards	—	—	(143)	—	—	(143)
Change in fair value of debt due to change in credit risk	—	—	—	—	(1,700)	(1,700)
Proceeds from issuance of ordinary shares, net of offering costs	15,451,612	155	23,479	—	—	23,634
Balance at December 31, 2022	99,161,375	$ 992	$ 619,323	$ (569,222)	$ —	$ 51,093

See accompanying notes to consolidated financial statements.

RVL PHARMACEUTICALS PLC
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss from continuing operations	$ (51,692)	$ (82,849)
Net income from discontinued operations	—	17,929
Net loss	(51,692)	(64,920)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	375	8,175
Share compensation	4,070	7,594
Reclassification adjustment of cumulative foreign currency translation losses to earnings	—	2,229
Change in fair value of debt	(10,000)	(318)
Change in fair value of warrants	(1,269)	(5,571)
Impairments of intangible assets	13,310	7,880
Deferred income tax benefit	(90)	(194)
(Gain) loss on sale of fixed and leased assets	(878)	1,180
Gain on sales of product rights, net	—	(5,636)
Gain on sales of discontinued operations	—	(4,062)
Amortization of deferred financing and loan origination fees	3,063	1,606
Write off of deferred financing and loan origination fees	—	1,462
Financing fees recognized in earnings associated with debt	914	3,306
Change in operating assets and liabilities:		
Accounts receivable and other receivables	(898)	7,108
Inventories, net	54	2,595
Prepaid expenses and other current and non-current assets	4,283	(6,198)
Trade accounts payable	(1,370)	(134)
Accrued and other current liabilities	2,318	(10,834)
Net cash used in operating activities	(37,810)	(54,732)
Cash Flows from Investing Activities:		
Proceeds from product rights disposal	—	7,300
Proceeds from discontinued operations	—	110,845
Proceeds from sale of fixed and leased assets	878	90
Purchases of property, plant and equipment	(752)	(1,782)
Net cash provided by investing activities	126	116,453
Cash Flows from Financing Activities:		
Payments on finance lease obligations	(9)	(37)
Proceeds from insurance financing loan	1,724	3,317
Payments on insurance financing loan	(2,700)	(909)
Payments for taxes related to net share settlement of share-based awards	(143)	(783)
Proceeds from issuance of debt, net of issuance costs	19,086	51,795
Proceeds from issuance of ordinary shares, net of issuance costs	23,634	32,414
Proceeds from issuance of ordinary shares under the ESP Plan	191	233
Debt repayments	—	(221,360)
Net cash provided by (used in) financing activities	41,783	(135,330)
Net change in cash and cash equivalents	4,099	(73,609)
Cash and cash equivalents, beginning of period	40,444	114,053
Cash and cash equivalents, end of period	$ 44,543	$ 40,444

See accompanying notes to consolidated financial statements.

RVL PHARMACEUTICALS PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Nature of Operations

RVL Pharmaceuticals plc, an Irish public limited company, together with its subsidiaries (collectively, the "Company"), is a specialty pharmaceutical company focused on the development and commercialization of products that target markets with underserved patient populations in the ocular medicine and medical aesthetics therapeutic areas.

In July 2020, the Company received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution), 0.1%, for the treatment of acquired blepharoptosis, or droopy or low-lying eyelids, in adults. Upneeq was commercially launched in September 2020 to a limited number of eye care professionals with commercialization operations expanded in 2021 among ophthalmology, optometry and oculoplastic specialties. In February 2022, Upneeq was commercially expanded into the medical aesthetics market in the United States.

The Company's commercial operations are conducted by its wholly-owned subsidiaries, RVL Pharmaceuticals, Inc. ("RVL Pharmaceuticals") and RVL Pharmacy, LLC ("RVL Pharmacy"). RVL Pharmacy conducts pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

Unless otherwise indicated or required by the context, references throughout to the "Company," refer to the Company's continuing operations following the sale of its Legacy Business (see Note 4).

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

Basis of Presentation—The accompanying consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Principles of Consolidation—The accompanying consolidated financial statements include the accounts of RVL Pharmaceuticals plc and its wholly-owned domestic and foreign subsidiaries. All inter-company transactions and balances have been eliminated in consolidation. The Company is not involved with variable interest entities.

Discontinued Operations—Upon divestiture of a business, the Company classifies such business as a discontinued operation, if the divested business represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. The results of businesses that have qualified as discontinued operations have been presented as such for all reporting periods. Results of discontinued operations include all revenues and expenses directly derived from such businesses; general corporate overhead is not allocated to discontinued operations.

Summary of Significant Accounting Policies

Use of Estimates—The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the consolidated financial statements and accompanying notes. Management bases it estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Foreign Currency Translation—The financial position and results of operations of the Company's non-U.S. subsidiaries are generally determined using U.S. Dollars as the functional currency. Foreign currency transaction gains and losses are included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss. Foreign currency transaction gains were less than $0.1 million and $1.4 million for the years ended December 31, 2022 and 2021, respectively.

Our subsidiary in Argentina had operated in a highly inflationary environment, as a result, we had previously recognized cumulative foreign currency translation losses in accumulated other comprehensive income (loss) in accordance with U.S. GAAP. During the year ended December 31, 2021, the Company curtailed its operations in Argentina and, upon the related liquidation becoming substantially complete, reclassified all accumulated foreign currency translation losses to selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Cash and Cash Equivalents—The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents.

Accounts Receivable and Allowance for Credit Losses—Accounts receivable result primarily from sales of pharmaceutical products and from amounts due under revenue sharing, license and royalty arrangements. Other receivables result primarily from payroll retention credits and other miscellaneous activities.

The Company is exposed to credit losses primarily through sales of its products. Accounts receivable are recorded at amortized cost less an allowance for expected credit losses that are not expected to be recovered. The Company's expected loss methodology for accounts receivable is developed using historical collection experience, a review of the current status of a customer's trade receivables, and current and future market conditions. Due to the short-term nature of such accounts receivables, the estimated portion thereof that may not be collected is based on the aging of accounts receivable balances and the financial condition of customers. The Company's monitoring activities include timely account reconciliations, dispute resolution, payment confirmation, consideration of customers' financial condition and macroeconomic conditions. Balances are written-off when determined to be uncollectible. Except for the allowance for credit losses, which is reflected as part of selling, general and administrative expenses, the provisions for all other customer reserves are reflected as a reduction of revenues in the consolidated statements of operations and comprehensive loss.

The Company considered the current and expected future economic and market conditions surrounding a novel strain of the coronavirus, referred to as COVID-19, and determined that its estimate of credit losses was not significantly impacted.

Fair Value of Financial Instruments—The Company applies Accounting Standards Codification ("ASC") 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Inventories—Inventories are stated at the lower of cost or net realizable value at approximate costs determined on the first-in first-out basis. The Company maintains an allowance for excess and obsolete inventory as well as inventory where the cost is in excess of its net realizable value based on management's assessments. The Company considers the shelf life of the product in relation to the product timeline for approval. Sample inventory utilized for promoting the Company's products are expensed and included in cost of goods sold when the sample units are purchased or manufactured.

Property, Plant and Equipment—Property, plant and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs are charged to expense when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized and depreciated over the remaining useful lives of the assets. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings. Depreciation is provided using the straight-line method in amounts considered to be sufficient to amortize the cost of the assets to operations over their estimated useful lives or lease terms, as follows:

Asset category	Depreciable life
Leasehold improvements	Lesser of the useful life of the improvement or the terms of the underlying lease
Machinery	3 - 15 years
Furniture, fixtures and equipment	3 - 10 years
Computer hardware and software	3 - 12 years

Goodwill and Indefinite Lived Intangible Assets—Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company is organized in one reporting unit and evaluates the goodwill for the Company as a whole. Goodwill is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. Under the authoritative guidance issued by the Financial Accounting Standards Board (the "FASB"), the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying value, then no impairment is recognized. If the carrying value exceeds the fair value, then an impairment charge is recognized for the difference. The judgments made in determining the estimate of fair value can materially impact the Company's financial condition and results of operations.

In-Process Research and Development ("IPR&D") intangible assets represent the value assigned to incomplete Research & Development ("R&D") projects that principally represent rights to develop and sell a product that the Company has acquired through business combinations or developed internally which, at that time, have not reached technological feasibility. These assets are not amortized but are subject to impairment testing until regulatory approval is obtained and the product is launched, subject to certain specified conditions and management judgment, or abandonment of a project. At the time of any transfer from an IPR&D asset to an amortizing asset an impairment evaluation is performed. The useful life of any resultant amortizing asset is generally determined by identifying the period in which substantially all of the cash flows are expected to be generated. Such assets will be amortized over their respective estimated useful lives. Impairment testing of IPR&D assets requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, research and development expenses, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream,

the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D project, the assets are reduced to zero. IPR&D assets are assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. If the fair value of the IPR&D asset is less than its carrying amount, an impairment is recognized for the difference.

Impairment charges resulting from annual or interim goodwill and indefinite-lived intangible asset impairment assessments, if any, are classified within total operating expenses, in the accompanying consolidated statements of operations and comprehensive loss.

Product Sales—Revenue is recognized at the point in time when the Company's performance obligations with the applicable customers have been satisfied. At contract inception, the Company determines if the contract is within the scope of ASC Topic 606, *Revenue Recognition,* and then evaluates the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue at the point in time when the entity satisfies a performance obligation.

Revenue is recorded at the transaction price, which is the amount of consideration the Company expects to receive in exchange for transferring products to a customer. The Company determines the transaction price based on fixed consideration. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which included discounts and allowances at the time revenues were recognized. In determining the transaction price, a significant financing component does not exist since the customer typically pays for the product in advance of the transfer of the product or shortly thereafter.

Royalty Revenue—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

Licensing Revenue— For arrangements that include development and regulatory milestone revenue from milestone events, the Company recognizes revenue from milestone events that have been achieved and the Company is reasonably certain such revenues would not have to be reversed. Sales deductions, such as returns on product sales, government program rebates, price adjustments, and prompt pay discounts in regard to licensing revenue is generally the responsibility of the Company's commercial partners and not recorded by the Company.

Freight—The Company records amounts billed to customers for shipping and handling as revenue, and records shipping and handling expenses related to product sales as cost of goods sold. The Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. When shipping and handling costs are incurred after a customer obtains control of the products, the Company also has elected to account for these as costs to fulfill the promise and not as a separate performance obligation.

Business Combinations—The Company accounts for its business combinations under the provisions of ASC Topic 805, *Business Combinations*, which requires that the purchase method of accounting be used for all business combinations. Assets acquired, and liabilities assumed, are recorded at the date of acquisition at their respective fair values. Amounts allocated to acquire IPR&D are capitalized at the date of an acquisition and are not amortized. As products in development are approved for sale, amounts are allocated to product rights and licenses and amortized over their estimated useful lives. Definite-lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill represents the excess purchase price over the fair value of the tangible net assets and intangible assets acquired in a business combination. Acquisition-related expenses are recognized separately from business combinations and are expensed as incurred. If the business combination provides for contingent consideration, the Company records the

contingent consideration at fair value at the acquisition date. Changes in fair value of contingent consideration resulting from events after the acquisition date, such as earn-outs, are recognized as follows: 1) if the contingent consideration is classified as equity, the contingent consideration is not re-measured and its subsequent settlement is accounted for within equity, or 2) if the contingent consideration is classified as a liability, the changes in fair value are recognized in earnings.

Purchases of developed products and licenses that are accounted for as an asset acquisition are capitalized as intangible assets and amortized over an estimated useful life. IPR&D assets acquired as part of an asset acquisition are expensed immediately if they have no alternative future uses.

Research and Development Costs—Research and development costs are expensed as incurred. These expenses include the costs of proprietary efforts, as well as costs incurred in connection with certain licensing arrangements. Upfront payments are recorded when incurred, and milestone payments are recorded when the specific milestone has been achieved.

Advertising—Advertising expense consists primarily of print and digital media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2022 and 2021 amounted to $15.9 million and $14.9 million, respectively.

Share-based Compensation—Some of our employees and directors are compensated with share-based awards, including stock options, restricted stock units, performance stock units, and other share-based awards. The Company recognizes share-based compensation expense for all share-based awards and other arrangements within the scope of ASC 718, *Stock Compensation* ("ASC 718"). Share compensation expense is included in selling, general and administrative expenses and research and development expenses in the consolidated statement of operations and comprehensive loss.

Share compensation expense is measured at the date of grant, based on the fair value of an award and recognized ratably over its vesting term, which is generally the vesting period on a graded vesting basis. Share compensation expense for awards with vesting conditions other than service are recognized at the time that those conditions will be achieved. Forfeitures of unvested awards are recognized as they occur by reversing any expense previously recorded in the period of forfeiture. The Company typically issues new ordinary shares upon exercise or vesting of awards.

The grant date fair value of restricted stock units is based on the market price of ordinary shares as of the grant date. The grant date fair value of stock options and performance stock units is measured using a Black-Scholes Merton option-pricing model and a Monte Carlo simulation model, respectively, using assumptions based on the terms of each award, the expected behavior of grant recipients and peer company data. Expected volatility is calculated based on a weighting of our own stock price volatility and/or the historical stock price trends of similar entities within our industry over a period of time commensurate with the expected term. The risk-free interest rate is based on U.S. Treasury observed market rates continuously compounded over the duration of the expected term. The expected term of stock options is estimated as the midpoint of the weighted average vesting period and the contractual term.

The Company accounts for purchases made under its employee share purchase plan using the estimate grant date fair value in accordance with ASC 718. A purchase price discount and look-back feature under the plan cause it to be compensatory and the Company to recognize share compensation expense on a straight-line basis over the requisite service period. The Company values related shares using a Black-Scholes Merton option-pricing model.

When share-based compensation arrangements are modified, the modification is treated as an exchange of the original award for a new award with immediate expense recognition for any incremental value. The incremental value, if any, is measured as the excess of the fair value of new award over the fair value of the original award, each based on circumstances and assumptions as of the modification date.

Leasing—The Company assesses whether an arrangement is a lease or contains a lease at inception. For arrangements considered leases or that contain a lease that is accounted for separately, the Company determines the classification and initial measurement of the right-of-use asset and lease liability at the lease commencement date, which is the date that

the underlying asset becomes available for use. The Company has elected to account for non-lease components associated with leases and lease components as a single lease component.

The Company recognizes a right-of use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments are calculated using either the implicit interest rate in the lease or an incremental borrowing rate.

Income Taxes—Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

Comprehensive Income or Loss—Comprehensive income or loss refers to revenues, expenses, gains and losses that under U.S. GAAP are included in comprehensive income or loss but are excluded from net income or loss as these amounts are recorded directly as an adjustment to accumulated other comprehensive income or loss. The Company's other comprehensive income or loss is typically comprised of i) foreign currency translation adjustments and ii) the portions of the total change in fair value of indebtedness accounted for under the fair value option that is attributable to changes in instrument-specific credit risk.

Basic and Diluted Earnings or Loss Per Share—Basic earnings or loss per share is determined by dividing net income or loss by the weighted average ordinary shares outstanding during the period. Diluted earnings or loss per share is determined based on the weighted average number of ordinary shares outstanding increased by the number of additional ordinary shares that would have been outstanding had the potentially dilutive shares been issued and reduced by the number of ordinary shares we could have repurchased with the proceeds from the issuance of the potentially dilutive shares. Potentially dilutive shares include ordinary shares issuable through contingent share arrangements, share options and warrants. In periods of net loss, diluted calculations are equal to basic calculations because the inclusion of potentially dilutive shares would be anti-dilutive.

In periods of cumulative retained earnings, if ever, as a result of the holders of warrants being entitled to dividends (see Note 20), the warrants are participating securities and will be included in the computation of basic and diluted earnings or loss per share following the two-class method.

Segment Reporting—The Company operates in one business segment which focuses on developing and commercializing pharmaceutical products. The chief operating decision maker reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions. The consolidated financial statements reflect the financial results of the Company's one reportable operating segment. The Company has no significant revenues from external customers attributable to, or tangible assets held by, any subsidiary outside of the United States.

Supplemental Cash Flow Disclosures—Supplemental cash flow disclosures are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Cash paid for:		
Interest	$ 4,890	$ 8,518
Income taxes	$ 184	$ 2,361
Non-cash financing activities:		
Allocation of equity offering proceeds to warrant liability (see Note 20)	$ —	$ 8,791
Allocation of debt offering proceeds to ordinary shares (see Note 20)	$ —	$ 9,243
Recognition of financial commitment asset from ordinary share issuance (see Notes 12 & 20)	$ —	$ 3,361

The Company received $3.1 million in tax refunds during the year ended December 31, 2022 related to income taxes paid in prior periods.

Recently Adopted Accounting Standards

In December 2019, the FASB issued Accounting Standards Update No. 2019-12, *Income Taxes Topic 740, Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). The Company adopted ASU 2019-12 as required effective January 1, 2021. Among other updates to the accounting for income taxes, ASU 2019-12 removed the exception to the incremental approach for intra-period tax allocation when there is a loss from continuing operations and income or a gain from other items. Accordingly, the Company's loss from continuing operations for the year ended December 31, 2021 does not reflect a tax benefit amounting to $3.2 million that would have been recognized if ASU 2019-12 was not adopted.

Recently Issued Accounting Standards

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). This standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The standard requires entities to provide expanded disclosures about the terms and features of convertible instruments and amends certain guidance related to the computation of earnings per share for convertible instruments and contracts on an entity's own equity. The standard, which allows entities to adopt the guidance through either a modified or fully retrospective method of transition, becomes effective for the Company, as a smaller reporting company, for fiscal years beginning after December 15, 2023, with early adoption permitted. The Company is currently assessing the impact of adoption of ASU 2020-06.

There are no other recently issued accounting standards that are expected to have a material impact to the Company's financial position or results of operations upon adoption.

Note 3. Liquidity

At December 31, 2022, the Company had cash and cash equivalents of $44.5 million, an accumulated deficit of $569.2 million, and total long-term debt with aggregate principal maturities of $75.0 million, with such maturities commencing in March 2024 and extending through October 2026 (see Note 12). In addition, the Company's primary indebtedness contains various restrictive covenants including minimum liquidity and minimum quarterly product sales requirements. For the years ended December 31, 2022 and 2021, the Company incurred losses from continuing operations of $51.7 million and $82.8 million, respectively, and used $37.8 million and $54.7 million, respectively, in cash from operating activities.

The divestiture of the Legacy Business in 2021 resulted in the loss of substantially all the Company's revenue generating assets (see Note 4). The Company's current business plan is focused on the continued commercialization and growth of Upneeq, which has and will continue to diminish the Company's cash flows in at least the near term. The Company will

require additional capital to fund its operating needs, including the expanded commercialization of Upneeq and other activities. The Company expects to incur significant expenditures and sustain operating losses in the future.

Management of the Company does not believe that current sources of liquidity will be sufficient to fund the Company's planned expenditures and meet its obligations, including the minimum liquidity covenant, for at least 12 months following the date the accompanying consolidated financial statements are issued without raising additional funding. As a result, there is a substantial doubt as to the Company's ability to operate as a going concern. The Company's ability to continue as a going concern will require it to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

Management's plans to address these conditions include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or is entirely within its control, (i) raise funds through additional sales of ordinary shares, through equity sales agreements with brokers/dealers or other public or private equity financings, (ii) raise funds through borrowings under new and/or existing debt facilities and/or convertible debt, and/or (iii) raise non-dilutive funds through product collaborations and/or to partner or sell a portion or all rights to any of the Company's assets.

There can be no assurance that the Company will receive cash proceeds from any of these potential sources or, to the extent cash proceeds are received, such proceeds would be sufficient to support its current operating plan for at least the next 12 months from the date the accompanying consolidated financial statements are issued. The sale of additional equity or convertible debt securities may result in dilution to the Company's shareholders. If the Company raises additional funds through the issuance of debt securities or preferred shares, these securities could provide for rights senior to those of its ordinary shares and could contain covenants that would further restrict its operations. Additional funds may not be available when the Company needs them, on terms that are acceptable to it, or at all.

The accompanying consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business, and therefore do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern.

Note 4. Discontinued Operations

On August 27, 2021, the Company announced the closing of the divestiture of its legacy portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility (collectively, the "Legacy Business") to certain affiliates of Alora Pharmaceuticals LLC ("Alora") for $111 million in cash upon closing, subject to certain adjustments, and up to $60 million in additional contingent milestone payments. Pursuant to the divestiture, the Company retained the rights to Upneeq and to arbaclofen extended release ("ER") tablets which is under development for the treatment of spasticity in multiple sclerosis. For the year ended December 31, 2022, the Company received an aggregate of $5.0 million in cash from Alora related to contingent milestone payments earned in connection with the sale of the Legacy Business, with such income being recognized and classified within other non-operating income or expense, net in the accompanying consolidated statements of operations and comprehensive loss.

The Company determined that the divestiture of the Legacy Business represented a strategic shift that would have a major effect on its business and therefore met the criteria for classification as discontinued operations. Accordingly, the Legacy Business is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. The results of operations from the Legacy Business are classified as discontinued operations in the accompanying consolidated financial statements of operations and comprehensive loss.

The following table presents the results of discontinued operations (in thousands):

	Year Ended December 31, 2021
Total revenues	$ 62,395
Cost of goods sold (inclusive of depreciation and amortization)	30,018
Selling, general and administrative expenses	5,468
Research and development expenses	5,882
Income from operations	21,027
Interest expense and amortization of debt discount	6,399
Other non-operating expense, net	1,058
Income from discontinued operations before gain on disposal and provision for income taxes	13,570
Income tax benefit	297
Income from discontinued operations before gain on disposal	13,867
Gain on sales of discontinued operations	4,062
Income from discontinued operations, net of tax	$ 17,929

As a result of the legal requirement to repay certain existing indebtedness upon the disposition of the Legacy Business, the Company allocated interest expense (inclusive of amortization of debt discount) on such debt to the discontinued operations for periods prior to the disposal based on the ratio of repaid debt to total debt.

The following table presents the significant non-cash items and purchases of property, plant and equipment for the discontinued operations that are included in the accompanying consolidated statements of cash flows (in thousands):

	Year Ended December 31, 2021
Cash flows from operating activities:	
Depreciation and amortization	$ 6,583
Share compensation	619
Cash flows from investing activities:	
Purchases of property, plant and equipment	$ (1,335)

Note 5. Revenues

The Company's performance obligations are to provide its pharmaceutical products based upon purchase orders from customers. The performance obligations are satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. Predominately, the Company collects payment in advance from its customers. From time to time, the Company may invoice a customer after the products have been delivered in which case payments are typically due within 30 days.

The following table presents disaggregated revenues from contracts with customers (in thousands):

	Year Ended December 31,	
	2022	2021
Net product sales - Upneeq	$ 34,221	$ 7,511
Royalty and licensing revenue	15,500	9,990
Total revenues	$ 49,721	$ 17,501

On July 28, 2020, RVL Pharmaceuticals entered into a License Agreement with Santen Pharmaceutical Co. Ltd ("Santen"), granting Santen exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as Europe, the Middle East and Africa ("EMEA") countries (the "License Agreement"). Under the License Agreement, RVL Pharmaceuticals is entitled to certain development and regulatory

milestone payments. RVL Pharmaceuticals is also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories.

On March 29, 2022, RVL Pharmaceuticals entered into the First Amendment to License Agreement (the "Amendment") with Santen, amending the License Agreement. Under the terms of the Amendment, effective March 31, 2022, RVL Pharmaceuticals became entitled to receive an upfront cash payment of $15.5 million, and the remaining developmental and regulatory cash milestone payments, were removed. Pursuant to the terms of the Amendment, new developmental and regulatory cash milestone payments with an aggregate value of up to $1.0 million will be payable to RVL Pharmaceuticals if achieved. In addition, the territories were expanded to include additional EMEA countries and Canada, and during the first five years following the effective date of the Amendment, Santen was granted an option to expand the territories to include Russia, subject to additional upfront and milestone payments of $2.0 million and $1.0 million, respectively. Further, under the terms of the Amendment, if RVL Pharmaceuticals desires to enter into an agreement to license certain rights related to the License Agreement to a third party in Russia, then Santen will have a right to exercise an option to expand the territories to include Russia or to match the terms of the agreement with the third party.

During the years ended December 31, 2022 and 2021, the Company recognized $15.5 million and $10.0 million, respectively, in license revenue from Santen under the Amendment and the License Agreement, respectively, as all performance obligations were met.

A contract liability is recorded as deferred revenue on the consolidated balance sheets when customers are billed in advance of performance obligations being satisfied, and revenue is recognized upon satisfaction of all performance obligations. The amount of revenue recognized during the years ended December 31, 2022 and 2021 that was included in the opening deferred balance of the same fiscal year was less than $0.1 million for both reporting periods.

During the year ended December 31, 2022, the Company's deferred revenue balance increased as a result of higher sales volumes and from an increase in consideration received for performance obligations yet to be satisfied at December 31, 2022. At December 31, 2022, all deferred revenue was expected to become recognized as revenues within one year and is included within accrued expenses, a component of current liabilities, in the accompanying consolidated balance sheets (see Note 10).

Contract assets primarily relate to rights to consideration for goods or services transferred to the customer when the right is conditional on something other than the passage of time. Contract assets are transferred to accounts receivable when the rights become unconditional. The Company had no contract assets at December 31, 2022 and 2021.

The following table presents the various adjustments recognized against gross product sales (in thousands):

	Year Ended December 31,	
	2022	2021
Gross product sales	$ 35,588	$ 7,997
Less provisions for:		
Chargebacks	(11)	(2)
Discounts and allowances	(1,356)	(484)
Net product sales	$ 34,221	$ 7,511

Note 6. Accounts Receivable, Other Receivables, Discounts and Allowances

Accounts receivable result primarily from sales of pharmaceutical products and from amounts due under revenue sharing, license and royalty arrangements. Other receivables result primarily from payroll retention credits and other miscellaneous activities.

The following table presents the components of accounts receivable and other receivables (in thousands):

	December 31, 2022	December 31, 2021
Trade accounts receivable	$ 947	$ —
Other receivables	2,084	2,133
Total accounts receivable and other receivables	$ 3,031	$ 2,133

The following table presents the periodic activity within various reserves recognized against gross accounts receivable (in thousands):

	Chargebacks	Commercial Rebates	Discounts and Allowances	Total
Balance at January 1, 2021	$ —	$ 4	$ 1	$ 5
Provision	2	—	484	486
Charges processed	(2)	(4)	(485)	(491)
Balance at December 31, 2021	—	—	—	—
Provision	11	—	1,356	1,367
Charges processed	(11)	—	(1,356)	(1,367)
Balance at December 31, 2022	$ —	$ —	$ —	$ —

Note 7. Inventories

At December 31, 2022 and 2021, the Company had finished goods inventory of $0.8 million and $0.8 million, respectively.

The Company maintains an allowance for excess and obsolete inventory, as well as inventory where its cost is in excess of its net realizable value. The following table presents activity in the allowance for excess and obsolete inventory (in thousands):

	Year Ended December 31,	
	2022	2021
Balance at beginning of period	$ 34	$ —
Provision	(1)	34
Charges processed	(31)	—
Balance at end of period	$ 2	$ 34

Note 8. Property, Plant and Equipment, Net

The following table presents the components of property, plant and equipment (in thousands):

	Year Ended December 31,	
	2022	2021
Leasehold improvements	$ 386	$ 1,129
Machinery	17	—
Furniture, fixtures and equipment	—	4
Computer hardware and software	1,324	1,302
	1,727	2,435
Accumulated depreciation	(1,151)	(1,641)
	576	794
Construction in progress	700	72
	$ 1,276	$ 866

Depreciation expense was $0.4 million and $1.5 million for the years ended December 31, 2022 and 2021, respectively.

Note 9. Goodwill and Indefinite-Lived Intangible Assets

Goodwill

Goodwill is presented net of accumulated impairment charges of $47.8 million at December 31, 2022 and 2021. The following table sets forth the changes in the carrying value of goodwill (in thousands):

	Goodwill
January 1, 2021	$ 55,847
Impairments	—
December 31, 2021	55,847
Impairments	—
December 31, 2022	$ 55,847

In conjunction with the sale of the Legacy Business, the Company evaluated goodwill for impairment and determined that there were no indications that the fair value of goodwill was less than its carrying value. As of October 1, 2022, the Company performed a qualitative assessment for goodwill and concluded there were no indications that the fair value of goodwill was less than its carrying value.

Indefinite-Lived Intangible Assets

Subsequent to the divestiture of the Legacy Business in 2021 (see Note 4), the Company retained the rights to arbaclofen ER tablets which is under development for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis for which the Company has completed Phase III clinical trials and for which the Company is exploring opportunities to divest, out-license or otherwise partner with a third party to monetize its net investment (see Note 3).

At December 31, 2022 and 2021, the Company held indefinite-lived intangible assets for the right to develop and sell arbaclofen ER that had a gross recognized carrying value of $64.0 million at each date, aggregate impairment losses of $50.1 million and $36.8 million, respectively, and a net carrying amount of $13.9 million and $27.2 million, respectively.

Based on the results of a quantitative impairment assessment performed in conjunction with the announcement of the sale of the Legacy Business relative to arbaclofen ER, the Company recognized an impairment charge of $7.9 million during the year ended December 31, 2021, related to a delay in anticipated commercialization of the product candidate, if approved. During the fourth quarter of 2022, the Company, having received a potentially adverse response letter from the U.S. Food and Drug Administration (“FDA”) subsequent to an October 10, 2022 filing of a new Special Protocol

Assessment, performed a quantitative IPR&D impairment assessment and conclude that the IPR&D asset was impaired. Accordingly, the Company recognized an impairment charge of $13.3 million during the year ended December 31, 2022, related to a further delay and potentially increased costs in anticipated commercialization of the product candidate, if approved.

A quantitative impairment test for indefinite-lived intangible assets, when performed, is determined using a discounted cash flow model that necessitates the development of estimated net cash flows for each asset, the appropriate discount rate to select for each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. IPR&D assets are also subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development.

A variety of the above-referenced valuation assumptions are based on significant inputs not observable in the market and thus the Company's quantitative impairment tests, when performed, represent Level 3 measurements within the fair value hierarchy. The POS factor applied during the IPR&D quantitative impairment assessments was 69.6% and the discount rates applied were 17.5% and 12.5%, during the years ended December 31, 2022 and 2021, respectively. The Company believes the estimated net cash flows, POS factor, discount rates and other inputs and assumptions are consistent with those that a market participant would use.

Note 10. Accrued Liabilities

The following table presents the components of accrued liabilities (in thousands):

	December 31, 2022	December 31, 2021
Accrued expenses and other liabilities	$ 5,894	$ 7,897
Accrued compensation	3,908	4,504
Accrued interest	2,300	—
Accrued royalties	1,144	200
Deferred revenue	1,923	67
Accrued research and development	226	409
Total accrued liabilities	$ 15,395	$ 13,077

Note 11. Leases

The Company leases office space in Bridgewater, New Jersey for its principal office and leases office and warehouse space in Sayreville, New Jersey for its pharmacy operations both under a non-cancelable lease that expires in November 2023. The Company also leases certain vehicles under operating leases. At December 31, 2022, the Company's operating leases had remaining lease terms ranging from 0.9 years to 1.5 years.

The following table presents lease assets and liabilities and identifies their classification in the accompanying consolidated balance sheets (in thousands):

Leases	Classification	December 31, 2022	December 31, 2021
Assets			
Operating	Operating lease assets	$ 512	$ 1,368
Finance	Property, plant and equipment, net	28	5
Total leased assets		$ 540	$ 1,373
Liabilities			
Current			
Operating	Current portion of lease liability	$ 435	$ 839
Finance	Current portion of obligations under finance leases	10	5
Non-current			
Operating	Long-term portion of lease liability	94	592
Finance	Long-term portion of obligations under finance leases	18	—
Total lease liabilities		$ 557	$ 1,436

The Company recognizes lease expense on a straight-line basis over the lease term. The following table presents the various components of lease cost and identifies their classification in the accompanying consolidated statements of operations and comprehensive loss (in thousands):

Lease Cost	Classification	Year Ended December 31, 2022	Year Ended December 31, 2021
Operating lease cost	Selling, general and administrative expenses	$ 1,111	$ 1,425
	Research and development expenses	—	28
	Cost of goods sold	42	41
Finance lease cost			
Amortization of leased assets	Cost of goods sold	10	24
Interest on lease liabilities	Interest expense and amortization of debt discount	—	—
Total lease cost		$ 1,163	$ 1,518

The table below presents the future minimum rental payments, exclusive of taxes, insurance and other costs, under operating leases (in thousands):

Year Ending December 31,	Operating Leases
2023	$ 445
2024	93
Total lease payments	538
Less: interest	9
Present value of lease payments	$ 529

At December 31, 2022, there is an insignificant amount of future minimum lease payments required under finance leases.

The following tables presents the weighted-average remaining lease term and the weighted-average discount rate of our leases (in thousands):

	December 31,	
Lease Term and Discount Rate	**2022**	**2021**
Weighted average remaining lease term (years)		
Operating leases	1.2	1.8
Finance leases	2.5	0.6
Weighted average discount rate		
Operating leases	3.56 %	4.15 %
Finance leases	10.50 %	2.06 %

	December 31,	
Other Information	**2022**	**2021**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ (1,153)	$ (1,478)
Operating cash flows for finance leases	(2)	—
Financing cash flows for finance leases	(10)	(16)

For the years ended December 31, 2022 and 2021, the Company recorded less than $0.1 million and $0.7 million, respectively, of leased assets obtained in exchange for new operating lease liabilities and an insignificant amount of leased assets obtained in exchange for new finance lease liabilities in each period. During the years ended December 31, 2022 and 2021, the Company disposed of less than $0.1 million of leased assets in each period.

Note 12. Financing Arrangements

The following table presents the components of long-term debt and financing obligations (in thousands):

	December 31, 2022	December 31, 2021
Senior Secured Notes (measured at fair value)	$ 55,500	$ 43,800
Note payable — insurance financing	1,432	2,409
Total debt and financing obligations	56,932	46,209
Less: current portion of debt	(1,432)	(2,409)
Long-term debt	$ 55,500	$ 43,800

The following table presents the aggregation of principal maturities of long-term debt and financing obligations (in thousands):

Year Ending December 31,	Debt Obligations
2023	$ 1,432
2024	15,000
2025	15,000
2026	45,000
Total future minimum payments	76,432
Less: current portion of debt principal	(1,432)
Non-current portion of debt principal	$ 75,000

Senior Secured Notes

On October 1, 2021, the Company entered into a note purchase agreement (the "Note Purchase Agreement") with, among others, Athyrium Opportunities IV Acquisition LP (the "Administrative Agent") and Athyrium Opportunities IV Acquisition 2 LP, as a purchaser, providing for the issuance of senior secured notes in three separate tranches (the "Senior Secured Notes"). On October 12, 2021, the Company issued $55.0 million first tranche Senior Secured Notes, a portion of the proceeds of which, together with the proceeds from a concurrent underwritten equity offering (see Note 20), were used to repay in full the Prior Term Loans (defined below).

Prior to October 12, 2022, upon satisfaction of certain conditions, including a minimum net product sales target for Upneeq over a specified period of time, the Company could request second tranche Senior Secured Notes of up to $20.0 million. Additionally, prior to October 12, 2023, the Company could request third tranche Senior Secured Notes of up to $25.0 million, in the sole discretion of the purchaser.

On August 4, 2022, the Company entered into a first amendment to the Note Purchase Agreement (the "First Amendment") with, among others, Athyrium Opportunities IV Co-Invest 1 LP (the "New Purchaser"), certain other purchasers party thereto (together with the New Purchaser, the "Purchasers") and the Administrative Agent, which amended the Note Purchase Agreement (as amended, the "Amended Note Purchase Agreement").

The First Amendment provided, among other things, for the issuance of $20.0 million of secured second tranche Senior Secured Notes, dated as of August 8, 2022. Furthermore, under the First Amendment, the Purchasers committed to purchase certain third tranche Senior Secured Notes in an aggregate principal amount of up to $25.0 million at any time prior to April 15, 2023, upon the satisfaction of certain conditions, including a minimum net product sales target for Upneeq over a specified period of time.

Further, the First Amendment provided for the replacement of a LIBOR-based interest rate under the Note Purchase Agreement with a Term SOFR-based interest rate. After September 30, 2022, the Senior Secured Notes bear interest at an annual rate of 9.0% plus adjusted three-month term SOFR, with a floor of 1.50% and a cap of 3.00%, payable in cash quarterly in arrears. At December 31, 2022, the interest rate applicable to the aggregate outstanding Senior Secured Notes is 12.0%.

The Senior Secured Notes require quarterly repayments equal to 5.0% of the principal outstanding beginning on March 31, 2024 with any residual balance due at maturity on October 12, 2026. The Senior Secured Notes may be voluntarily prepaid upon the satisfaction of certain conditions and with each such prepayment being accompanied by, as applicable, (i) a make-whole premium, (ii) an exit fee of 2.0% of the principal amount of the Senior Secured Notes prepaid, (iii) certain other fees, indemnities and expenses, and (iv) all accrued interest on the Senior Secured Notes being so prepaid. The First Amendment provided for the reset of the date from which the make-whole premium is applicable with respect to the first tranche Senior Secured Notes. Specifically, the make-whole premium start date with respect to the first tranche Senior Secured Notes changed from October 12, 2021, to either (A) March 1, 2022, if the third tranche Senior Secured Notes are not issued or (B) August 8, 2022, if the third tranche Senior Secured Notes are issued.

The Senior Secured Notes must be prepaid upon the receipt of cash under certain defined conditions, including from voluntary and involuntary asset dispositions, extraordinary receipts, issuance of new indebtedness, and contingent milestone payments for the Legacy Business paid by Alora, each such prepayment being accompanied by, as applicable, the fees described in (i) through (iv) above. The exit fee described in (ii) above is payable on the principal amount of all notes prepaid or repaid, including upon the repayment of the notes upon maturity.

The Senior Secured Notes are guaranteed on a senior secured basis by the Company and certain of its subsidiaries. The Senior Secured Notes and guarantees are secured by substantially all of the assets of the Company and its U.S. subsidiaries. Subject to certain exceptions and qualifications, the Amended Note Purchase Agreement contains covenants that, among other things, limit the Company's ability and the ability of its restricted subsidiaries, including the guarantors, to (i) incur additional indebtedness or issue certain disqualified capital stock, (ii) create liens, (iii) transfer or sell assets, (iv) make certain investments, loans, advances and acquisitions, (v) engage in consolidations, amalgamations

or mergers, or sell, transfer or otherwise dispose of all or substantially all of their assets, and (vi) enter into certain transactions with affiliates. The Amended Note Purchase Agreement also provides for customary events of default.

In addition, the restrictive covenants in the Amended Note Purchase Agreement require the Company to comply with certain minimum liquidity requirements and minimum quarterly product sales requirements. Under the terms of the Amended Note Purchase Agreement, the Company is required to maintain unrestricted cash and cash equivalents greater than or equal to $15.0 million (with a decrease to $12.5 million, if the third tranche Senior Secured Notes have been issued and the Consolidated Upneeq Net Product Sales (as defined in the Note Purchase Agreement) are greater than or equal to $55.0 million), and, as of the end of each fiscal quarter, it is required to maintain consolidated Upneeq net product sales greater than or equal to specified quarterly thresholds (currently at $7.0 million for the fiscal quarter ending March 31, 2023, and increasing in $1.0 million increments each quarter thereafter until the quarter ending June 30, 2024, for which quarter and all subsequent quarters the threshold is $12.0 million). At December 31, 2022, the Company was in compliance with all covenants under the Amended Note Purchase Agreement.

During the year ended December 31, 2021, the Company incurred aggregate debt issuance costs of $2.1 million related to the Senior Secured Notes, $1.5 million and $0.6 million of which were recognized as financial commitment assets underlying the first and second tranche Senior Secured Notes, respectively.

The Company elected the fair value option of accounting on the first tranche Senior Secured Notes upon issuance and, accordingly, a proportionate amount of related debt issuance costs of $1.5 million were immediately written off to selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss. The Company's residual financial commitment asset related to the undrawn second tranche Senior Secured Notes, was being amortized over the relevant one-year commitment period, however, upon the issuance of the second tranche Senior Secured Notes in August 2022 the residual financial commitment asset was immediately expensed. As of December 31, 2021, the second tranche financial commitment asset had a carrying value of $3.1 million and was recorded within current assets in the accompanying consolidated balance sheet. During the year ended December 31, 2022, the Company recognized $3.1 million of amortization expense from the second tranche Senior Secured Notes financial commitment asset with such expense being recorded within interest expense and amortization of debt discount in the accompanying consolidated statements of operations and comprehensive loss.

The Company also elected the fair value option of accounting on the second tranche Senior Secured Notes upon issuance and, accordingly, $0.9 million of related debt issuance costs were immediately written off in August 2022, with such expense being recorded within selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

On a recurring basis, changes in fair value of Senior Secured Notes will be presented in the accompanying consolidated statements of operations and comprehensive loss at each reporting period (see Note 21).

In the year ended December 31, 2022, the Company obtained waivers from the applicable purchasers of mandatory repayments of an aggregate of $5.0 million in principal of the Senior Secured Notes as otherwise required under the Note Purchase Agreement, in exchange for a consent fee of $0.2 million, resulting in net retained proceeds of $4.8 million.

Prior Credit Agreement

Prior to October 12, 2021, the Company was party to a Credit Agreement, dated February 3, 2016, and as amended from time-to-time, under which an aggregate principal amount of $327.5 million of secured term loans were previously issued (the "Prior Term Loans") and that provided for revolving credit commitments up to $50.0 million (the "Prior Revolving Facility," and together with the Prior Term Loans, the "Prior Credit Agreement").

During the six months ended June 30, 2021, pursuant to the terms of the Prior Credit Agreement, the Company exercised its right to cure a shortfall in certain financial covenants which resulted in the mandatory prepayment of $5.3 million against the Prior Term Loans.

On June 25, 2021, the Company amended the Prior Credit Agreement (the “Fifth Amendment”), pursuant to which liens on the Legacy Business were released and the parties agreed to (i) reduce the outstanding Prior Term Loans balance to $30.0 million upon the closing of the divestiture of the Legacy Business, (ii) terminate the Prior Revolving Facility (50% upon signing of the Fifth Amendment and the remaining 50% upon closing of the Legacy Business divestiture), and (iii) shorten the maturity of any remaining term loans to November 21, 2021.

On August 27, 2021, the Company announced the closing of the divestiture of the Legacy Business (see Note 4). Proceeds from the divestiture of the Legacy Business, together with cash on hand were used to repay $186.1 million of debt under the Prior Term Loans and the Prior Revolving Facility expired without ever having been drawn upon.

On October 12, 2021, using a portion of the proceeds from the issuance of Senior Secured Notes, together with the proceeds from a concurrent equity offering (see Note 20), the Company repaid the final $30.0 million outstanding principal under the Prior Term Loans.

As a result of the complete principal repayments under the Prior Term Loans during the year ended December 31, 2021, the Company incurred immaterial fees and expenses upon extinguishment and also wrote off an aggregate of $1.5 million in debt issuance costs with the related expense classified within other non-operating gain or loss in the consolidated statements of operations and comprehensive loss.

Note 13. Concentrations and Credit Risk

For the year ended December 31, 2022, the Company has a significant concentration of credit risk with one customer representing 94% of trade accounts receivable.

Purchasing

The Company has an exclusive supply agreement with a third party for the manufacturing and delivery of Upneeq.

Sales by Product & Geography

For the years ended December 31, 2022 and 2021, Upneeq sales in the United States accounted for 100% of the Company's total gross product sales.

Note 14. Share-Based Compensation

Overview of Plans

Our outstanding share-based compensation awards have been issued under a succession of plans sponsored by various companies within our consolidation group, including, (i) the Amended and Restated 2018 Incentive Plan, which first became effective upon the Company’s initial public offering on October 22, 2018 (the "2018 Plan"), (ii) the Amended and Restated 2016 Equity Incentive Plan, which first became effective in February 2016 (the “2016 Plan”) and (iii) the 2018 Employee Share Purchase Plan, which became effective in September 2019 upon adoption and approval by the Company’s Board of Directors (the “ESP Plan”).

2016 Plan - The 2016 Plan allowed for the issuance of ordinary shares of the Company in satisfaction of awards issued thereunder. In connection with its initial public offering, the Company modified the terms of certain performance-based awards previously issued under the 2016 Plan by converting those awards to time-based awards vesting in equal annual installments on the first four anniversaries of the initial public offering, subject to continuous employment. The conversion of such legacy awards upon the initial public offering was accounted for as a modification where the fair value of such awards determined on the modification date was recognized over their remaining vesting period. At December 31, 2022, no ordinary shares were available for future issuance under the 2016 Plan.

2018 Plan - The 2018 Plan allows for the issuance of ordinary shares of the Company in satisfaction of awards issued thereunder, including, stock options, stock appreciation rights, restricted and unrestricted share and share units, performance awards, and other awards that are convertible into or otherwise based on the Company's ordinary shares to employees and non-employee directors, consultants, and advisors. In October 2018, in connection with Company's initial public offering, and in 2021 and 2022, the Company granted stock options under the 2018 Plan that vest on the fourth anniversary of the grant date, subject to the employee's continued employment through such vesting date. The 2018 Plan will automatically terminate on April 9, 2031, and no awards may be granted after this date.

ESP Plan - The ESP Plan allows each eligible employee who is participating in the plan to purchase shares by authorizing payroll deductions of up to $2,000 per payroll period. Unless the participating employee has previously withdrawn from the offering, accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85 percent of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of ordinary shares, valued at the start of the purchase period, under the ESP Plan in any calendar year. There is no minimum holding period associated with shares purchased pursuant to this plan. An employee's purchase rights terminate immediately upon termination of employment.

Share-based Compensation

The compensation cost, that has been charged against income for all incentive plans, excluding the ESP Plan, was $3.9 million for the year ended December 31, 2022 and $6.8 million for the year ended December 31, 2021.

Share-Based Award Activity

The following tables of share-based award activity are based on the historical activity of the continuing and discontinued operations of the Company on a combined basis.

A summary of stock option activity under the 2016 Plan as of December 31, 2022 and 2021, and changes during the years then ended is presented below:

2016 Plan - Share Options	**Number of Share Options**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term**
Outstanding at January 1, 2021	2,827,100	$ 14.95	
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(312,690)	$ 14.95	
Outstanding at December 31, 2021	2,514,410	$ 14.95	
Vested at December 31, 2021	2,514,410	$ 14.95	
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(239,874)	$ 14.95	
Outstanding at December 31, 2022	2,274,536	$ 14.95	3.4 years
Vested at December 31, 2022	2,274,536	$ 14.95	3.4 years

The aggregate intrinsic value of options outstanding under the 2016 Plan at December 31, 2022 was $0. The fair value of options vested under the 2016 Plan during the year ended December 31, 2021 was immaterial.

A summary of option activity under the 2018 Plan as of December 31, 2022 and 2021, and changes during the year then ended is presented below:

2018 Plan - Share Options	Number of Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2021	96,400	$ 7.00	
Granted	3,174,886	1.80	
Exercised	—	—	
Expired / Forfeited	(88,850)	$ 5.98	
Outstanding at December 31, 2021	3,182,436	$ 1.84	
Vested Options at December 31, 2021	—		
Granted	114,700	$ 1.24	
Exercised	—	—	
Expired / Forfeited	(796,914)	$ 1.82	
Outstanding at December 31, 2022	2,500,222	$ 1.82	8.8 years
Vested Options at December 31, 2022	659,119	$ 1.94	8.8 years

The aggregate intrinsic value of options outstanding under the 2018 Plan at December 31, 2022 was $0. The weighted average grant date fair value for the options granted during the years ended December 31, 2022 and 2021 was $1.24 and $1.25, respectively. The fair value of options vested under the 2018 Plan during the years ended December 31, 2022 and 2021 were both $0.

The fair value of option awards is estimated using the Black-Scholes option-pricing model. Exercise price of each award is generally not less than the per share fair value in effect as of that award date. The determination of fair value using the Black-Scholes model is affected by the Company's share fair value as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, risk-free interest rate and projected employee share option exercise behaviors.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected volatility	84 %	81 %
Risk-free interest rate	1.63 - 3.78 %	1.25% - 1.29 %
Expected dividend yield	— %	— %
Expected life of options in years	6.25	6.08 - 6.25

The estimated fair value of the options is expensed over the requisite service period, which is generally the vesting period on a graded vesting basis. As of December 31, 2022 there was $1.2 million of aggregate unrecognized share compensation expense related to unvested options granted under the 2018 Plan, which is expected to be recognized over a weighted-average period of 1.6 years.

For all periods prior to the IPO, our Board of Directors has determined the fair value of the common unit underlying our option with assistance from management and based upon information available at the time of grant. Prior to our IPO, given the absence of a public trading market for our common units, estimating the fair value of our common units was based on the actual operational and financial performance, current business conditions and discounted cash flow projections. The estimated fair value of our common units, prior to our IPO was adjusted for lack of marketability and control existing at the grant date.

Restricted and Performance Stock Units

On May 18, 2020 and May 20, 2020, the Company granted performance stock units ("PSUs") under the 2018 Plan to certain key employees of the Company that gives holders the potential to receive a certain number of earned PSUs at the end of a pre-determined term. Unless earlier terminated, forfeited, relinquished or expired, the earned PSUs will vest in full on the vesting date, subject to the grantee remaining in continuous employment from the date of grant through the vesting date. The vesting date is the third anniversary from the grant date for the PSUs granted on May 18, 2020 and the fifth anniversary from the grant date for the PSUs granted on May 20, 2020. The number of PSUs that become earned PSUs as of the end of the performance period shall be equal to the number of PSUs multiplied by the applicable percentage based on Stock Price Hurdle attainment, as set forth in the PSU Award Agreement and 2018 Plan.

A summary of PSU activity under the 2018 Plan as of December 31, 2021, and changes during the year then ended is presented below:

2018 Plan - PSUs

	Number of PSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Term (Years)
Outstanding at January 1, 2021	789,799	$ 4.99	
PSUs granted	—	—	
PSUs vested	—	—	
PSUs forfeited	(789,799)	4.99	
Outstanding at December 31, 2021	—	$ —	—

Closing of the Legacy Business divestiture triggered acceleration of vesting of the PSUs, however the PSUs were automatically forfeited due to market conditions not being met in accordance with the 2018 Plan.

A summary of RSU activity under the 2018 Plan as of December 31, 2022 and 2021, and changes during the years then ended is presented below:

2018 Plan - RSUs

	Number of RSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term
Outstanding at January 1, 2021	1,991,557	$ 5.99	
RSUs granted	161,188	3.25	
RSUs vested	(601,306)	6.05	
RSUs forfeited	(199,164)	4.73	
Outstanding at December 31, 2021	1,352,275	$ 5.82	
RSUs granted	75,000	1.88	
RSUs vested	(310,783)	5.76	
RSUs forfeited	(82,843)	5.18	
Outstanding at December 31, 2022	1,033,649	$ 5.60	1.5 years

During the years ended December 31, 2022 and 2021 we granted RSUs covering an equal number of our ordinary shares to employees and certain directors with a weighted average grant date fair value of $1.88 and $3.25, respectively. The fair value of RSUs are determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized ratably over the vesting period of four years for employees and one to three years for directors. At December 31, 2022 aggregate unrecognized share compensation expense related to unvested RSUs was $1.9 million which is expected to be recognized over a weighted average period of 1.5 years.

ESP Plan

The Company accounts for employee stock purchases made under its ESP Plan using the estimate grant date fair value in accordance with ASC 718. The purchase price discount and the look-back feature cause the ESP Plan to be compensatory and the Company to recognize compensation expense. Share compensation expense is recognized on a straight-line basis over the requisite service period. The Company recognized $167,731 and $134,077 of share compensation expense from the ESP Plan for the years ended December 31, 2022 and 2021, respectively. The Company values ESP Plan shares using the Black-Scholes model.

As of December 31, 2022 there were no unrecognized share compensation expense related to the ESP Plan. There were 207,903 and 76,432 ordinary shares issued under the ESP Plan during the years ended December 31, 2022 and 2021, respectively. On January 5, 2023, the Company issued 96,612 ordinary shares to the employees who participated in the ESP Plan during the offering period ended December 31, 2022.

Note 15. Earnings or Loss Per Ordinary Share

The following potentially dilutive securities have been excluded from the weighted average ordinary shares outstanding in the computation of diluted earnings or loss per share because the impact of including them would have been anti-dilutive:

	Year Ended December 31,	
	2022	2021
Performance and restricted stock units	1,033,649	1,352,275
Share options to purchase ordinary shares	4,774,758	5,696,846
Warrants to purchase ordinary shares	16,100,000	16,100,000
Ordinary shares to be purchased through employee stock purchase plan	96,612	129,258

Note 16. Commitments and Contingencies

Contingent Milestone Payments

Upon closing of the Legacy Business divestiture, the only strategic business agreements remaining with the Company are contingent payment obligations related to the acquisition of Upneeq and its related intellectual property, including contingent earn out obligations pursuant to the acquisition of RevitaLid, Inc., the original owner of Upneeq. The aggregate amount of future contingent payments due under the strategic business agreements, based on defined regulatory milestone events and milestones based on levels of US and ex-US net product sales of Upneeq, was $0.8 million in the aggregate at December 31, 2022.

The aggregate expense associated with contingent payments related to the acquisitions of Upneeq and Revitalid in the years ended December 31, 2022 and 2021 was $2.8 million and $0.5 million, respectively, with such amounts classified within cost of goods sold in the accompanying consolidated statements of operations and comprehensive loss.

Royalty Obligations

The Company does not have agreements with third parties that require the Company to make minimum royalty payments.

Supply Agreement Obligations

The only supply agreement remaining with the Company after the divestiture of the Legacy Business is that related to the supply of Upneeq, which contains no minimum purchase obligations. The Company has no enforceable and legally binding purchase obligations at December 31, 2022.

Defined Contribution Plan

The Company maintains a 401(k) plan that covers eligible employees subject to certain age and length of service requirements. The 401(k) plan provides for employer matching contributions equal to 100% of each employee's elective deferrals up to 3% of base salary, plus 50% of each employee's elective deferrals between 3% and 5% of base salary. For the years ended December 31, 2022 and 2021, the Company recognized expenses related to its contributions under the Plan of $0.7 million and $0.7 million, respectively.

Legal Proceedings

The Company is a party in legal proceedings and potential claims arising from time to time in the ordinary course of its business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, management of the Company believes that the ultimate disposition of such proceedings and exposures will not have a material adverse impact on the financial condition, results of operations, or cash flows of the Company.

On February 16, 2018, the Company received FDA approval for its amantadine extended release tablets under the trade name Osmolex ER. On that same date the Company filed in the Federal District Court for the District of Delaware a Complaint for Declaratory Judgment of Noninfringement of certain patents owned by Adamas Pharmaceuticals, Inc. (Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals, LLC vs. Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC). Adamas was served with the Complaint on February 21, 2018. Adamas filed an answer on April 13, 2018 denying the allegations in the Complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. On December 2, 2020, we entered into an agreement to settle the litigation with Adamas. Under the terms of the agreement, both parties agreed to drop their respective claims relating to the patent litigation, and Adamas agreed to acquire the global rights to Osmolex ER from the Company for $7.5 million. The sale of the global rights to Osmolex ER closed in January 2021 at which time the related gain of $5.6 million was recorded in the consolidated statements of operations and comprehensive loss under gain on sale of product rights, net.

Additionally, in connection with the settlement and the sale of the global rights to Osmolex ER, the parties entered into a supply agreement pursuant to which the Company agreed to supply Adamas with amantadine extended release tablets for a six-year term, subject to possible two-year extensions and customary closing conditions.

On April 30, 2019, the Company was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*. On May 10, 2019, a Complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints named the Company, certain of the Company's directors and officers and the underwriters of the Company's initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for the Company's initial public offering of ordinary shares. On July 22, 2019, the plaintiffs filed an amended complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. The parties participated in a mediation and reached an agreement in principle to settle the litigation on December 15, 2020. The parties subsequently negotiated a settlement agreement setting forth the terms of the settlement. On May 18, 2021, plaintiffs filed an unopposed motion for preliminary approval of the settlement and notice to the proposed settlement class, which motion was granted by the court on June 11, 2021. The settlement, which was finally approved by the Court on November 10, 2021, calls for a payment by the Company of $5.25 million (a portion of which was covered by applicable insurance) and fully resolves all claims asserted in the litigation against all defendants named in the litigation, including the Company. No party admitted any wrongdoing as part of the settlement, which was reached to avoid the further cost and distraction of litigation.

On April 19, 2021, we were served with a complaint in an action entitled *United States ex rel. Lupinetti, et al. v. Exeltis USA, Inc., et al., Northern District of Illinois, No. 1:19-cv-00825*. The complaint named us and four other pharmaceutical manufacturers as defendants in a suit alleging violations of the federal False Claims Act and state corollary statutory schemes related to the labelling, marketing, and reimbursement of several prenatal vitamins. The United States government declined to intervene in the action and the plaintiff chose to proceed with the litigation as a qui tam relator on behalf of the federal government and 29 individual states seeking monetary damages, statutory civil penalties, and costs and fees. On June 18, 2021, we and the other defendants in the action filed a Joint Motion to Dismiss. On November 19, 2021, the Court granted defendants Joint Motion to Dismiss and on November 23, 2021, the Court dismissed the action with prejudice.

Note 17. Income Taxes

RVL Pharmaceuticals plc is an Irish public limited company. Since the majority of the Company's operations is in the U.S., the statutory income tax rate that is applicable is the U.S. federal income tax rate of 21%. On August 27, 2021, and in connection with the divestiture of the Legacy Business, the Company sold its interest in certain subsidiaries which resulted in a federal capital loss.

The following table shows the components of loss before income taxes and the related current and deferred income taxes from continuing operations (in thousands):

	December 31, 2022	December 31, 2021
Loss before income taxes		
U.S. operations	$ (48,197)	$ (68,975)
Non-U.S. operations	(3,515)	(13,559)
Total loss before income taxes	(51,712)	(82,534)
Current income tax expense (benefit)		
Federal	86	192
State	105	(41)
Foreign	(68)	20
Total current income tax expense (benefit)	123	171
Deferred income tax expense (benefit)		
Federal	(90)	149
Foreign	(53)	(5)
Total deferred income tax expense (benefit)	(143)	144
Total income tax expense (benefit)	$ (20)	$ 315

The following table provides a reconciliation of the U.S. statutory federal income tax rate to the Company's effective income tax rate from continuing operations:

	December 31, 2022	December 31, 2021
U.S. federal income tax at 21% statutory rate	21.00 %	21.00 %
State and local income taxes, net of federal benefit	6.28 %	2.65 %
Differences in tax effects on foreign income	0.23 %	8.81 %
Federal tax credits	0.95 %	0.29 %
Uncertain tax positions	(0.01)%	— %
NOL carryback rate differential	— %	(0.03)%
Tax audit adjustments	0.11 %	0.01 %
Change in valuation allowance	(23.24)%	(33.83)%
Permanent adjustments	(0.63)%	(0.01)%
Return to provision	(4.65)%	— %
Other	— %	0.73 %
Effective income tax rate	0.04 %	(0.38)%

Deferred income taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial statement purposes and the comparable amounts recorded for income tax purposes. The following table depicts the significant components of deferred tax assets (liabilities) (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Accrued expenses	$ 714	$ 827
Inventories	4	—
Net operating losses	26,944	21,134
Capital losses	23,805	23,845
Right of use liabilities	120	340
Tax credits	8,207	7,232
Debt costs	3,311	4,740
Interest expense	4,367	2,168
Share compensation	709	285
Other	3,561	2,916
Less: valuation allowance	(64,872)	(52,853)
Deferred tax liabilities:		
Property plant & equipment	(28)	—
Intangible assets	(2,339)	(6,353)
Debt costs	(4,447)	(4,107)
Right of use assets	(117)	(325)
Total deferred income taxes	$ (61)	$ (151)

At December 31, 2022, the Company had federal net operating loss carryforwards of $70.2 million, state net operating loss carryforwards of $139.2 million, net operating loss carryforwards in certain foreign tax jurisdictions of $109.9 million, which will begin to expire in 2026 and total tax credit carryforwards of $8.6 million, primarily consisting of Federal Orphan Drug Tax Credits that are expected to be fully realized prior to their expiration, beginning in 2036. The Company also had federal capital loss carryforwards of $95.8 million at December 31, 2022, which will expire in 2026.

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on actual and forecasted operating results in order to determine the proper amount, if any, required for a valuation allowance. The Company maintains valuation allowances on deferred tax assets applicable to entities in the U.S. and foreign jurisdictions for which separate income tax returns are filed, where realization of the related deferred tax assets from future profitable operations is not reasonably assured. During the years ended December 31, 2022 and 2021, the

valuation allowance increased by $12.0 million and $25.1 million, respectively. Should applicable deferred tax assets ultimately become realizable, such resulting reduction in the valuation allowance would generally be recognized as an income tax benefit.

The Company files income tax returns in U.S. federal, state and certain international jurisdictions. For U.S. federal and certain state income tax purposes, the Company's 2016 through 2022 tax years remain open for examination by the tax authorities under the normal statute of limitations. For certain international income tax purposes, the Company's 2016 through 2022 tax years remain open for examination by the tax authorities under the normal statute of limitations.

No provision is made for foreign withholding or income taxes associated with the cumulative undistributed earnings of the foreign subsidiaries. Any future foreign withholding or income taxes associated with the undistributed earnings are not anticipated to be material.

The following table provides a reconciliation of the beginning and ending amounts of unrecognized tax benefits, excluding accrued interest (in thousands):

	December 31, 2022	December 31, 2021
Balance at beginning of period	$ 175	$ 171
Additions related to current period tax positions	4	4
Balance at end of period	$ 179	$ 175

It is not anticipated that the amount of unrecognized tax benefits will materially change in the next 12 months. If recognized, the total amount of unrecognized tax benefits would have an immaterial impact on the Company’s effective income tax rate.

The Company classifies interest expense related to unrecognized tax benefits as components of the income tax expense or benefit. Interest and penalties recognized in the consolidated statements of operations were immaterial.

Note 18. Related Parties

In August 2022, affiliates of Avista Capital Partners, an entity that holds significant influence over the Company, and two of the Company’s executive officers, one of whom is also a director, among other parties participated in a private placement of ordinary shares at the then-current market trading price (see Note 20).

There were no other related party transactions and no related expenses were recognized for the years ended December 31, 2022 and 2021.

Note 19. Restructuring Expenses

In April and September 2022, as part of initiatives to refine the Company’s go to market strategy, the Company recognized an aggregate of $2.9 million in expenses primarily associated with employee severance benefits that were classified in selling, general and administrative expenses in the accompanying consolidated financial statements of operations and comprehensive loss.

In April 2021, the Company curtailed operations and implemented workforce reductions in its research and development subsidiary in Buenos Aires, Argentina. These restructuring activities were associated with the Company’s plans to reduce expenses and better align business activities with the Company’s corporate strategy. As a result, the Company recognized $4.5 million of restructuring expenses in the year ended December 31, 2021. The restructuring expenses consisted of $3.2 million for one-time employee related termination benefits, and $1.3 million of asset disposal costs related to leasehold improvements at the Buenos Aires location. Of the $4.5 million of restructuring expenses, $2.0 million were recognized in selling, general and administrative expenses, $1.2 million were recognized in research and

development expenses, and $1.3 million of asset disposal costs were recognized in non-operating expenses, each in the accompanying statements of operations and comprehensive loss.

Note 20. Shareholders' Equity and Warrant Liabilities

2022 Equity Offering

As a condition to the effectiveness of the First Amendment (see Note 12), on August 4, 2022 the Company entered into a series of share subscriptions (collectively, the "Share Subscription Agreements") with Athyrium Opportunities IV Co-Invest 2 LP ("Athyrium"), Avista Healthcare Partners, L.P. ("Avista"), Brian Markison, Chief Executive Officer, and James Schaub, Executive Vice President and Chief Operating Officer, (together, the "Equity Purchasers") pursuant to which the Company sold and issued to the Equity Purchasers, in a private placement (the "Private Placement"), an aggregate of 15,451,612 ordinary shares of the Company, nominal value $0.01 per share, at a purchase price of $1.55 per Ordinary Share, the closing market trading price on August 4, 2022.

Pursuant to the Share Subscription Agreements, the closing of the Private Placement occurred on August 8, 2022. The Company issued and allotted (i) 6,451,612 ordinary shares to Athyrium: (ii) 8,000,000 ordinary shares to Avista; (iii) 850,000 ordinary shares to Brian Markison; and (iv) 150,000 ordinary shares to James Schaub, for aggregate gross proceeds to the Company of $23.9 million, before deducting offering expenses of $0.3 million. Proceeds from the Private Placement were used for working capital and general corporate purposes. The Share Subscription Agreements also provide the Equity Purchasers with certain registration rights. The ordinary shares issued pursuant to the Share Subscription Agreements were registered on the Company's Registration Statement on Form S-3 (File No. 333-266984), filed with the Securities and Exchange Commission ("SEC") on August 19, 2022, and declared effective on August 26, 2022.

2021 Equity Offering and Warrants

On October 6, 2021, in order to raise capital to fund the Company's planned expenditures and meet its obligations, the Company initiated a follow-on equity offering for the issuance and allotment of 14,000,000 ordinary shares and warrants to purchase up to an additional 14,000,000 ordinary shares in an underwritten public offering, at a public offering price of $2.50 per share and accompanying warrant less underwriting discounts and commissions. In addition, the Company granted the underwriter a 30-day option to purchase up to an additional 2,100,000 ordinary shares at the public offering price and/or warrants to purchase an additional 2,100,000 ordinary shares at an exercise price of $0.00001 per warrant. On October 11, 2021, the underwriter exercised its option to purchase 2,100,000 optional warrants. Subsequently, the underwriter's option to purchase additional ordinary shares expired unexercised.

On October 12, 2021 the Company closed the follow-on offering via the issuance and allotment of 14,000,000 ordinary shares and warrants to purchase 16,100,000 ordinary shares (the "Warrants") raising aggregate gross proceeds of $35.0 million to the Company. $8.8 million of the gross proceeds, equal to the fair value of the Warrants determined using the Black-Scholes Merton option-pricing model, were allocated to the warrants liability, and the remaining proceeds of $26.2 million were allocated to the ordinary shares. The Company incurred a total of $2.6 million in aggregate issuance costs, including $1.9 million attributable to the ordinary share issuance and thereby deducted from proceeds in equity and $0.7 million attributable to the Warrants and thereby recognized as a component of selling, general and administrative expenses in the year ended December 31, 2021.

The Warrants are exercisable for the Company's ordinary shares at any time and may only be exercised for a whole number of ordinary shares at an exercise price of $3.10 per warrant, subject to adjustments as provided under the terms of the form of warrant. Additionally, the holders of Warrants are entitled, prior to exercise, to participate in any dividend or other distribution of the Company's assets to holders of ordinary shares presuming the Warrants had been exercised. If exercised for cash by the holders, the Warrants would result in additional gross proceeds to the Company of $49.9 million. In the event of a "Fundamental Transaction" (as defined in the form of warrant), the holders of the Warrants have the contingent right to require the Company (or a successor entity) to redeem the Warrants for cash. The Warrants will expire three and one-half years from issuance on March 12, 2025.

The Warrants are accounted for as liabilities in accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity's Own Equity,* and are presented within warrant liabilities on the accompanying consolidated balance sheet. On a recurring basis, changes in fair value of Warrant liabilities will be presented in the accompanying consolidated statement of operations and comprehensive loss at each reporting period. The estimated fair value of Warrants is considered to be a Level 3 measurement in the fair value hierarchy. See Note 21 for a description of the valuation methodology of the Warrants.

2021 Debt Refinancing

On October 12, 2021, the Company issued and allotted 6,148,832 of the Company's ordinary shares, to the purchaser of the Senior Secured Notes for a price of $0.01 per share, pursuant to a Share Subscription Agreement between the Company and Purchaser, dated October 1, 2021. The number of shares issued and allotted to purchaser was equal to $15.0 million divided by the volume weighted average price per ordinary share in the 60 trading days ended October 8, 2021. The ordinary shares were recognized in shareholders' equity at their fair value at issuance of $12.6 million. The ordinary shares were subsequently registered on the Company's Registration Statement on Form S-3 (File No. 333-260529), filed with the SEC on October 27, 2021 and declared effective on December 9, 2021.

2021 ATM Equity Offerings

On September 8, 2021, the Company entered into a sales agreement with Cantor Fitzgerald & Co., ("Cantor") under which it may offer and sell its ordinary shares having aggregate sales proceeds of up to $75.0 million from time to time through Cantor as its sales agent by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including, without limitation, sales made directly on the Nasdaq Global Select Market or any other existing trading market for the Company's ordinary shares (each an "ATM Equity Offering"). During the year ended December 31, 2021 the Company sold 146,162 of its ordinary shares under ATM Equity Offerings at the weighted-average price of $3.13, generating aggregate proceeds of $0.5 million and net proceeds of $0.0 million, after deducting commissions and offering expenses payable by us. The Company also incurred a total of $0.4 million in direct issuance costs, which were attributable to the establishment of the sales agreement and in support of sales of ordinary shares by ATM Equity Offerings and therefore were recognized as a reduction of equity.

Ordinary Share Repurchase Program

In September 2019, the Company's board of directors authorized the repurchase of up to 5,251,892 ordinary shares pursuant to a share repurchase program. Purchases under the ordinary share repurchase program can be made on the open market or in privately negotiated transactions, with the size and timing of these purchases based on a number of factors, including the price of our ordinary shares, our business and market conditions.

The Company retires ordinary shares acquired under the ordinary share repurchase program. The Company did not repurchase any shares during the years ended December 31, 2022 and 2021.

Note 21. Financial Instruments and Fair Value Measurements

The Company's financial instruments subject to fair value measurements include cash and cash equivalents, accounts receivable and other receivables, trade accounts payable, accrued liabilities, long-term debt and warrant liabilities.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial Assets – Cash and cash equivalents, generally consisting of investments in interest-bearing money market accounts, are measured at fair value on a recurring basis using Level 1 measurements. Fair value inputs for these investments are considered Level 1 measurements within the fair value hierarchy because money market account fair values are known and observable through daily published floating net asset values. The fair value of the Company's cash and cash equivalents, being the same as their carrying value, were $44.5 million and $40.4 million at December 31, 2022 and 2021, respectively.

Financial Liabilities – The Senior Secured Notes, a material component of long-term debt (see Note 12), and Warrants, as reflected within warrant liabilities, a material component of total liabilities, (see Note 20), have each been measured and carried at fair value since their issuance in October 2021. Such instruments represent financial liabilities whose measurement contains significant unobservable inputs, which management considers to be Level 3 measurements under the fair value hierarchy.

The Company uses a discounted cash flow technique, an income-based approach, to determine the fair value of the Senior Secured Notes. This technique relies upon an assumption of pricing the Senior Secured Notes to their maturity (without mandatory or voluntary prepayments) and incorporates inputs such as contractual repayment terms, maturity, and discount rate. The most significant unobservable input for the Senior Secured Notes is the discount rate which we estimate by performing a yield analysis that relies upon the discount rate observed in the initial issuance of the Senior Secured Notes as well as certain benchmark debt instruments with observable pricing from which we draw conclusions on the change in the discount rate from period to period.

The Company uses the Black-Scholes Merton option-pricing model to value the Warrants. This model incorporates transaction details such as the Company's stock price, contractual terms, maturity, risk free rates, and volatility. The most significant unobservable input for the warrant liabilities is volatility. Given the limited trading volume and period of time the Company's stock has been traded in an active market, the expected volatility is estimated by taking the average historical price volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate to the expected term of the warrants.

The following tables show financial liabilities subject to fair value measurement on a recurring basis and related information on fair values, valuation techniques and unobservable inputs (dollars in thousands):

	At December 31, 2022			
Financial Instrument	**Fair Value**	**Valuation Technique**	**Unobservable Inputs**	
Senior Secured Notes	$ (55,500)	Income Approach - DCF	Discount rate	24.6 %
			Term (in years)	3.8
Warrants	$ (1,951)	Black-Scholes Merton	Equity volatility	60.0 %
			Term (in years)	2.3

	At December 31, 2021			
Financial Instrument	**Fair Value**	**Valuation Technique**	**Unobservable Inputs**	
Senior Secured Notes	$ (43,800)	Income Approach - DCF	Discount rate	17.9 %
			Term (in years)	4.8
Warrants	$ (3,220)	Black-Scholes Merton	Equity volatility	65.0 %
			Term (in years)	3.3

The following table shows changes in the fair value of financial liabilities subject to Level 3 fair value measurements on a recurring basis (in thousands):

	Senior Secured Notes	Warrants
Balance, At December 31, 2021	$ (43,800)	$ (3,220)
Principal issuance of second tranche Senior Secured Notes (Note 8)	(20,000)	-
Cash payments for interest	4,843	-
Fair value adjustments through earnings (inclusive of related accrued interest expense)	2,857	1,269
Fair value adjustments through accumulated other comprehensive income or loss	(1,700)	-
Accrued interest (Note 10)	2,300	-
Balance, At December 31, 2022	$ (55,500)	$ (1,951)

Changes in the fair value of debt that is accounted for at fair value, inclusive of related accrued interest expense, are presented as gains or losses in the accompanying consolidated statements of operations and comprehensive loss under change in fair value of debt. The portion of total changes in fair value of debt attributable to changes in instrument-specific credit risk are determined through specific measurement of periodic changes in the discount rate assumption for company-specific credit risk, exclusive of base market changes, and are presented within change in fair value of debt due to change in credit risk, net of tax, a component of comprehensive income or loss in the accompanying consolidated statements of operations and comprehensive loss.

No financial liabilities were subject to fair value measurements on a recurring basis prior to October 2021.

Non-recurring Fair Value Measurements

As part of the Company's goodwill and intangible asset impairment assessments performed at quarterly intervals or whenever indicators of impairment are identified or when IPR&D assets are placed into service, the Company estimates the fair values of the subject assets using an income approach that utilizes a discounted cash flow model, or, where appropriate, a market approach. Such valuations typically employ assumptions that are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. See Note 9 for discussions of relevant non-recurring fair value measurements, significant assumptions and the associated impairment charges recognized when relevant, performed during the years ended December 31, 2022 and 2021.

Note 22. Subsequent Events

In February 2023, the Company received $5.0 million in cash from Alora related to a contingent milestone payment earned in connection with the sale of the Legacy Business (see Note 4). In March 2023, the Company paid the $5.0 million to the Purchasers in satisfaction of mandatory repayment conditions required under its Amended Note Purchase Agreement (see Note 12), thereby reducing the outstanding principal balance of the second tranche Senior Secured Notes by $4.3 million.

On March 8, 2023, the Company entered into a second amendment to the Note Purchase Agreement (the "Second Amendment") with, among others, the Purchasers and the Administrative Agent, which further amended the Amended Note Purchase Agreement (see Note 12). The Second Amendment provided solely for the immediate reduction of the minimum liquidity requirement from $15.0 million to $12.5 million.

Between January and March 2023, the Company received an aggregate of $4.1 million in federal tax refunds related to income taxes paid in prior periods. The Company is continuing to pursue the collection of $1.8 million of additional federal refund claims.

In March 2023, the Company amended a lease agreement for its Sayreville, NJ location, the operations site of RVL Pharmacy, to extend the lease for an additional 36 months through December 31, 2026.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the 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 and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and

monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain information regarding our executive officers is set forth at the end of Part I, Item 1 of this Form 10-K under the heading, "Information about our Executive Officers." The remaining information required with respect to this Item 10 is incorporated by reference to the information to be contained in our Proxy Statement for the 2022 Annual Meeting of Shareholders, or the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the information to be contained in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated by reference to the information to be contained in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated by reference to the information to be contained in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated by reference to the information to be contained in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

None.

Financial Statement Schedules

None.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibits

Exhibit No.	Description
2.1	Purchase and Sale Agreement, dated as of June 24, 2021, by and among the Company, Acella Holdings, LLC, Alora Pharmaceuticals, LLC and the Sellers listed therein (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on June 30, 2021, Commission File No. 001-38709)
2.2	Stock Purchase Agreement, dated as of October 24, 2017, by and between RevitaLid, Inc. and Osmotica Pharmaceutical Corp. (incorporated by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
3.1	Memorandum and Articles of Association of RVL Pharmaceuticals plc (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 18, 2022, Commission File No. 001-38709)
4.1	Shareholders' Agreement (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 28, 2019, Commission File No. 001-38709)
4.2	Amendment No. 1, dated as of November 20, 2020, to the Shareholders Agreement, dated as of October 17, 2018, by and among Osmotica Pharmaceuticals plc, ACP Holdco (Offshore), L.P., ACP III AIV, L.P., Altchem Limited, Orbit Co-Invest A-I LLC, Orbit Co-Invest I LLC, Orbit Co-Invest III LLC, and the management shareholders identified therein (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 30, 2021, Commission File No. 001-38709)
4.3	Form of Ordinary Share Certificate (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
4.4	Description of Registrant's Securities (incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)
10.1†	License Agreement dated as of August 31, 2011 by and between VOOM, LLC and Revitalid, Inc. (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.2†	Exclusive Supply Agreement, dated as of February 7, 2013, by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc. (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.3†	First Amendment to Exclusive Supply Agreement, dated as October 24, 2017 by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc. (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.5	Amendment to License Agreement, effective as of March 31, 2022, by and between RVL Pharmaceuticals, Inc. and Santen Pharmaceutical Co. Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 4, 2022, Commission File No. 001-38709)
10.6+	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.7+ Form of Osmotica Holdings US LLC Director and Corporate Secretary Indemnification Agreement (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.8+ Form of Nonqualified Option Award Agreement under the RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)

10.9+ RVL Pharmaceuticals plc Amended and Restated 2018 Employee Share Purchase Plan (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)

10.10+ Form of Nonqualified Option Award Agreement under the Amended and Restated RVL Pharmaceuticals plc 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.11+ Amended and Restated RVL Pharmaceuticals plc 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)

10.12+ RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)

10.13+ Osmotica Pharmaceuticals plc 2018 Annual Cash Incentive Plan (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.14+ Employment Agreement, dated December 3, 2015, by and between Vertical/Trigen Holdings, LLC and Brian A. Markison (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709)

10.15+ Amendment to Employment Agreement, dated July 29, 2021, by and between RVL Pharmaceuticals, Inc. and Brian A. Markison (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on March 30, 2022, Commission File No. 001-38709).

10.16+ Amendment to Employment Agreement, dated November 5, 2021, by and between RVL Pharmaceuticals, Inc. and Brian A. Markison (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 10, 2021, Commission File No. 001-38709)

10.17+ Employment Agreement, dated December 16, 2013, by and between Vertical/Trigen Opco, LLC and James Schaub (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.18+ Employment Agreement, dated May 2, 2016, by and between Vertical/Trigen Opco, LLC and Tina deVries (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

10.19+ Employment Agreement, dated December 16, 2013, by and between Vertical/Trigen Opco, LLC and Christopher Klein (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)

10.20+	Form of Initial Retainer Agreement (In Lieu of Equity Awards) with RVL Pharmaceuticals plc Directors (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)
10.21+	Form of Additional Annual Retainer Agreement (In Lieu of Equity Awards) with RVL Pharmaceuticals plc Directors (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)
10.22	Contingent Amendment Agreement, dated June 24, 2021, by and among Osmotica Pharmaceutical Corp., Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the loan parties thereto, and the lenders party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 30, 2021, Commission File No. 001-38709)
10.23	Sales Agreement, dated as of September 8, 2021, by and between Osmotica Pharmaceuticals, plc and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on September 8, 2021, commission File No. 333-236193)
10.24	Note Purchase Agreement, dated October 1, 2021, between Osmotica Pharmaceutical Corp., Osmotica Pharmaceuticals plc, Osmotica Holdings US LLC, Athyrium Opportunities IV Acquisition LP and the Purchasers from time to time party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2021, Commission File No. 001-38709)
10.25	First Amendment to Note Purchase Agreement, dated August 4, 2022, by and among Osmotica Pharmaceutical Corp., the Guarantors party thereto, the Purchasers party thereto and Athyrium Opportunities IV Acquisition LP, as the Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2022, Commission File No. 001-38709)
10.26	Second Amendment to Note Purchase Agreement, dated March 8, 2023, by and among RevitaLid Pharmaceutical Corp., the Guarantors party thereto, the Purchasers party thereto and Athyrium Opportunities IV Acquisition LP, as the Administrative Agent
10.27	Share Subscription Agreement, dated October 1, 2021, between Osmotica Pharmaceuticals plc and Athyrium Opportunities IV Acquisition LP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 6, 2021, Commission File No. 001-38709)
10.28	Share Subscription Agreement, dated August 4, 2022, by and between RVL Pharmaceuticals plc and Avista Healthcare Partners, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2022, Commission File No. 001-38709)
10.29	Share Subscription Agreement, dated August 4, 2022, by and between RVL Pharmaceuticals plc and Athyrium Opportunities IV Co-Invest 2 LP (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2022, Commission File No. 001-38709)
10.30	Share Subscription Agreement, dated August 4, 2022, by and between RVL Pharmaceuticals plc and Brian Markison (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2022, Commission File No. 001-38709)
10.31	Share Subscription Agreement, dated August 4, 2022, by and between RVL Pharmaceuticals plc and James Schaub (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2022, Commission File No. 001-38709)
21.1	Subsidiaries of RVL Pharmaceuticals plc

23.1	Consent of Ernst & Young LLP independent registered public accounting firm
31.1	Principal Executive Officer and Principal Financial Officer Certification Pursuant to Securities Exchange Act Rules13a-14 and 15d-14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Principal Executive Officer and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)

The Company agrees to furnish supplementally to the SEC a copy of any omitted schedule or exhibit to such agreement upon request by the SEC.

+ Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to a confidential treatment request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RVL Pharmaceuticals plc

Dated: March 20, 2023

By: /s/ Brian Markison
Brian Markison
Chief Executive Officer and Principal Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 20, 2023.

Signatures	Capacity in Which Signed
/s/ Brian Markison Brian Markison	Chief Executive Officer and Director (Chairman) (Principal Executive Officer and Principal Financial Officer)
/s/ Michael J. DePetris Michael J. DePetris	Principal Accounting Officer
/s/ Michael DeBiasi Michael DeBiasi	Director
/s/ David Burgstahler David Burgstahler	Director
/s/ Gregory L. Cowan Gregory L. Cowan	Director
/s/ Joaquin Benes Joaquin Benes	Director
/s/ Sriram Venkataraman Sriram Venkataraman	Director
/s/ Juan Vergez Juan Vergez	Director
/s/ Alisa Lask Alisa Lask	Director

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