

**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, 2021**

**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**  
(State or other jurisdiction of  
incorporation or organization)

**Not Applicable**  
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

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, 2021, based upon the closing price of \$3.01 of the registrant's ordinary shares as reported on the Nasdaq Global Select Market, was approximately \$61.5 million.

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

<u>Class</u>	<u>Outstanding at March 29, 2022</u>
Ordinary shares, \$0.01 nominal value per share	83,515,411 shares

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for the 2022 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 and the development, approval and introduction of new products; 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.*

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

- Our business may be adversely affected by the ongoing coronavirus outbreak.
- 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.
- 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.
- 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 decide to license or divest the product.
- 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 material adverse effect on our business, financial position and results of operations.
- If Upneeq does not produce the intended effects, our business may suffer.
- Failures of or delays in clinical trials are common and have many causes, and such failures or delays could result in increased costs to us and could prevent or delay our ability to obtain regulatory approval and commence product sales for new products.
- 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.
- We are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes.

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

We are a specialty pharmaceutical company focused on the commercialization and development 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, more commonly known as 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 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. Patients may purchase Upneeq either from eyecare or medical aesthetic professionals, or exclusively through RVL Pharmacy, Inc., our wholly-owned pharmacy.

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, or the Legacy Business, to certain affiliates of Alora Pharmaceuticals, or Alora, for \$111 million in cash upon closing, subject to certain post-closing adjustments, and up to \$60 million in contingent milestone payments, or the Transaction. Pursuant to the Transaction we retained the rights to Upneeq and to arbaclofen extended release, or ER, tablets, which is under development for the treatment of spasticity in multiple sclerosis.

On January 17, 2022, we changed the name of Osmotica Pharmaceuticals plc to RVL Pharmaceuticals plc, and our ordinary shares began trading under the symbol “RVLP.”

With the divestiture of the Legacy Business, our commercial operations are now conducted by our wholly-owned subsidiary, RVL Pharmaceuticals, Inc. and its subsidiary RVL Pharmacy, LLC or RVL Pharmacy. We process prescriptions and dispense Upneeq directly to patients from RVL Pharmacy. Our primary markets are self-pay segments in the ocular medicine and medical aesthetic therapeutic areas, where Upneeq is either sold and dispensed by us directly to the patient pursuant to a prescription submitted by a health care provider, or is sold to physician practices directly and dispensed by physicians in that practice. Upneeq is not covered or reimbursed by any third-party payor such as Medicaid, Medicare or commercial insurance. By focusing on the self-pay market segments, we believe we have streamlined and simplified patient access to Upneeq and are not exposed to reimbursement risk associated with reliance on payments from such third-party payors. In ocular medicine, our sales efforts focus on ophthalmologists, optometrists and oculoplastic surgeons. In aesthetics, our sales force focuses primarily on medical aesthetic practices.

We acquired the license to Upneeq in 2017 as part of our asset acquisition of RevitaLid, Inc. now known as RVL Pharmaceuticals, Inc. As part of the acquisition and under the terms of the acquired license, we agreed to make future earn-out, milestone and royalty payments based on net sales and regulatory developments with respect to Upneeq.

On July 28, 2020, we entered into a license agreement with Santen Pharmaceutical Co., Ltd, or Santen granting Santen the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Santen is responsible for further development of RVL-1201 in the licensed territories. Under the license agreement with Santen, we received an upfront cash payment of \$25.0 million, license milestone payments of \$10.0 million and may receive additional milestone payments up to \$54.0 million based on regulatory and sales achievements in Santen’s territories. We are also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories.

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 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 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, or 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, or 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, 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. We are reviewing the FDA’s comments and may request a Type A meeting with the Division to discuss the protocol. We intend to revise the protocol and statistical analysis plan and resubmit the SPA agreement request.

## 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 to launch Upneeq into the medical aesthetic market through our dedicated aesthetics sales force, while continuing to broaden penetration into the ocular medicine markets. While promotion of the product relies heavily on our sales force engaging eye care and 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 are planning to increase direct-to-consumer advertising in 2022.

*Broaden Distribution Channels for Upneeq.* In September 2021, we initiated the Direct Dispense program to eye care professionals. Under the program we sell Upneeq directly to ECP practices where the practice is then able to resell and dispense Upneeq to appropriate patients. To address certain instances where an ECP 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 ECP practices for resale to 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. Our late stage product candidate, arbaclofen ER, a treatment for spasticity associated with multiple sclerosis, we consider 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:



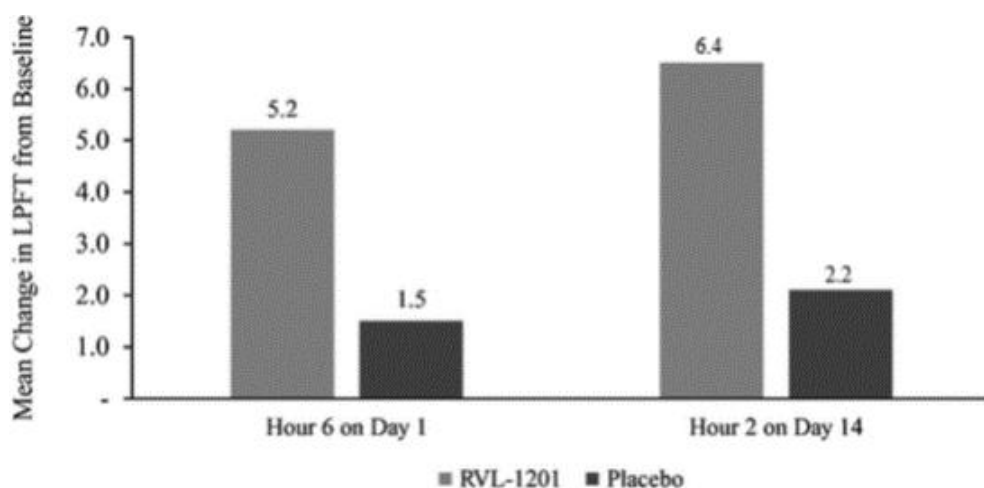
According to a 2018 survey of U.S. optometrists, ophthalmologists and surgeons, approximately 38% of blepharoptosis cases were mild and 48% were moderate. While no robust epidemiological studies exploring the prevalence of blepharoptosis exist, we believe it is a condition affecting millions of Americans. 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 \$1.3 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<sub>b</sub> 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, or arbaclofen, using our proprietary Osmodex drug delivery system for the treatment of spasticity in multiple sclerosis patients. Arbaclofen has received orphan drug designation by the FDA in this indication, and we have patent coverage for arbaclofen 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 complete response letter, or 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 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, or 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. We are reviewing the FDA's comments and may request a Type A meeting with the Division to discuss the protocol. We intend to revise the protocol and statistical analysis plan and resubmit the SPA agreement request. If we are required to conduct any additional clinical trials for arbaclofen, our development costs will increase, our regulatory approval process could be delayed or denied and we may not be able to commercialize and commence sales of 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, 2021, we owned or had license rights to 24 U.S. patents, 14 patents outside the United States and 12 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](http://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, 2021, had eight 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 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; 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. Companies required to register and submit information and who fail to do so may be subject to fines and other penalties.

#### ***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**, 62, 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 Avista Healthcare Public Acquisition Corp., National Spine and Pain Centers, LLC and Braeburn Pharmaceuticals, Inc. He is also a Director of the College of New Jersey. Mr. Markison received a B.S. degree from Iona College.

**Tina deVries, Ph.D.**, 61, became our Executive Vice President, Research & Development in May 2016. Dr. deVries most recently served as the Principal of TM deVries Consulting, LLC from October 2014 to April 2016. From October 2013 to September 2014, she held the position of Vice President of Nonclinical and Clinical Pharmacology at

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Actavis plc. Dr. deVries previously served as the Vice President of Clinical Pharmacology at Warner Chilcott plc, a specialty pharmaceutical company, from April 1996 until the company was acquired by Actavis in October 2013. Dr. deVries holds a B.S. in Pharmacy and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

**Andrew Einhorn**, 62, became our Chief Financial Officer in September 2017. Mr. Einhorn has more than 15 years of experience in the pharmaceutical industry. From March 2014 to March 2017, Mr. Einhorn served as the Chief Financial Officer of Edge Therapeutics, Inc., a clinical-stage biotechnology company that he joined as Executive Vice President of Corporate Development in May 2013. Prior to that, he was a co-founder, Executive Vice President and Chief Financial Officer at Oceana Therapeutics, Inc. from May 2008 to January 2012. Previously, Mr. Einhorn was a co-founder and Chief Financial Officer of both Esprit Pharma, Inc., from June 2005 to October 2007, and ESP Pharma, Inc., from April 2003 to March 2005. From 1983 to 2003, Mr. Einhorn was an investment banker with Credit Lyonnais Securities, PNC Capital Markets, Chase Securities, Inc., Bankers Trust Company and the Chase Manhattan Bank. Mr. Einhorn is licensed as a Certified Public Accountant in the State of New Jersey and holds a B.S. in Finance and Accounting from The American University.

**James Schaub**, 40, has served as our Executive Vice President and Chief Operating Officer since 2016. Prior to that he served as Chief Operating Officer, 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**, 58, 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, 2021, we had a total of 156 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 25-28 North Wall Quay, Dublin 1, Ireland and our telephone number is (908) 809-1300. Our website address is [www.rvlpharma.com](http://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 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, such as restrictions on travel, access, gatherings and stay at home orders put into place by businesses and governments, 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. In some instances, our sales force has encountered challenges engaging with eye care providers during this on-going pandemic. Although many areas of the United States have re-opened, or begun to re-open, access to offices and other commercial facilities, there continue to be areas where restrictions remain in place or may be reinstated as a result of concerns about the spread of new variants, such as the Delta or Omicron 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. Additionally, new variants, including the Delta and Omicron variants, which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future, and our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted.

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, including arbaclofen ER. It is unknown how long these disruptions could continue. Other known and unknown factors caused by COVID-19 could also materially delay our clinical trials that may be required for our current and future product candidates, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and/or approval of our current and future product candidates.

The extent to which the COVID-19 pandemic impacts our results will depend on future developments, including the spread of variants of the virus such as the Omicron variant, 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.

***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 resulted in the loss of substantially all of our revenue generating assets, and our business plan is focused on the continued launch and commercialization of Upneeq. With the sale of the Legacy Business, our cash flows have been diminished and we expect our cash flows to continue to be diminished in at least the near term, in particular cash inflows from product sales. We will require additional capital to fund our operating needs, including the commercialization of Upneeq and other activities. Accordingly, we expect to incur significant expenditures and increasing operating losses in the future. These conditions give rise to substantial doubt as to our ability to operate as a going concern as our current sources of liquidity will not be sufficient to meet our obligations through the end of the third quarter of 2022.

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 pursue 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.

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 products 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 assets, 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 future progression of the COVID-19 pandemic and its long-term effects may also adversely impact the accuracy of such estimates and our potential market opportunity for Upneeq. Upneeq is only available 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 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 with an in-person sales effort focused on ophthalmologists and optometrists. Despite these efforts, Upneeq may not produce sufficient treatment results such that patients or eye care specialists 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 2021 and into 2022, we continued expanding our sales force and increasing the number of managers and sales people with eye care and 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 privacy and data security laws applicable only to health care providers. For example, although our companies may be subject to federal and state privacy laws generally applicable to business entities, none of our companies have historically been a covered entity under the Health Insurance Portability and Accountability Act, or HIPAA. Going forward, if our business model changes and RVL Pharmacy engages in certain electronic standard transactions involving individually identifiable information, such as submission of claims to third party payors, 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 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. 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 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 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.



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. If practitioners are unwilling to purchase Upneeq as part of the Direct Dispense or Virtual Inventory programs, or if one or more states prohibit implementation of the models, we may not be successful with the Direct Dispense and/or Virtual Inventory 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 \$64.9 million for the year ended December 31, 2021. 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;
- conduct clinical trials and seek regulatory approval for arbaclofen ER and possibly 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.

***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 \$7.9 million and \$28.9 million for the years ended December 31, 2021 and 2020, 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, 2021, 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 is distributed to patients through our pharmacy, RVL Pharmacy, in Sayreville, New Jersey and through a contract pharmacy, KnippeRx, in Charlestown, Indiana. 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 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, 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 raw material suppliers, including suppliers of 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, Tina deVries, Andrew Einhorn 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, 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, but we are still investigating the data that may have been accessed by the attacker. 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 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;
- 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 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.

NDAAs 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. 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 will review the SPA and notify us whether or not it agrees with our proposed study design. The FDA's review of arbaclofen ER, as well as any required subsequent clinical testing, has delayed and may prevent the commercial launch of 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 given that the primary endpoint for Study OS440-3004, change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 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.***

We are developing arbaclofen ER for which we intend to seek FDA approval 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, we may not obtain or maintain the benefits associated with Orphan Drug Designation, including market exclusivity for arbaclofen.***

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 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, 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.

***Failures of or delays in clinical trials are common and have many causes, and such failures or delays could result in increased costs to us and could prevent or delay our ability to obtain regulatory approval and commence product sales for new products.***

We may experience failures of or delays in clinical trials of our current and future product candidates. Our clinical trials may fail or be delayed for a variety of reasons, including, among others: delays in obtaining regulatory approval to commence a trial; imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them; delays in obtaining required IRB approval at each site; difficulties or delays enrolling a sufficient number of patients or in having patients complete participation in a trial or return for post-treatment follow-up, or clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment; time required to add new clinical sites; or delays or failure by us or our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

In addition, identifying and qualifying patients to participate in clinical trials of our current and future product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our current and future product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials, in a timely manner. Patient enrollment and completion of the trials is affected by factors including: the severity of the disease under investigation; the design of the trial protocol; the size of the patient population; the eligibility criteria for the trial in question; the perceived risks and benefits of the product candidate under trial; the proximity and availability of clinical trial sites for prospective patients; the availability of

competing therapies and clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; and the ability to monitor patients adequately during and after treatment.

If we are unable to initiate or complete our planned clinical trials or any such clinical trial is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could fail or be delayed and our ability to commercialize and commence sales of our current and future product candidates could be materially harmed, which could have a material adverse effect on our business.

Moreover, clinical data are often susceptible to varying interpretations, and many companies that have believed their drug candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their drug candidate. Furthermore, results from our clinical trials may not meet the level of statistical significance or otherwise provide the level of evidence or safety and efficacy required by the FDA or other regulatory authorities for approval of a drug candidate. Finally, clinical trials are expensive and require significant operational resources to implement and maintain.

Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in later-stage clinical trials even after achieving promising results in earlier-stage clinical trials. For example, the results from completed preclinical studies and clinical trials may not be replicated in later clinical trials, and ongoing clinical trials for our drug candidates may not be predictive of the results we may obtain in later-stage clinical trials or of the likelihood of approval of a drug candidate for commercial sale. In addition, from time to time, we report interim data from our clinical trials. Interim data from a clinical trial may not be predictive of final results from the clinical trial. Failure to advance drug candidates through clinical development could impair our ability to ultimately commercialize products, which could materially harm our business and long-term prospects.

#### **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 eight patents listed in the FDA Orange Book, three of which expire August 26, 2031 and five 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 proprietary 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. However, this may change for Upneeq in the future, or products we may develop 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 U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or Affordable Care Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there were ongoing efforts to modify or repeal all or certain provisions of the Affordable Care Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under the Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Affordable Care Act has also been subject to judicial challenge. On June 17, 2021, the U.S. Supreme Court dismissed



the latest judicial challenge to the Healthcare Reform Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act.

Beyond the Affordable Care Act, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. Additional reform efforts are likely. The Biden administration has focused on reforms that would address the high cost of drugs. In response to an Executive Order from President Biden, the Secretary of HHS issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. Also, Democrats included drug pricing reform provisions reflecting elements of the plan in a broader proposed spending package in late 2021, such as capping Medicare Part D patients out-of-pocket costs; establishing penalties for drug prices that increase faster than inflation in Medicare; and authorizing the federal government to negotiate prices on certain, select high cost drugs under Medicare Parts B and D. Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge.

Future healthcare reform could also have a significant impact on our business. Any additional federal healthcare reform measures adopted in the future could limit the amounts that federal and state governments will pay for healthcare products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability. There is no certainty regarding the nature, scope or impact of any such reform. Due to such uncertainty, we cannot predict which, if any, of the future reform proposals will be adopted or the effect such adoption may have on us.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will currently remain in effect through 2030 (except May 1, 2020 to December 31, 2022). 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.

***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;
- 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 will take effect on January 1, 2023, though the obligations will 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. However, any person may 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.

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 a third-party manufacturing facility may damage our reputation for quality production, require costly remedial activities 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. 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, or the Note Purchase Agreement 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. At any time, we are required to maintain unrestricted cash and cash equivalents greater than or equal to \$15 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 (beginning at \$3 million for the quarter ending March 31, 2022, 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 could result in an event of default under the Note Purchase Agreement. Such an event of default may 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 Notes, the noteholders could proceed against the collateral granted to them to secure the Notes which could force us into bankruptcy or liquidation. In the event the noteholders accelerate the repayment of the Notes, we and our subsidiaries may not have sufficient assets to repay such 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 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 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 Notes to increase significantly.***

The Notes accrue interest at a variable rate, which exposes us to interest rate risk. Specifically, the Notes bear interest at a rate per annum equal to the sum of 9.00% plus the three-month London Inter-Bank Offered Rate, or LIBOR. The Note Purchase Agreement includes a LIBOR floor of 1.50% with a cap of 3.00%. An increase in LIBOR could result in a substantial increase in our annual interest expense associated with the Note Purchase Agreement.

***If a Benchmark Transition Event occurs with respect to LIBOR, the interest rate for the Notes will no longer be determined by reference to LIBOR.***

The LIBOR benchmark has been the subject of national, international and other regulatory guidance and proposals to reform. In July 2017, the Chief Executive of the United Kingdom Financial Conduct Authority, which regulates LIBOR, announced that banks are no longer compelled to submit rates for the calculation of LIBOR to the administrator of LIBOR after 2021. In March 2021, ICE Benchmark Administration, the administrator for LIBOR, confirmed its intention to cease publishing one week and two-month USD LIBOR after December 2021 and all remaining USD LIBOR tenors in mid-2023. Concurrently, the United Kingdom Financial Conduct Authority announced the cessation or loss of representativeness of the USD LIBOR tenors from those dates. The Alternative Reference Rates Committee, a group of market participants convened by the U.S. Federal Reserve Board and the Federal Reserve Bank of New York, has recommended the Secured Overnight Financing Rate, or SOFR, a rate calculated based on repurchase agreements backed by treasury securities, as its recommended alternative benchmark rate to replace USD LIBOR. At this time, it is not known whether or when SOFR or other alternative reference rates will attain market traction as replacements for LIBOR. These reforms may cause LIBOR to perform differently than it has in the past, and it is expected that LIBOR will cease to be available after 2021 or mid-2023, as applicable. After the cessation of LIBOR, alternative benchmark rates will replace LIBOR and could affect our indebtedness and payments thereon. At this time, it is not possible to predict the effect of the cessation of LIBOR or the establishment of alternative benchmark rates. Any new benchmark rate will likely not replicate LIBOR exactly. In addition, changes to benchmark rates may have an uncertain impact on our cost of funds and our access to the capital markets, which could impact our results of operations and cash flows.

**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 for up to five years, 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 \$1.07 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, 2021, investment funds affiliated with the Sponsors beneficially owned approximately 48.4% 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 disappplied 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 and current U.S. legislative proposals such as the “Build Back Better Act” introduced in 2021 and similar 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 including minimum tax proposals. Our effective tax rate could be adversely affected to the extent that countries adopt such OECD proposals or corresponding European Union 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 charge of Irish capital gains tax as a result of a deemed disposal of our assets. Our actual effective tax rate may vary from our expectation and that variance may be material. 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 2021 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 2022 taxable year. However, no assurance can be given in this regard because the determination of whether we are a PFIC is made annually after the end of such taxable year and 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) that are subject to change and also may be affected by the application of the PFIC rules, which are subject to differing interpretations. In addition, the value of our assets for purposes of the asset test, including the value of our goodwill, 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 and any cash received in the divestiture of our Legacy Business and related transactions. 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 are not a PFIC for the current taxable year or that we will not become a PFIC for any future taxable year.

If we are a PFIC, U.S. holders of our ordinary shares would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on

certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. If we are classified as a PFIC in any taxable year with respect to which a U.S. holder owns our ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless the U.S. holder makes a “deemed sale election.” Furthermore, whether or not U.S. holders of our ordinary shares make timely qualified electing fund, or QEF, elections, if we provide the necessary information to such U.S. holders to make such elections, or mark-to-market elections may affect 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 receive.

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 could be treated as CFCs due to the application of certain attribution rules that currently apply in determining CFC status. If certain non-U.S. subsidiaries are classified as CFCs, any U.S. Shareholder 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. 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 under the caption “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 the 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 18,000 square feet of office space pursuant to a lease that expires in July 2022 and an additional 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 2023. 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 addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our business, financial condition or results of operations.

On April 30, 2019, Osmotica Pharmaceuticals plc 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 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. 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.

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 29, 2022, there were five 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, 2021.

### **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). This discussion and analysis is based upon the historical financial statements of RVL Pharmaceuticals plc included in this Annual Report on Form 10-K.*

We are a specialty pharmaceutical company focused on the commercialization and development 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 and expanded our commercialization

efforts in 2021 among ophthalmology, optometry and oculoplastic specialties. We currently make Upneeq available exclusively through RVL Pharmacy, Inc., our wholly-owned pharmacy.

On August 27, 2021, we announced the closing of the divestiture of the Company's Legacy Business, to 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 Transaction we retained the rights to Upneeq and to arbaclofen extended release tablets, which is under development for the treatment of spasticity in multiple sclerosis. As a result, our business is now primarily focused on the commercialization and development of Upneeq. Following the Transaction, on January 17, 2022 we formally changed our name to RVL Pharmaceuticals plc.

The Legacy Business met the criteria within Accounting Standards Codification, or ASC, 205-20, *Presentation of Financial Statements* to be reported as discontinued operations because the transaction was a strategic shift in business that had a major effect on our operations and financial results. Therefore, we have reported the historical results of the Legacy Business including the results of operations and cash flows as discontinued operations, and related assets and liabilities were retrospectively reclassified as assets and liabilities of discontinued operations for all periods presented herein. Unless otherwise noted, applicable amounts in the prior year have been recast to conform to this discontinued operations presentation. Refer to Note 2, "Summary of Significant Accounting Policies" of our condensed consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Unless otherwise indicated, the following information relates to our continuing operations following the sale of our Legacy Business to Alora. A description of our business prior to the consummation of the transaction is included in Item 1. "Business," in Part I of the Annual Report on Form 10-K for the year ended December 31, 2020, that was previously filed with the SEC on March 30, 2021.

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. RVL Pharmacy operates pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

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.

On July 8, 2020, the FDA approved our NDA for Upneeq for the treatment of acquired blepharoptosis in adults. Upneeq was approved based on three Phase III clinical studies that supported Upneeq's efficacy and safety. Results from Upneeq's first Phase III clinical trial showed that the formulation met its primary efficacy endpoint and was well-tolerated.

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 granting Santen the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Santen is responsible for further development of RVL-1201 in the licensed territories. Under the license agreement with Santen, we have received an upfront payment of \$25.0 million in 2020, license milestone payments of \$10.0 million in 2021 and may receive additional milestone payments up to \$54.0 million based on regulatory and sales achievements in Santen's territories. We are also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories.

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 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 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 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 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, 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. We are reviewing the FDA's comments and may request a Type A meeting with the Division to discuss the protocol. We intend to revise the protocol and statistical analysis plan and resubmit the SPA agreement request.

#### *Business Update Regarding COVID-19*

The ongoing COVID-19 pandemic has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and/or could adversely affect our commercialization plans and results. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

The continuing COVID-19 pandemic has 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. In some instances our sales force has encountered challenges engaging with eye care providers during this on-going pandemic. Although many areas of the United States have re-opened, or begun to re-open, access to offices and other commercial facilities, there continue to be areas where restrictions remain in place or may be reinstated as a result of concerns about the spread of new variants, such as the Delta or Omicron 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. Additionally, new variants, including the Delta and Omicron variants, which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future, and our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted.

To date, we have been able to continue to supply Upneeq to patients without significant disruptions, and we do not currently anticipate significant interruption in the near term. However, we are continuing to monitor the potential impact of the COVID-19 pandemic on our business and operations, including our sales, expenses, and pharmacy operations.

Our third-party contract manufacturing partner for Upneeq has been able to operate its manufacturing facility at or near normal levels. While we currently do not anticipate significant interruptions in our manufacturing supply chain, the COVID-19 pandemic and related mitigation efforts may have a negative impact in the future on our third party suppliers' and contract manufacturing partner's ability to manufacture Upneeq or to have Upneeq reach all markets.

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 – Continuing Operations**

#### *Revenues*

As a result of the divestiture, all revenues of the Legacy Business have been reclassified under discontinued operations. Our revenues consist of product sales, royalty revenues and licensing revenue.

*Net product sales*—Our revenues consist of sales of Upneeq and sales of Osmolex the products rights to which were sold to Adamas in January 2021. Osmolex was shipped to customers pursuant to purchase orders, which in certain cases were pursuant to a master agreement with that customer, and we invoiced the customer upon shipment. For these sales we recognized revenue when control transferred to the customer, typically on delivery to that customer. The amount of revenue we recognized was equal to the selling price, adjusted for any variable consideration, which included estimated chargebacks, commercial rebates, discounts and allowances at the time revenues were recognized.

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. We refer to these revenues as Direct Dispense sales. All sales are paid for using credit cards for which we are paid prior to shipment. We recognize revenue when control has transferred to the customer, which is typically on delivery to the customer for Pharmacy Sales, or in the case of Direct Dispense sales, when the product is shipped to the physician. Accordingly, Pharmacy Sales revenue is not recognized until we have evidence that the product was delivered to the customer. 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 condensed consolidated financial statements as prepaid expenses or accrued expenses as applicable.

**Results of Operations – Continuing Operations**

**Comparison of Years Ended December 31, 2021 and 2020**

*Financial Operations Overview*

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

	<b>Year Ended December 31,</b>		<b>% Change</b>
	<b>2021</b>	<b>2020</b>	
Net product sales	\$ 7,511	\$ 1,942	287 %
Royalty and licensing revenue	9,990	25,820	(61)%
<b>Total revenues</b>	<b>17,501</b>	<b>27,762</b>	<b>(37)%</b>
Cost of goods sold	3,618	3,293	10 %
<b>Gross profit</b>	<b>13,883</b>	<b>24,469</b>	<b>(43)%</b>
Gross profit percentage	79 %	88 %	
Selling, general and administrative expenses	87,463	72,824	20 %
Research and development expenses	6,930	13,387	(48)%
Impairment of intangible assets	7,880	28,910	(73)%
<b>Total operating expenses</b>	<b>102,273</b>	<b>115,121</b>	<b>(11)%</b>
Gain on sales of product rights, net	5,636	—	NM %
Operating loss	(82,754)	(90,652)	(9)%
Interest expense and amortization of debt discount	3,036	4,095	(26)%
Change in fair value of debt and interest expense	982	—	NM %
Change in fair value of warrants	(5,571)	—	NM %
Other non-operating expense, net	1,333	48	2,677 %
<b>Total other non-operating (income) expense</b>	<b>(220)</b>	<b>4,143</b>	<b>(105)%</b>
Loss before income taxes	(82,534)	(94,795)	(13)%
Income tax expense (benefit), continuing operations	315	(5,782)	(105)%
Loss from continuing operations	(82,849)	(89,013)	(7)%
Gain on sales of discontinued operations	4,062	—	NM %
Income from discontinued operations before income taxes	13,570	10,508	29 %
Income tax (benefit) expense, discontinued operations	(297)	1,084	(127)%
Income from discontinued operations, net of tax	17,929	9,424	90 %
<b>Net loss</b>	<b>\$ (64,920)</b>	<b>\$ (79,589)</b>	<b>(18)%</b>

NM – Not Meaningful

*Revenues*

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

<b>Pharmaceutical Products</b>	<b>Year Ended December 31,</b>		<b>% Change</b>
	<b>2021</b>	<b>2020</b>	
Upneeq	\$ 7,511	\$ 526	1,328 %
Osmolex	—	1,416	(100)%
Net product sales	7,511	1,942	287 %
Royalty and licensing revenue	9,990	25,820	(61)%
<b>Total revenues</b>	<b>\$ 17,501</b>	<b>\$ 27,762</b>	<b>(37)%</b>



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Total revenues decreased to \$17.5 million for the year ended December 31, 2021, from \$27.8 million for the year ended December 31, 2020 primarily due to lower licensing revenue from Santen and the absence of sales of Osmolex which was divested in January 2021.

*Net Product Sales.* Net product sales increased by \$5.6 million to \$7.5 million for the year ended December 31, 2021, as compared to \$1.9 million for the year ended December 31, 2020. This increase was due to higher volumes of Upneeq sold in 2021, reflecting its first full year of sales following its commercial launch in September 2020, partially offset by the absence of Osmolex sales.

*Royalty and Licensing Revenue.* Royalty and licensing revenue decreased by \$15.8 million to \$10.0 million predominately reflecting lower regulatory milestones received under the license agreement with Santen in 2021 as compared to \$25.8 million received during the year ended December 31, 2020.

#### *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):

	<u>Year Ended December 31,</u>		
	<u>2021</u>	<u>2020</u>	<u>% Change</u>
Depreciation expense	\$ 55	\$ 8	588 %
Royalty expense	487	74	558 %
Other costs of goods sold	3,076	3,211	(4)%
Total costs of goods sold	<u>\$ 3,618</u>	<u>\$ 3,293</u>	<u>10 %</u>

Total cost of goods sold increased \$0.3 million in the year ended December 31, 2021 to \$3.6 million as compared to \$3.3 million in the year ended December 31, 2020, primarily driven by higher volumes of Upneeq sold and higher royalties incurred during 2021, partially offset by lower sample and regulatory costs for Upneeq, and the absence of product costs for Osmolex during 2021.

Gross profit percentage decreased to 79% for the year ended December 31, 2021 compared to 88% for the year ended December 31, 2020 largely due to lower license revenue during 2021 as compared to 2020.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased \$14.7 million in the year ended December 31, 2021 to \$87.5 million as compared to \$72.8 million in the year ended December 31, 2020. The increase in our selling, general and administrative expenses reflects the expansion of our salesforce and higher marketing expenses associated with the launch of Upneeq, severance and other expenses related to the cessation of operations in the Company's subsidiary in Argentina, debt and equity issuance costs incurred in connection with the issuance of the Notes and ordinary shares in the fourth quarter of 2021, and higher legal and transactional expenses associated with the divestiture of the Legacy Business, partially offset by lower securities litigation costs.

Selling, general and administrative expenses include share compensation expense of \$5.8 million and \$3.7 million for the years ended December 31, 2021 and 2020, respectively. The increase in share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy Business during the third quarter of 2021.

### Research and Development Expenses

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

	Year Ended December 31,		% Change
	2021	2020	
Arbaclofen ER	\$ 702	\$ 3,146	(78)%
RVL-1201	1,198	3,257	(63)%
Other	5,030	6,984	(28)%
Total	<u>\$ 6,930</u>	<u>\$ 13,387</u>	<u>(48)%</u>

Research and development expenses decreased by \$6.5 million in the year ended December 31, 2021 to \$6.9 million as compared to \$13.4 million in the year ended December 31, 2020. The decrease primarily reflects lower headcount, lower spending on arbaclofen ER, Upneeq and other R&D projects, partially offset by severance costs related to the cessation of operations in the Company's Argentine subsidiary during the second quarter of 2021.

Research and development expenses include share compensation expense of \$0.9 million and \$0.2 million for the years ended December 31, 2021 and 2020, respectively. The increase of share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy Business during the third quarter of 2021.

### Impairment of Intangible Assets

Impairment of intangible assets for the years ended December 31, 2021 and 2020 was \$7.9 million and \$28.9 million, respectively, due to write-downs to fair value for arbaclofen ER, an indefinite-lived In-Process R&D asset, due to delays in the anticipated launch of the product candidate, if approved.

### Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by \$1.1 million in the year ended December 31, 2021 to \$3.0 million as compared to \$4.1 million in the year ended December 31, 2020. The decrease is primarily attributable to the recognition of \$1.3 million of interest expense on our senior secured notes in the fourth quarter of 2021 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).

### 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 (losses) gains of \$(1.0) million and \$5.6 million, respectively. Changes in the fair value of our senior secured notes includes \$1.3 million of related interest expense. See Note 21, *Financial Instruments and Fair Value Measurements* to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

### Other Non-operating Expense, Net

Other non-operating expense, net was \$1.3 million and less than \$0.1 million for the years ended December 31, 2021 and 2020, respectively. The increase was primarily due to asset disposal costs related to leasehold improvements associated with the curtailment of operations in Argentina during the second quarter of 2021.

### *Income Tax Expense (Benefit)*

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

	<u>Year Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Income tax expense (benefit)	\$ 315	\$ (5,782)
Effective tax rate	(0.4)%	6.1 %

Income tax expense (benefit) changed from a \$5.8 million benefit in the year ended December 31, 2020 to a \$0.3 million expense in the year ended December 31, 2021. The significant change in the 2021 income tax expense was primarily the result of the sale of the Legacy Business.

### **Components of Results of Operations – Discontinued Operations**

On August 27, 2021 we announced the closing of the divestiture of the Legacy Business comprising our discontinued operations. The components of our discontinued operations described below include results for the period from January 1, 2021 to August 27, 2021, or the “2021 period,” and the twelve months ended December 31, 2020.

#### *Revenues*

Our revenues from discontinued operations consisted of product sales, royalty revenues and licensing and contract revenue.

*Net product sales*—Our revenues consisted primarily of product sales of our promoted products, principally Divigel and the OB Complete family of prescription prenatal dietary supplements, M-72, Lorzone, and our non promoted products. We shipped our products to our customers pursuant to purchase orders, which in certain cases were pursuant to a master agreement with that customer, and we invoiced the customer upon shipment. For these sales we recognized revenue when control was transferred to the customer, which was typically on delivery to the customer. The amount of revenue we recognized was equal to the selling price, adjusted for any variable consideration, which included estimated chargebacks, commercial rebates, discounts and allowances at the time revenues were recognized.

*Royalty revenue*—For arrangements that included sales-based royalties, including milestone payments based on the level of sales, and the license was deemed to be the predominant item to which the royalties related, we recognized revenue at the later of (a) when the related sales occurred, or (b) when the performance obligation to which some or all the royalty had been allocated had been satisfied (or partially satisfied).

*Licensing and contract revenue*—We had arrangements with commercial partners that allowed for the purchase of product from the Company by the commercial partners for purpose of sub-distribution. Licensing revenue was recognized when the performance obligation identified in the arrangement was completed. Variable considerations, such as returns on product sales, government program rebates, price adjustments and prompt pay discounts associated with licensing revenue, were generally the responsibility of our commercial partners.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses consisted primarily of personnel expenses, including salaries and benefits for employees in sales, marketing, accounting, legal and human resource functions. General and administrative expenses also included corporate facility costs, including rent, utilities, insurance, legal and other fees related to accounting and other consulting services.

### *Research and Development Expenses*

Costs for research and development were charged as incurred and included employee related expenses (including salaries and benefits, 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 regulatory operations.

Costs for certain development activities, such as clinical studies, were 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 were based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and were reflected in our consolidated financial statements as prepaid expenses or accrued expenses as applicable.

### **Results of Operations – Discontinued Operations**

#### **Comparison of Years Ended December 31, 2021 and 2020**

##### *Financial Operations Overview*

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

	<b>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Total revenues	\$ 62,395	\$ 150,122
Cost of goods sold (inclusive of depreciation and amortization)	30,018	71,187
Selling, general and administrative expense	5,468	9,137
Impairment of intangible assets	—	43,273
Research and development expenses	5,882	6,309
Income from operations	21,027	20,216
Interest expense and amortization of debt discount	6,399	10,301
Other non-operating loss (income), net	1,058	(593)
Income from discontinued operations before costs of disposal and provision for income taxes	13,570	10,508
Income tax (benefit) expense	(297)	1,084
Income from discontinued operations before gain on disposal	13,867	9,424
Gain on sales of discontinued operations	4,062	—
Income from discontinued operations, net of tax	<u>\$ 17,929</u>	<u>\$ 9,424</u>

## Revenues

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

	Year Ended December 31,	
	2021	2020
Venlafaxine ER (VERT)	\$ 5,141	\$ 25,576
Methylphenidate ER	16,015	31,699
Divigel	18,295	31,629
Nitrofurantoin	3,136	10,443
Lorzone	113	4,058
OB Complete	3,031	6,948
Other	13,819	33,556
Net product sales	59,550	143,909
Royalty revenue	2,207	3,287
Licensing and contract revenue	638	2,926
Total revenues	\$ 62,395	\$ 150,122

Total revenues decreased by \$87.7 million to \$62.4 million for the year ended December 31, 2021, as compared to \$150.1 million for the year ended December 31, 2020 primarily due to a decrease in net product sales.

*Net Product Sales.* Net product sales decreased by \$84.3 million to \$59.6 million for the year ended December 31, 2021, as compared to \$143.9 million for the year ended December 31, 2020. Approximately \$41.5 million of this decrease was attributable to less than eight months of operations during the 2021 period. Approximately \$19.2 million of the decrease was due to lower realized prices, while approximately \$23.6 million was due to lower volumes of products sold. Net sales of methylphenidate ER (including M-72) decreased \$15.7 million, of which, \$10.1 million is attributable to the absence of methylphenidate sales during the period from August 28, 2021 to December 31, 2021, or the “remainder of 2021.” During the 2021 period, net product sales of methylphenidate ER (including M-72), decreased \$5.6 million due to price erosion from generic competitors resulting in significantly lower net selling prices and lower volumes. Net sales of VERT decreased \$20.4 million, of which, \$6.0 million is attributable to the absence of VERT sales during the remainder of 2021. Product sales from VERT decreased by \$14.4 million for the 2021 period due to additional generic competition resulting in lower volumes and net realized selling prices.

Product sales of Lorzone decreased \$3.9 million during 2021 as compared to 2020. Product sales from Lorzone declined \$4.2 million for the 2021 period, reflecting continued erosion of pricing and volumes due to the launch of generic competition. Product sales of Divigel decreased \$13.3 million, of which, \$11.4 million was attributable to the absence of Divigel sales during the remainder of 2021. Product sales from the OB Complete family of prescription prenatal dietary supplements decreased \$3.9 million, of which, \$2.1 million is attributable to the absence of OB Complete sales during the period of 2021 following the divestiture of the Legacy Business. Product sales from OB Complete decreased by \$1.8 million during the 2021 period due to lower volumes sold reflecting a reduction of promotional activity beginning in 2020 and continuing into 2021. Product sales of Nitrofurantoin decreased \$7.3 million, of which, \$1.9 million is attributable to the absence of Nitrofurantoin sales during the remainder of 2021. Sales of Nitrofurantoin decreased \$5.4 million in the 2021 period due to additional competitors entering the market. Other product sales decreased by \$19.7 million, largely due to decreased pricing and volumes of other non-promoted products sold during the year.

*Royalty Revenue.* Royalty revenue decreased by \$1.1 million for the year ended December 31, 2021, of which \$0.4 million was due to lower product sales by license partners during the 2021 period, with the remainder of the decrease due to the absence of the Legacy Business for the remainder of 2021.

*Licensing and Contract Revenue.* Licensing and contract revenue decreased by \$2.3 million in 2021, of which \$0.6 million was due to lower sales activity by collaboration partners during the 2021 period, with the remainder of the decrease due to the absence of the Legacy Business for the remainder of 2021.

### *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):

	<u>Year Ended December 31,</u>		<u>% Change</u>
	<u>2021</u>	<u>2020</u>	
Amortization of intangible assets	\$ 5,233	\$ 16,046	(67)%
Depreciation expense	1,350	1,484	(9)%
Royalty expense	3,832	9,209	(58)%
Other costs of goods sold	19,603	44,448	(56)%
Total costs of goods sold	<u>\$ 30,018</u>	<u>\$ 71,187</u>	<u>(58)%</u>

Total cost of goods sold decreased \$41.2 million in the year ended December 31, 2021 to \$30.0 million as compared to \$71.2 million in the year ended December 31, 2020. Amortization of intangible assets decreased by \$10.8 million. Following the designation of the Legacy Business as a discontinued operation on June 24, 2021 the Company ceased recognizing amortization expense related to intangible assets of the Legacy Business. Royalty expense decreased by \$5.4 million, of which \$3.1 million was related to a decrease in net sales of certain licensed products during the 2021 period, with the remainder of the decrease due to the absence of the Legacy Business for the remainder of 2021. Other cost of goods sold decreased \$24.8 million, of which \$10.9 million related to lower volumes of product sold during the 2021 period, with the remainder of the decrease due to the absence of the Legacy Business for the remainder of 2021.

Gross profit percentage decreased to 51% for the year ended December 31, 2021 compared to 53% for the year ended December 31, 2020. Excluding amortization and depreciation, our gross profit percentage for the year ended December 31, 2021 was 62% as compared to 64% for the year ended December 31, 2020 largely due to higher unit production costs, partially offset by lower inventory reserves and royalty expense.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased \$3.6 million in the year ended December 31, 2021 to \$5.5 million as compared to \$9.1 million in the year ended December 31, 2020. The decrease in selling, general and administrative expenses primarily reflects lower marketing expenses as promotional resources were reallocated to Upneeq beginning in mid-2020, and lower general and administrative expenses related to insurance, costs of licenses and fees and lower headcount during 2021.

### *Research and Development Expenses*

Research and development expenses decreased by \$0.4 million in the year ended December 31, 2021 to \$5.9 million as compared to \$6.3 million in the year ended December 31, 2020. The decrease primarily reflects the completion of development programs for several non-promoted products during 2020.

*Impairment of Intangible Assets*

There was no impairment of intangible assets for the year-ended December 31, 2021.

Impairment of intangible assets for the year-ended December 31, 2020 were \$43.3 million primarily consisting of write-downs to fair value for methylphenidate ER, VERT, and Oxybutynin of \$19.5 million, \$20.2 million, and \$3.6 million, respectively. The impairments of methylphenidate ER, VERT and Oxybutynin reflect the competitive generic environment which has continued to erode net realized pricing and volumes of these products. In the fourth quarter of 2020 we recognized an impairment of finite-lived development technology and product rights for VERT of \$10.7 million and \$9.5 million, respectively due to the approval of a competing product and the anticipated deterioration of pricing and volumes.

The following table presents a breakdown of impairments recognized by asset and asset group for the period indicated (dollars in thousands):

Asset/Asset Group	Year Ended December 31, 2020	
	Impairment Charge	Reason For Impairment
<i>Product Rights</i>		
Methylphenidate ER	\$ 19,539	Lower revenue due to generic competition.
<i>Developed Technology</i>		
Venlafaxine ER	10,655	Lower revenue due to generic competition.
Oxybutynin	3,618	Lower revenue expectations
	14,273	Lower anticipated revenue due to generic competition.
<i>Distribution Rights</i>		
Venlafaxine ER	9,461	Lower revenue due to generic competition.
Total Impairment Charges	\$ 43,273	

*Interest Expense and Amortization of Debt Discount*

Interest expense and amortization of debt discount decreased by \$3.9 million in the year ended December 31, 2021 to \$6.4 million as compared to \$10.3 million in the year ended December 31, 2020. The decrease in borrowing costs reflects lower levels of indebtedness following the prepayment of debt in the third quarter of 2020, and lower interest rates during 2021.

*Other Non-operating Loss (Income), Net*

Other non-operating loss (income) was \$1.1 million and \$(0.6) million for the years ended December 31, 2021 and 2020, respectively.

*Income Tax (Benefit) Expense*

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

	Year Ended December 31,	
	2021	2020
Income tax (benefit) expense	\$ (297)	\$ 1,084
Effective tax rate	(1.7)%	10.3 %



Our income tax provision changed from an income tax expense of \$1.1 million in the year ended December 31, 2020 to an income tax benefit of \$0.3 million in the year ended December 31, 2021. The changes in the 2021 income tax benefit was the result of a valuation allowance recorded on the Hungarian entity.

### **Liquidity and Capital Resources**

Our principal sources of liquidity are cash and cash equivalents and borrowings available under our Note Purchase Agreement, dated October 1, 2021, with Athyrium Opportunities IV Acquisition LP, as administrative agent, and Athyrium Opportunities IV Acquisition 2 LP, as the Purchaser. At December 31, 2021, we had cash and cash equivalents of \$40.4 million and total debt obligations with aggregate principal amounts of \$57.4 million including an aggregate principal amount of \$55.0 million of long-term debt, the maturities of which commence in March 2024 and extend through October 2026. Our primary uses of cash are to fund operating expenses, including commercialization costs associated with Upneeq, capital expenditures, and debt service payments.

The Note Purchase Agreement provides for the issuance of the Notes to the Purchaser in an aggregate principal amount of up to \$100.0 million in three separate tranches. The first tranche of Notes was issued in an aggregate principal amount equal to \$55.0 million on October 12, 2021. At any time after October 12, 2021 but prior to the first anniversary thereof, 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 second tranche Notes in an aggregate principal amount of up to \$20.0 million. At any time after October 12, 2021 but prior to the second anniversary thereof, we may request the issuance of the third tranche Notes in an aggregate principal amount of up to \$25.0 million, which shall be funded in the sole discretion of the Purchaser. The minimum net product sales target for Upneeq is \$3.0 million for the quarter ending March 31, 2022, 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. The minimum liquidity requirement under the Note Purchase Agreement requires us to maintain, at any time, unrestricted cash and cash equivalents greater than or equal to \$15.0 million.

At December 31, 2021, the interest rate on our Notes was 10.5%.

On October 12, 2021 we completed a follow-on offering and issued and allotted 14,000,000 ordinary shares of the Company and warrants to purchase up to 14,000,000 ordinary shares, at a public offering price of \$2.50 per share and accompanying warrant. In addition, we granted the underwriter a 30-day option to purchase up to an additional 2,100,000 ordinary shares and/or warrants to purchase additional 2,100,000 ordinary shares at the public offering price, less the underwriting discounts and commissions. On October 11, 2021 the underwriter exercised its option to purchase additional warrants to purchase up to 2,100,000 ordinary shares. The warrants have an exercise price of \$3.10 per share, were immediately exercisable and will expire 3.5 years from the date of issuance. The aggregate net proceeds from the follow-on offering were approximately \$32.5 million after deducting underwriting commissions and offering expenses.

On September 8, 2021, we entered into a sales agreement, the Sales Agreement with Cantor Fitzgerald & Co., or Cantor under which we may offer and sell our 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. At December 31, 2021, we had sold 146,162 of our ordinary shares at a weighted-average price of \$3.13 for aggregate proceeds of \$0.5 million and net proceeds to us of \$0.0 million, after deducting commissions and offering expenses payable by us.

On July 16, 2020, we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.4 million after deducting offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

On January 13, 2020, we completed an equity offering and allotted 6.9 million ordinary shares at a public offering price of \$5.00 per share. The number of shares issued in this offering reflected the exercise in full of the underwriters’ option to purchase 900,000 ordinary shares. The aggregate net proceeds from the follow-on offering were approximately \$31.8

million after deducting underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

For the year ended December 31, 2020, we repurchased 1,435,725 ordinary shares, at a weighted-average price of \$5.62 for an aggregate of \$8.1 million pursuant to a share repurchase program authorized by our board of directors in September 2019. We did not repurchase any shares during the year ended December 31, 2021.

#### *Going Concern*

At December 31, 2021, we had cash and cash equivalents of \$40.4 million, an accumulated deficit of \$517.5 million and total long-term debt with aggregate principal amounts of \$55.0 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, 2021 and 2020, we incurred net losses from continuing operations of \$82.8 million and \$89.0 million, respectively. For the year ended December 31, 2021, we used \$54.7 million 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 launch and commercialization 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 sustained operating losses for the foreseeable future.

We do not believe that current sources of liquidity will be sufficient to fund our planned expenditures and meet our obligations 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. 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 our ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings, ii) raise capital through borrowings under existing debt facilities and/or convertible debt, and/or or iii) raise non-dilutive funds through product collaborations and/or 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,		\$ Change
	2021	2020	
Net cash provided by (used in) operating activities	\$ (54,732)	\$ 17,590	\$ (72,322)
Net cash provided by (used in) investing activities	116,453	(3,084)	119,537
Net cash provided by (used in) financing activities	(135,330)	3,682	(139,012)
Net increase (decrease) in cash and cash equivalents	<u>\$ (73,609)</u>	<u>\$ 18,188</u>	<u>\$ (91,797)</u>

### *Net cash provided by (used in) 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 \$54.7 million for the year ended December 31, 2021 and net cash provided by operating activities was \$17.6 million for the year ended December 31, 2020. The decrease in cash provided by operating activities in the year ended December 31, 2021, as compared to year ended December 31, 2020, was primarily as a result of lower net income after considering non-cash adjustments, and higher cash used by operating assets and liabilities, particularly higher prepaid assets and lower accrued expenses as compared to the year ended December 31, 2020.

### *Net cash provided by (used in) investing activities*

Cash provided by investing activities for the year ended December 31, 2021, was \$116.5 million primarily from proceeds from the divestitures of our Legacy Business and product rights related to Osmolex. Cash used in investing activities for the year ended December 31, 2020 primarily reflected purchases of property, plant and equipment.

### *Net cash provided by (used in) financing activities*

Net cash used in financing activities of \$135.3 million for the year ended December 31, 2021, largely reflected the repayment of borrowings under our term loan facility offset by net proceeds from the issuance of Notes, insurance financing loans and proceeds from the issuance of ordinary shares and warrants. Net cash provided by financing activities of \$3.7 million for the year ended December 31, 2020 largely reflects net proceeds from the issuance of ordinary shares offset by prepayments of debt and repurchases of ordinary shares during the year.

## Critical Accounting Estimates – Continuing Operations

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, 2021, the combined carrying value of goodwill and indefinite-lived intangible assets, net of accumulated amortization and or impairment charges, was \$83.1 million or 58% 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, 2021 and 2020. 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, 2021. 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 \$7.9 million and \$28.9 million during the years ended December 31, 2021 and 2020, respectively, related to delays in anticipated commercialization of the product candidate, if approved. At December 31, 2021, \$27.2 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, 2020 we recognized \$4.6 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, 2021, there were approximately:

- 3.2 million stock options outstanding under the 2018 Equity Incentive Plan, with aggregate unrecognized share compensation expense related to unvested awards of \$3.6 million, which is expected to be recognized over a weighted-average remaining service period of 2.1 years; and
- 1.4 million restricted stock units outstanding under the 2018 Equity Incentive Plan, with aggregate unrecognized share compensation expense related to unvested awards of \$4.5 million, which is expected to be recognized over a weighted-average remaining service period of 1.8 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. 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 2021 at the date of grant would increase our 2021 share compensation expense by an immaterial amount and also increase our aggregate unrecognized share compensation cost related to unvested awards at December 31, 2021 by less than \$0.2 million.

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

Our Notes, a material component of long-term debt at December 31, 2021, and warrants, as reflected within warrant liabilities, a material component of total liabilities, at December 31, 2021, 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 statement 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 Notes and warrants during the year ended December 31, 2021 resulted in (losses) gains recognized through earnings of \$(1.0) million and \$5.6 million, respectively, with a resultant carrying value at December 31, 2021 of \$(43.8) million and \$(3.2) million, respectively.

We use a discounted cash flow technique, an income-based approach, to determine the fair value of the Notes. This technique relies upon an assumption of pricing the 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 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 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.

Remeasuring the fair value of our 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 2021 and subsequent periods. For example, as of December 31, 2021:

- A 100 basis point, or one percent, decrease or increase to the rate we used to discount future cash flows under our Notes would have increased or decreased, respectively, the estimated fair value of our Notes and changed the associated gains or losses recognized through 2021 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 2021 earnings by \$1.2 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, 2021, the Company had a federal net operating loss carryforward of \$43.4 million, state net operating loss carryforwards of \$114.0 million, net operating loss carryforwards in certain foreign tax jurisdictions of \$104.2 million which will begin to expire in 2022 and total tax credit carryforward of \$7.2 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 a federal capital loss carryforward of \$104.6 million at December 31, 2021, which will expire in 2026.

At December 31, 2021, our valuation allowance on deferred tax assets was \$52.9 million, which primarily consists of \$21.1 million relating to \$157.4 million net operating loss carryforwards and \$23.8 million relating to \$104.6 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.

#### **Critical Accounting Estimates – Discontinued Operations**

In addition to the critical accounting policies and estimates discussed above with applicability to continuing operations, the following supplemental discussion is intended to enhance an understanding of policies and estimates relevant to the Legacy Business which qualifies for classification as a discontinued operation. See Note 4, *Discontinued Operations* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

#### **Revenue Recognition**

*Product Sales*—Revenue is recognized at the point in time when our performance obligations with our customers have been satisfied. At contract inception, we determine if the contract is within the scope of ASC 606, *Revenue Recognition*, and then evaluate 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 Company satisfies a performance obligation.

Revenue is recorded at the transaction price, which is the amount of consideration we expect to receive in exchange for transferring products to a customer. We consider the unit of account for each purchase order that contains more than one product. Because all products in a given purchase order are generally delivered at the same time and the method of revenue recognition is the same for each, there is no need to separate an individual order into separate performance obligations. In the event that we fulfilled an order only partially because a requested item is on backorder, the portion of the purchase order covering the item is generally cancelled, and the customer has the option to submit a new one for the backordered item.



We determine the transaction price based on fixed consideration in our contractual agreements, which includes estimates of variable consideration, and the transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. In determining the transaction price, a significant financing component does not exist since the timing from when we deliver product to when the customers pay for the product is less than one year and the customers do not pay for product in advance of the transfer of the product.

We record product sales net of any variable consideration, which includes estimated chargebacks, commercial rebates, discounts and allowances and doubtful accounts. We utilize the expected value method to estimate all elements of variable consideration included in the transaction. The variable consideration is recorded as a reduction of revenue at the time revenues are recognized. We will only recognize revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration amount received and we will re-assess these estimates each reporting period to reflect known changes in factors.

*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 (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 substantially satisfied).

*Licensing Revenue*— We recognize development and regulatory milestone revenue from milestone events under our license with Santen that have been achieved and the Company is reasonably certain such revenues would not have to be reversed.

*Freight*—We record amounts billed to customers for shipping and handling as revenue, and record shipping and handling expenses related to product sales as selling, general and administrative expenses. We account for shipping and handling activities related to 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, we also have elected to account for these as costs to fulfill the promise and not as a separate performance obligation.

#### ***Accounting for Sales Deductions***

Product sales are recorded net of estimated chargebacks, commercial and governmental rebates, discounts, allowances, copay discounts, advertising and promotions and estimated product returns, or collectively, “sales deductions.”

Provision for estimated chargebacks, certain commercial rebates, discounts and allowances and doubtful accounts settled in sales credits at the time of sales are analyzed and adjusted, if necessary, monthly and recorded against gross trade accounts receivable. Estimated product returns, certain commercial and governmental rebates and customer coupons settled in cash are analyzed and adjusted, if necessary, monthly and recorded as a component of accrued expenses.

Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and estimated customer inventory levels. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are chargebacks, commercial and governmental rebates, product returns, discounts and allowances and advertising and promotions.

Where available, we have relied on information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to days of sales outstanding, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we have evaluated market conditions for products primarily through the analysis of wholesaler and other third party sell-through, as well as internally-generated information, to assess factors that could impact expected product demand at period end. We believe that the estimated level of inventory held by our customers is within a reasonable range as compared to both: (i) historical amounts and (ii) expected demand for the products that represent a majority of the volume at period end.

If the assumptions we use to calculate our allowances for sales deductions do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted.

See also Note 6, *Accounts Receivable, Net and Other Receivables, Sales Deductions and Allowances* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

#### ***Testing Finite-Lived, Long-Lived Assets, for Impairment***

As of December 31, 2020, our combined finite-lived, long-lived assets balance, principally property, plant and equipment and finite-lived intangible assets was \$56.3 million, which is classified within assets held for sale in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K as a result of the classification of the Legacy Business as a discontinued operation.

Long-lived assets, other than goodwill and other indefinite-lived intangible assets, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group.

Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations.

Evaluations of the recoverability of an asset are generally based on fair value estimates determined using either discounted cash flow models or preliminary offers from prospective buyers. The discounted cash flow models include assumptions related to product revenue, growth rates and operating margin. These assumptions are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of future product cash flows. These estimates are subject to the economic environment in which we operate, demand for the products and competitor actions. The use of different assumptions could increase or decrease our estimated discounted future cash flows and the resulting estimated fair values of these assets, causing increases or decreases in the recoverability of assets, potentially resulting in asset impairment charges. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted.

Based on the results of impairment assessments performed relative to finite-lived, long-lived assets, we recognized impairment charges of \$43.3 million during the year ended December 31, 2020, primarily consisting of write-downs to fair value for methylphenidate ER, VERT, and Oxybutynin reflecting unfavorable developments in the competitive generic environment which had continued to erode net realized pricing and volumes of these products.

Fixed asset impairments for the years ended December 31, 2021 and 2020 were immaterial and were attributable to the minor abandonment of information technology assets.

#### **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 and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

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 make 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, 2021, our liabilities denominated in foreign currencies were not material.

We are exposed to fluctuations in interest rates on our Notes. An increase in interest rates could have a material impact on our cash flow. At December 31, 2021, a 100 basis point increase in assumed interest rates for our Notes would have an annual impact of approximately \$0.5 million on interest expense.

At December 31, 2021, we had cash and cash equivalents of \$40.4 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

Inflation generally affects us by increasing our cost of labor, API costs and 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, 2021 and 2020.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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**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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 30, 2022

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 40,444	\$ 114,053
Accounts receivable, net and other receivables	2,133	3,149
Inventories, net	838	1,831
Prepaid expenses and other current assets	12,901	12,592
Financial commitment asset	3,063	—
Assets held for sale	—	41,529
Total current assets	59,379	173,154
Property, plant and equipment, net	866	2,391
Operating lease assets	1,368	1,953
Indefinite-lived intangible assets	27,210	35,090
Goodwill	55,847	55,847
Other non-current assets	—	373
Assets held for sale	—	102,141
Total assets	<u>\$ 144,670</u>	<u>\$ 370,949</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Trade accounts payable	\$ 3,777	\$ 3,128
Accrued liabilities	13,077	16,951
Current portion of debt	2,409	—
Current portion of obligations under finance leases	5	20
Current portion of lease liability	839	1,199
Income taxes payable - current portion	1	2
Liabilities held for sale	—	34,484
Total current liabilities	20,108	55,784
Long-term debt (\$43,800 and \$0 measured at fair value and \$55,000 and \$221,400 of aggregate unpaid principal balance at December 31, 2021 and 2020, respectively)	43,800	219,525
Warrant liability	3,220	—
Long-term portion of lease liability	592	871
Income taxes payable - long term portion	66	—
Deferred taxes	151	345
Liabilities held for sale	—	568
Total liabilities	67,937	277,093
Commitments and contingencies (See Note 16)		
Shareholders' equity:		
Ordinary shares (\$0.01 nominal value 400,000,000 shares authorized, 83,297,567 and 62,545,832 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively)	833	625
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	591,730	548,070
Accumulated deficit	(517,530)	(452,610)
Accumulated other comprehensive income (loss)	1,700	(2,229)
Total shareholders' equity	76,733	93,856
Total liabilities and shareholders' equity	<u>\$ 144,670</u>	<u>\$ 370,949</u>

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,	
	2021	2020
Net product sales	\$ 7,511	\$ 1,942
Royalty and licensing revenue	9,990	25,820
Total revenues	17,501	27,762
Cost of goods sold	3,618	3,293
Gross profit	13,883	24,469
Selling, general and administrative expenses	87,463	72,824
Research and development expenses	6,930	13,387
Impairment of intangible assets	7,880	28,910
Total operating expenses	102,273	115,121
Operating loss before gain on sales of product rights, net	(88,390)	(90,652)
Gain on sales of product rights, net	5,636	—
Operating loss	(82,754)	(90,652)
Interest expense and amortization of debt discount	3,036	4,095
Change in fair value of debt and interest expense	982	—
Change in fair value of warrants	(5,571)	—
Other non-operating expense, net	1,333	48
Total other non-operating (income) expense	(220)	4,143
Loss before income taxes	(82,534)	(94,795)
Income tax expense (benefit), continuing operations	315	(5,782)
Loss from continuing operations	(82,849)	(89,013)
Gain on sales of discontinued operations	4,062	—
Income from discontinued operations before income taxes	13,570	10,508
Income tax (benefit) expense, discontinued operations	(297)	1,084
Income from discontinued operations, net of tax	17,929	9,424
Net loss	\$ (64,920)	\$ (79,589)
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	—
Other comprehensive income	3,929	—
Comprehensive loss	\$ (60,991)	\$ (79,589)
(Loss) earnings per ordinary share:		
Basic and diluted, continuing operations	\$ (1.23)	\$ (1.47)
Basic and diluted, discontinued operations	0.27	0.16
Basic and diluted	\$ (0.96)	\$ (1.31)
Weighted average ordinary shares outstanding:		
Basic and diluted	67,354,336	60,652,999

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, 2020	51,845,742	\$ 518	\$ 489,440	\$ (373,021)	\$ (2,229)	\$ 114,708
Repurchase of ordinary shares	(1,435,725)	(15)	(8,086)	—	—	(8,101)
Share compensation	235,815	3	5,144	—	—	5,147
Net loss	—	—	—	(79,589)	—	(79,589)
Payments for taxes related to the net share settlement of equity awards	—	—	(749)	—	—	(749)
Proceeds from issuance of ordinary shares, net of offering costs	11,900,000	119	62,321	—	—	62,440
Balance at December 31, 2020	<u>62,545,832</u>	<u>\$ 625</u>	<u>\$ 548,070</u>	<u>\$ (452,610)</u>	<u>\$ (2,229)</u>	<u>\$ 93,856</u>
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	202	36,625	—	—	36,827
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	<u>83,297,567</u>	<u>\$ 833</u>	<u>\$ 591,730</u>	<u>\$ (517,530)</u>	<u>\$ 1,700</u>	<u>\$ 76,733</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2021	2020
<b>Cash Flows from Operating Activities:</b>		
Net loss from continuing operations	\$ (82,849)	\$ (89,013)
Net income from discontinued operations	17,929	9,424
Net loss	(64,920)	(79,589)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	8,175	21,026
Share compensation	7,594	4,925
Reclassification adjustment of cumulative foreign currency translation losses to earnings	2,229	—
Change in fair value of debt	(318)	—
Change in fair value of warrants	(5,571)	—
Impairment of intangible assets	7,880	72,183
Deferred income tax benefit	(194)	(1,156)
Loss on sale of fixed and leased assets	1,180	287
Gain on sale of product rights, net	(5,636)	—
Gain on sales of discontinued operations	(4,062)	—
Bad debt provision	—	6
Amortization of deferred financing and loan origination fees	1,606	1,269
Write off of deferred financing and loan origination fees	1,462	496
Financing fees recognized in earnings associated with debt and warrants	3,306	—
Change in operating assets and liabilities:		
Accounts receivable, net and other receivables	7,108	17,496
Inventories, net	2,595	3,371
Prepaid expenses and other current assets	(6,198)	(3,209)
Trade accounts payable	(134)	(1,723)
Accrued and other current liabilities	(10,834)	(17,792)
Net cash provided by (used in) operating activities	(54,732)	17,590
<b>Cash Flows from Investing Activities:</b>		
Proceeds from product rights disposal	7,300	—
Proceeds from discontinued operations	110,845	—
Proceeds from sale of fixed and leased assets	90	50
Payments on disposal of leased assets	—	(214)
Purchases of property, plant and equipment	(1,782)	(2,920)
Net cash provided by (used in) investing activities	116,453	(3,084)
<b>Cash Flows from Financing Activities:</b>		
Payments on finance lease obligations	(37)	(127)
Proceeds from insurance financing loan	3,317	—
Payments on insurance financing loan	(909)	—
Payments for taxes related to net share settlement of share-based awards	(783)	(749)
Proceeds from issuance of debt, net of issuance costs	51,795	—
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	32,414	62,440
Proceeds from issuance of ordinary shares under ESPP	233	219
Debt repayments	(221,360)	(50,000)
Repurchases of ordinary shares	—	(8,101)
Net cash provided by (used in) financing activities	(135,330)	3,682
Net change in cash and cash equivalents	(73,609)	18,188
Cash and cash equivalents, beginning of period	114,053	95,865
Cash and cash equivalents, end of period	\$ 40,444	\$ 114,053

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 (the “Company”), together with its subsidiaries, is a specialty pharmaceutical company focused on the development and commercialization of products that target markets with underserved patient populations. 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 September 2020 to a limited number of eye care professionals with commercialization operations expanded in 2021 among ophthalmology, optometry and oculoplastic specialties.

On August 27, 2021, the Company closed the divestiture of its portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility, (the “Legacy Business”) to certain affiliates of Alora Pharmaceuticals, or Alora, for \$111 million in cash upon closing, subject to certain adjustments, and up to \$60 million in contingent milestone payments. Pursuant to the agreement the Company post-closing retained the rights to Upneeq and to arbaclofen extended release tablets which is under development for the treatment of spasticity in multiple sclerosis. With the divestiture of the Legacy Business, the primary focus of the Company is on the commercialization and development of specialty pharmaceuticals in the ocular and medical aesthetics therapeutic areas.

With the divestiture of the Legacy Business the Company’s commercial operations are conducted by its wholly-owned subsidiaries, RVL Pharmaceuticals, Inc. and RVL Pharmacy, LLC, or RVL Pharmacy. RVL Pharmacy operates pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

Unless otherwise indicated or required by the context, references throughout to “RVL,” or the “Company,” refer to the Company’s continuing operations following the sale or the Legacy Business to Alora.

**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.

The divestiture of the Legacy Business qualifies as a discontinued operation and therefore has been presented as such.

**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 its 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 statement of operations and comprehensive loss. Foreign currency transaction gains were \$1.4 million and immaterial for the year ended December 31, 2021 and 2020, 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 statement 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 Doubtful Accounts*—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 customer’s trade receivables, and current and future market conditions. Due to the short-term nature of such receivables, the estimate of accounts receivable 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 statement 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 (“NRV”) 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:

<b>Asset category</b>	<b>Depreciable life</b>
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

*Long-Lived Assets, Including Definite-Lived Intangible Assets*—Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis or based on the expected pattern of cash flows over estimated useful lives ranging from 5 to 15 years. The Company periodically reviews the estimated useful lives of intangible assets and makes adjustments when events indicate that a shorter life is appropriate.

Long-lived assets, other than goodwill and other indefinite-lived intangibles, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets.

Factors that the Company considers in deciding when to perform an impairment review include significant changes in the Company’s forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes, or planned changes in the Company’s use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group. If impairment is indicated, the asset is written down by the amount by which the

carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the consolidated statement of operations and comprehensive loss.

*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 1<sup>st</sup> 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 recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The judgments made in determining the projected cash flows used to estimate the 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 acquired Research & Development (“R&D”) projects that principally represent rights to develop and sell a product that the Company has acquired which have not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. Impairment testing 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 product, the assets are reduced to zero. IPR&D is assessed for impairment on an annual basis as of October 1<sup>st</sup> 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 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 recorded to impairment on intangible assets in the accompanying consolidated statement 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 pays for the product in advance of the transfer of the product.

*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*—The Company recognizes development and regulatory milestone revenue from milestone events under its license with Santen 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.

*In-Process Research and Development*—In-process research and development represent the fair value assigned to incomplete research projects that the Company acquires through business combinations or developed internally which, at that time, have not reached technological feasibility. Intangible assets associated with IPR&D projects are not amortized until regulatory approval is obtained and product is launched, subject to certain specified conditions and management judgment. At the time of any transfer an impairment evaluation is performed. The useful life of any resultant amortizing asset generally is 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 respectful estimated useful lives. Amortizing assets are subsequently evaluated periodically for indicators of impairment.

*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 media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2021 and 2020 amounted to \$14.9 million and \$6.8 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 (Loss)**—Comprehensive income (loss) refers to revenues, expenses, gains and losses that under U.S. GAAP are included in comprehensive income (loss) but are excluded from net income (loss) as these amounts are recorded directly as an adjustment to accumulated other comprehensive income (loss). The Company's other comprehensive income (loss) is 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 (Loss) Per Share**—Basic earnings (loss) per share is determined by dividing net income (loss) by the weighted average ordinary shares outstanding during the period. Diluted earnings (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 (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 that target markets with underserved patient populations. 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 or tangible assets outside of the United States.

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

	Year Ended December 31,	
	2021	2020
Cash paid for:		
Interest	\$ 8,518	\$ 14,745
Income taxes	\$ 2,361	\$ 2,044
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	\$ —

### 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.

### **Note 3. Liquidity**

At December 31, 2021, the Company had cash and cash equivalents of \$40.4 million, an accumulated deficit of \$517.5 million, and total long-term debt with aggregate principal maturities of \$55.0 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, 2021 and 2020, the Company incurred net losses from continuing operations of \$82.8 million and \$89.0 million, respectively. For the year ended December 31, 2021, the Company used \$54.7 million in cash for operating activities.

The divestiture of the Legacy Business in 2021 resulted in the loss of substantially all the Company's revenue generating assets. The Company's current business plan is focused on the continued launch and commercialization 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 sustained operating losses for the foreseeable 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 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 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 additional 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 Business, to certain affiliates of Alora for \$111 million in cash upon closing, subject to certain post-closing adjustments, and up to \$60 million in additional contingent milestone payments.

The Company has determined the divestiture of the Legacy Business represents a strategic shift that will have a major effect on its business and therefore met the criteria for classification as discontinued operations at December 31, 2021. Accordingly, the Legacy Business is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. The related assets and liabilities of the Legacy Business are classified as assets and liabilities of discontinued operations in the accompanying consolidated balance sheet at December 31, 2020. Applicable amounts in prior years have been recast to conform to this discontinued operations presentation. The Company recognized a gain on the sale of the Legacy Business upon closing.

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

	Year Ended December 31,	
	2021	2020
Total revenues	\$ 62,395	\$ 150,122
Cost of goods sold (inclusive of depreciation and amortization)	30,018	71,187
Selling, general and administrative expense	5,468	9,137
Impairment of intangible assets	—	43,273
Research and development expenses	5,882	6,309
Income from operations	21,027	20,216
Interest expense and amortization of debt discount	6,399	10,301
Other non-operating loss (income), net	1,058	(593)
Income from discontinued operations before costs of disposal and provision for income taxes	13,570	10,508
Income tax (benefit) expense	(297)	1,084
Income from discontinued operations before gain on disposal	13,867	9,424
Gain on sales of discontinued operations	4,062	—
Income from discontinued operations, net of tax	\$ 17,929	\$ 9,424

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.

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The following table presents the carrying amounts of major classes of assets and liabilities of discontinued operations (in thousands):

	<b>December 31, 2020</b>	
Cash and cash equivalents	\$	—
Accounts receivable, net		23,263
Inventories		16,103
Prepaid expenses and other current assets		2,163
<b>Total current assets of discontinued operations</b>		<b>41,529</b>
Property, plant and equipment, net		25,663
Operating lease right-of-use assets		803
Goodwill		45,008
Intangible assets, net		30,667
<b>Total non-current assets of discontinued operations</b>		<b>102,141</b>
<b>Total assets of discontinued operations</b>	<b>\$</b>	<b>143,670</b>
Accounts payable	\$	3,640
Accrued liabilities		30,566
Current portion of operating lease liabilities		278
<b>Total current liabilities of discontinued operations</b>		<b>34,484</b>
Operating lease liabilities, net of current portion		568
<b>Total non-current liabilities of discontinued operations</b>		<b>568</b>
<b>Total liabilities of discontinued operations</b>		<b>35,052</b>
<b>Net assets of discontinued operations</b>	<b>\$</b>	<b>108,618</b>

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):

	<b>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Cash flows from operating activities:		
Depreciation and amortization	\$ 6,583	\$ 17,531
Share compensation	619	1,008
Impairment of intangible assets	—	43,273
Cash flows from investing activities:		
Purchases of property, plant and equipment	\$ (1,335)	\$ (2,304)

#### **Note 5. Revenues**

The Company's performance obligations are to provide its pharmaceutical products based upon purchase orders from customers. The performance obligation is satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. The Company collects payment in advance from its customers.

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

Pharmaceutical Product	Year Ended December 31,	
	2021	2020
Upneeq	\$ 7,511	\$ 526
Osmolex	—	1,416
Net product sales	7,511	1,942
Royalty and licensing revenue	9,990	25,820
Total revenues	\$ 17,501	\$ 27,762

On July 28, 2020, the Company entered into a License Agreement with Santen Pharmaceutical Co. Ltd, 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 countries. Under the agreement the Company is entitled to certain development and regulatory milestone payments. The Company is also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories. During the year ended December 31, 2021, the Company received a \$10.0 million milestone payment which was recognized as licensing revenue as all performance obligations were met.

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of products to the customer under the terms of a contract, the Company records a contract liability. The Company classifies contract liabilities as deferred revenue. The Company had an immaterial amount of deferred revenue at December 31, 2021.

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, 2021 and 2020. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs*.

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

	Year Ended December 31,	
	2021	2020
Gross product sales	\$ 7,997	\$ 2,510
Less provisions for:		
Chargebacks	(2)	(6)
Government and managed care rebates	—	(155)
Commercial rebates	—	(56)
Product returns	—	(53)
Discounts and allowances	—	(14)
Advertising and promotions	(484)	(284)
Net product sales	\$ 7,511	\$ 1,942

#### Note 6. Accounts Receivable, Net and Other Receivables, Sales Deductions 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, net and other receivables (in thousands):

	December 31, 2021	December 31, 2020
Gross accounts receivable:		
Accounts receivable	\$ —	\$ 196
Royalty accounts receivable	—	55
Other receivable	2,133	2,903
Less reserves for:		
Commercial rebates	—	(4)
Discounts and allowances	—	(1)
Total accounts receivable, net and other receivables	<u>\$ 2,133</u>	<u>\$ 3,149</u>

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

	Commercial Rebates	Discounts and Allowances	Total
Balance at January 1, 2020	\$ 7	\$ 2	\$ 9
Provision	56	14	70
Charges processed	(59)	(15)	(74)
Balance at December 31, 2020	4	1	5
Provision	—	—	—
Charges processed	(4)	(1)	(5)
Balance at December 31, 2021	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

#### Note 7. Inventories

The following table presents the components of inventories, net of allowances (in thousands):

	Year Ended December 31,	
	2021	2020
Finished goods	\$ 838	\$ 1,593
Work in process	—	90
Raw materials and supplies	—	148
Total inventories	<u>\$ 838</u>	<u>\$ 1,831</u>

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 accounts (in thousands):

	Year Ended December 31,	
	2021	2020
Balance at beginning of period	\$ —	\$ —
Provision	34	—
Charges processed	—	—
Balance at end of period	<u>\$ 34</u>	<u>\$ —</u>



**Note 8. Property, Plant and Equipment, Net**

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

	Year Ended December 31,	
	2021	2020
Leasehold improvements	\$ 1,129	\$ 2,214
Machinery	—	1,045
Furniture, fixtures and equipment	4	28
Computer hardware and software	1,302	1,209
	<u>2,435</u>	<u>4,496</u>
Accumulated depreciation	(1,641)	(2,131)
	<u>794</u>	<u>2,365</u>
Construction in progress	72	26
	<u>\$ 866</u>	<u>\$ 2,391</u>

Depreciation expense was \$1.5 million and \$1.9 million for the years ended December 31, 2021 and 2020, respectively. There was less than \$0.1 million of remaining construction in progress expenditures to substantially complete projects in progress at December 31, 2021.

**Note 9. Goodwill and Indefinite-Lived Intangible Assets****Goodwill**

Goodwill is presented net of accumulated impairment charges of \$47.8 million at December 31, 2021 and 2020. The following table sets forth the changes in the carrying value of goodwill (in thousands):

	Goodwill
January 1, 2020	\$ 55,847
Impairments	—
December 31, 2020	<u>55,847</u>
Impairments	—
December 31, 2021	<u>\$ 55,847</u>

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, 2021, 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**

At December 31, 2021 and 2020, 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, aggregate impairment losses of \$36.8 million and \$28.9 million, respectively, and net carrying amounts of \$27.2 million and \$35.1 million, respectively.

Based on the results of quantitative IPR&D impairment assessments performed relative to arbaclofen ER, we recognized impairment charges of \$7.9 million and \$28.9 million during the years ended December 31, 2021 and 2020, respectively, related to delays in anticipated commercialization of the product candidate, if approved. As of October 1, 2021, the Company performed a qualitative assessment for the arbaclofen ER IPR&D and concluded that the asset was not impaired.

The 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 12.5% and 9.5%, during the years ended December 31, 2021 and 2020, respectively. The Company believes the 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, 2021	December 31, 2020
Accrued expenses and other liabilities	\$ 7,897	\$ 8,455
Accrued compensation	4,504	6,232
Accrued research and development	409	721
Accrued royalties	200	29
Deferred revenue	67	—
Accrued chargeback	—	1,376
Accrued product returns	—	88
Accrued government and managed care rebates	—	46
Customer coupons	—	4
Total accrued liabilities	<u>\$ 13,077</u>	<u>\$ 16,951</u>

#### Note 11. Leases

The Company leases office space in Bridgewater, New Jersey for its principal offices under two non-cancelable leases that expire in July 2022 and November 2023, in addition to office and warehouse space in various domestic and international locations. The Company also leases certain vehicles under operating leases. At December 31, 2021, the Company's operating leases had remaining lease terms ranging from 0.5 years to 2.8 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,	
		2021	2020
<b>Assets</b>			
Operating	Operating lease assets	\$ 1,368	\$ 1,953
Finance	Property, plant and equipment, net	5	22
Total leased assets		<u>\$ 1,373</u>	<u>\$ 1,975</u>
<b>Liabilities</b>			
Current			
Operating	Current portion of lease liability	\$ 839	\$ 1,199
Finance	Current portion of obligations under finance leases	5	20
Non-current			
Operating	Long-term portion of lease liability	592	871
Total lease liabilities		<u>\$ 1,436</u>	<u>\$ 2,090</u>

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,	
		2021	2020
Operating lease cost	Selling, general and administrative expenses	\$ 1,425	\$ 1,471
	Research and development expenses	28	104
	Cost of goods sold	41	55
Finance lease cost			
Amortization of leased assets	Depreciation and amortization	24	26
Interest on lease liabilities	Interest expense and amortization of debt discount	—	1
Total lease cost		<u>\$ 1,519</u>	<u>\$ 1,657</u>

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
2022	\$ 876
2023	491
2024	112
Total lease payments	<u>1,479</u>
Less: interest	<u>48</u>
Present value of lease payments	<u>\$ 1,431</u>

The Company has future minimum lease payments required under finance leases of less than \$0.1 million less interest expense of less than \$0.1 million for total present value lease payments of less than \$0.1 million for the year ended December 31, 2022.

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

Lease Term and Discount Rate	December 31,	
	2021	2020
Weighted average remaining lease term (years)		
Operating leases	1.82	1.96
Finance leases	0.60	1.07
Weighted average discount rate		
Operating leases	4.15 %	5.37 %
Finance leases	2.06 %	1.67 %

Other Information	December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ (1,478)	\$ (1,630)
Operating cash flows for finance leases	(0)	(1)
Financing cash flows for finance leases	(16)	(26)

For the years ended December 31, 2021 and 2020, the Company recorded \$0.7 million and \$0.2 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, 2021 and 2020, the Company disposed of less than \$0.1 million and \$0.6 million, respectively, of leased assets.

**Note 12. Financing Arrangements**

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

	December 31,	
	2021	2020
Senior Secured Notes (measured at fair value)	\$ 43,800	\$ —
Prior Term Loans, net of deferred financing costs of \$1.8 million	—	219,525
Note payable — insurance financing	2,409	—
Total debt and financing obligations	46,209	219,525
Less: current portion of debt	(2,409)	—
Long-term debt	\$ 43,800	\$ 219,525

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

Year Ending December 31,	Debt Obligations
2022	\$ 2,409
2023	—
2024	11,000
2025	11,000
2026	33,000
Total future minimum payments	57,409
Less: current portion of debt principal	(2,409)
Non-current portion of debt principal	\$ 55,000

### *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 2 LP (“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 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.

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 may request second tranche notes of up to \$20.0 million. Prior to October 12, 2023, the Company may request third tranche notes of up to \$25.0 million, in the sole discretion of the Purchaser.

The Senior Secured Notes bear interest at an annual rate of 9.0% plus adjusted three-month LIBOR, with a LIBOR floor of 1.50% and LIBOR cap of 3.00%, payable in cash quarterly in arrears. At December 31, 2021, the interest rate applicable to the Senior Secured Notes was 10.5%.

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% of the principal amount of the notes prepaid, (iii) certain other fees, indemnities and expenses, and (iv) all accrued interest on the notes being so prepaid. 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 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 Note Purchase Agreement also provides for events of default that we consider to be usual and customary.

In addition, the restrictive covenants in the Note Purchase Agreement require the Company to comply with certain minimum liquidity requirements and minimum quarterly product sales requirements. At any time, the Company is required to maintain unrestricted cash and cash equivalents greater than or equal to \$15.0 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 (beginning at \$3.0 million for the quarter ending March 31, 2022, 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, 2021, the Company was in compliance with all conditions of the 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 notes, respectively.

The Company elected the fair value option of accounting on the 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 statement of operations and comprehensive loss. The

Company's residual financial commitment asset related to the undrawn second tranche notes, which additionally includes the value of \$3.4 million relating to the Share Subscription Agreement (see Note 20), is being amortized over the relevant one-year commitment period. During the year ended December 31, 2021, the Company recognized \$0.9 million of amortization expense from the second tranche financial commitment asset with such expense being recorded within interest expense and amortization of debt discount in the accompanying consolidated statement of operations and comprehensive loss. At 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. If the second tranche notes are drawn within the one-year commitment period, the Company will expense the remaining balance under the fair value option of accounting.

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

#### *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 year ended December 31, 2020, the Company prepaid \$50.0 million against the Prior Term Loans and, consequently, wrote off \$0.5 million in debt issuance costs with the related expense classified within other non-operating gain or loss in the accompanying consolidated statement of operations and comprehensive loss.

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. In addition, the Company agreed to transfer upon the closing of the divestiture of the Legacy Business, substantially all of the Company's cash on hand to subsidiaries subject to the lien of the Prior Credit Agreement.

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 statement of operations and comprehensive loss.

### **Note 13. Concentrations and Credit Risk**

The Company does not have significant concentrations of credit risk with its customers.

#### *Purchasing*

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

#### *Sales by Product*

For the years ended December 31, 2021 and 2020, one product accounted for 100% and 73%, respectively, of the Company's total gross product sales.

#### *Royalty Sales*

The Company does not have significant concentrations of royalty 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 is being recognized over their remaining vesting period through October 2022. At December 31, 2021, 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 November 2021, 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 \$6.8 million for the year ended December 31, 2021 and \$4.5 million for the year ended December 31, 2020.

*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 granted under the 2016 Plan and the Amended 2016 Plan as of December 31, 2020, and changes during the year then ended is presented below:

<b>2016 Plan - Share Options</b>	<b>Number of Share Options</b>	<b>Weighted Average Exercise Price Per Option</b>	<b>Weighted Average Remaining Term</b>
Outstanding at January 1, 2020	2,959,886	\$ 14.96	6.4 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(132,786)	\$ 15.21	
Outstanding at December 31, 2020	2,827,100	\$ 14.95	5.4 years
Vested at December 31, 2020	2,099,950	\$ 14.95	5.4 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(312,690)	\$ 14.95	
Outstanding at December 31, 2021	2,514,410	\$ 14.95	4.4 years
Vested at December 31, 2021	2,514,410	\$ 14.95	4.4 years

There were no options granted during 2021 and 2020, respectively, under the 2016 Plan. The intrinsic value of options under the 2016 Plan outstanding at each of December 31, 2021 and 2020, was \$0. The fair value of options vested under the 2016 Plan during the years ended December 31, 2021 and 2020 were \$1,941 and \$8,832, respectively.

A summary of option activity granted under the 2018 Plan as of December 31, 2021 and 2020, and changes during the year then ended is presented below:

<b>2018 Plan - Share Options</b>	<b>Number of Share Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>
Outstanding at January 1, 2020	134,200	\$ 7.00	8.7 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(37,800)	\$ 7.00	
Outstanding at December 31, 2020	96,400	\$ 7.00	7.7 years
Vested Options at December 31, 2020	—		
Granted	3,174,886	\$ 1.80	
Exercised	—	—	
Expired / Forfeited	(88,850)	\$ 5.98	
Outstanding at December 31, 2021	3,182,436	\$ 1.84	9.8 years
Vested Options at December 31, 2021	—	—	

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There were 3,174,886 and 0 options granted during 2021 and 2020, respectively, under the 2018 Plan. The intrinsic value of options under the 2018 Plan outstanding at each of December 31, 2021 and 2020, was \$0. The weighted average fair value for the options granted during 2021 was \$1.25. The fair value of options vested under the 2018 Plan during the years ended December 31, 2021 and 2020 were both \$0, respectively.

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.

	<u>Year Ended</u> <u>December 31,</u> <u>2021</u>
Expected volatility	81 %
Risk-free interest rate	1.25% - 1.29 %
Expected dividend yield	— %
Expected life of options in years	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, 2021 and 2020, there was \$3.6 million and \$0.8 million of aggregate unrecognized share compensation expense related to unvested options granted under the 2018 Plans, which is expected to be recognized over a weighted-average period of 2.09 years and 1.3 years, respectively.

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.

The fair value of these market-based awards is estimated on the date of grant using a Monte Carlo simulation model with the following assumptions:

	<u>Year Ended</u> <u>December 31,</u> <u>2020</u>
Expected volatility	90 %
Risk-free interest rate	.21% - .24 %
Expected dividend yield	— %
Performance period in years	3.00

The Company estimates its expected volatility by using a combination of historical share price volatilities of similar companies within our industry. The risk-free interest rate assumption is based on observed interest rates for the appropriate term of the Company's options on a grant date.

The following table summarizes the information as of December 31, 2021 and activity during 2021 related to our PSUs:

**2018 Plan - PSUs**

	<b>Number of PSUs</b>	<b>Weighted- Average Grant Date Fair Value</b>	<b>Weighted- Average Remaining Contractual Term (Years)</b>
Outstanding at January 1, 2020	—	\$ —	—
PSUs granted	825,997	4.99	—
PSUs vested	—	—	—
PSUs forfeited	(36,198)	4.90	—
Outstanding at December 31, 2020	<u>789,799</u>	<u>\$ 4.99</u>	<u>3.01</u>
PSUs granted	—	—	—
PSUs vested	—	—	—
PSUs forfeited	<u>(789,799)</u>	<u>4.99</u>	—
Outstanding at December 31, 2021	<u>-</u>	<u>\$ —</u>	<u>—</u>

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.

The following table summarizes the information as of December 31, 2021 and activity during 2021 related to our RSUs:

**2018 Plan - RSUs**

	<b>Number of RSUs</b>	<b>Weighted- Average Grant Date Fair Value</b>	<b>Weighted- Average Remaining Contractual Term</b>
Outstanding at January 1, 2020	1,434,233	\$ 7.19	3.20
RSUs granted	976,429	4.46	—
RSUs vested	(300,788)	6.73	—
RSUs forfeited	(118,317)	6.07	—
Outstanding at December 31, 2020	<u>1,991,557</u>	<u>\$ 5.99</u>	<u>2.11</u>
RSUs granted	161,188	3.25	—
RSUs vested	(601,306)	6.05	—
RSUs forfeited	(199,164)	4.73	—
Outstanding at December 31, 2021	<u>1,352,275</u>	<u>\$ 5.82</u>	<u>2.17</u>

During 2021 and 2020 we granted restricted stock units, or RSUs, covering an equal number of our ordinary shares to employees and certain directors with a weighted average grant date fair value of \$3.25 and \$4.46, 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, 2021 and 2020 aggregate unrecognized share compensation expense related to unvested RSUs was \$4.5 million and \$8.5 million, respectively, which is expected to be recognized over a weighted average period of 1.8 years and 2.8 years, respectively.

*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 \$134,077 and \$113,860 of share compensation expense for the years ended December 31, 2021 and 2020, respectively. The Company values ESPP shares using the Black-Scholes model.

As of December 31, 2021 and 2020, there were no unrecognized share compensation expense related to the ESP Plan. There were 76,432 and 51,905 ordinary shares issued under the ESP Plan during the years ended December 31, 2021 and 2020, respectively. On January 3, 2022, the Company issued 129,258 ordinary shares to the employees who participated in the ESP Plan during the offering period ended December 31, 2021.

**Note 15. Earnings (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 (loss) per share because the impact of including them would have been anti-dilutive:

	<b>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Performance and restricted stock units	1,352,275	2,781,356
Share options to purchase ordinary shares	5,696,846	2,923,500
Warrants (see Note 20)	16,100,000	—
Ordinary shares to be purchased through employee stock purchase plan	129,258	39,321

## **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 those related to the acquisition of Upneeq and its related intellectual property. The amount of future contingent milestone payments under the intellectual property license agreement, based on certain levels of US and ex-US sales of Upneeq, was \$1.3 million in the aggregate at December 31, 2021. The total royalty expense was \$0.5 million at December 31, 2021. The Company believes the earn-out payments are currently immaterial to its financial statements. The Company is also obligated to pay earn out payments pursuant to the acquisition of RevitaLid, Inc., the original owner of Upneeq, as a percentage of US and ex-US sales of Upneeq.

### *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, 2021.

### *Defined Contribution Plan*

Vertical/Trigen and Legacy Osmotica both had a defined contribution plan under Section 401(k) of the Internal Revenue Code ("IRC") at December 31, 2016 pursuant to the Merger (the "Contribution Plans"). The employees of the respective companies are eligible to participate in the Contribution Plans. Participants may contribute amounts through payroll deductions not to exceed IRC limitations. For the year ended December 31, 2016, the Vertical/Trigen Plan provided for nonelective employer contributions equal to 3% of basic compensation. The separate Contribution Plans were merged into one plan effective January 1, 2017. Effective January 1, 2017, the 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, 2021 and 2020, the Company recognized expenses related to its contributions under the Plan of \$0.7 million and \$0.5 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 rate of 21%. On August 27, 2021, the Company sold its interest in certain subsidiaries which resulted in a capital loss.

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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, 2021	December 31, 2020
Loss before income taxes		
U.S. operations	\$ (68,975)	\$ (75,325)
Non-U.S. operations	(13,559)	(19,470)
Total loss before income taxes	<u>(82,534)</u>	<u>(94,795)</u>
Current income tax expense (benefit)		
Federal	192	(4,145)
State	(41)	232
Foreign	20	80
Total current income tax expense (benefit)	<u>171</u>	<u>(3,833)</u>
Deferred income tax expense (benefit)		
Federal	149	(1,660)
State	—	(190)
Foreign	(5)	(99)
Total deferred income tax expense (benefit)	<u>144</u>	<u>(1,949)</u>
Total income tax expense (benefit)	<u>\$ 315</u>	<u>\$ (5,782)</u>

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, 2021	December 31, 2020
U.S. federal tax at 21% statutory rate	21.00 %	21.00 %
State and local income taxes, net of federal benefit	2.65 %	1.15 %
Differences in tax effects on foreign income	8.81 %	(3.28)%
Federal tax credits	0.29 %	1.20 %
Uncertain tax positions	— %	0.83 %
NOL carryback rate differential	(0.03)%	3.46 %
Tax audit adjustment	0.01 %	(3.26)%
Change in valuation allowance	(33.83)%	(13.87)%
Permanent adjustments	(0.01)%	(0.60)%
Other	0.73 %	(0.50)%
Effective income tax rate	<u>(0.38)%</u>	<u>6.13 %</u>



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, 2021	December 31, 2020
<b>Deferred tax assets:</b>		
Accrued expenses	\$ 827	\$ 5,921
Inventories	—	295
Investment in partnership	—	2,393
Net operating losses	21,134	1,285
Capital losses	23,845	—
Operating lease liabilities	340	657
Tax credits	7,232	6,486
Debt costs	4,740	—
Interest expense	2,168	—
Share compensation	285	1,816
Intangible assets	—	19,082
Other	2,916	3,327
Less: valuation allowance	(52,853)	(27,811)
<b>Deferred tax liabilities:</b>		
Prepaid expenses	—	(658)
Property plant & equipment	—	(3,261)
Intangible assets	(6,353)	(9,254)
Debt costs	(4,107)	—
Operating lease assets	(325)	(623)
<b>Total deferred income taxes</b>	<b>\$ (151)</b>	<b>\$ (345)</b>

Included in the deferred tax balances above is a net deferred tax asset of \$14.9 million as of December 31, 2020 related to the assets and liabilities in Vertical/Trigen Holdings, LLC, which is a partnership for Federal income tax purposes. The Company sold its partnership interests in Vertical/Trigen Holdings, LLC on August 27, 2021 with the divestiture of the Legacy Business. As a result of the sale of the partnership interests, the deferred tax balances at December 31, 2021 do not include any balances of the partnership.

At December 31, 2021, the Company had a federal net operating loss carryforward of \$43.4 million and a state net operating loss of \$114.0 million. At December 31, 2021, the Company had net operating loss carryforwards in certain foreign tax jurisdictions of \$104.2 million, which will begin to expire in 2022. At December 31, 2021, the Company had total tax credit carryforwards of \$7.2 million primarily consisting of Federal Orphan Drug Tax Credits. These credit carryforwards begin to expire in 2036. 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 year ended December 31, 2021, the valuation allowance increased by \$25.1 million. 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 Coronavirus Aid Relief, and Economic Security Act (the “CARES Act”) was enacted on March 27, 2020 in the U.S. The Cares Act provides a five-year carryback for losses generated in 2018-2020. The Company incurred losses in the year ended December 31, 2020 that were carried back to the earliest year, 2015. The loss incurred in the year ended December 31, 2020 were carried back to a tax year with a higher income tax rate thereby providing an income tax benefit of \$3.2 million and producing a favorable impact to the Company’s effective income tax rate of 3.8%.

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 2021 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 2021 tax years remain open for examination by the tax authorities under the normal statute of limitations.

Two of the Company's subsidiaries, Osmotica Pharmaceutical Corp. and Valkyrie Group Holding Inc., finalized audits by the U.S. Internal Revenue Service (the "IRS") for tax years 2016 and 2017. The Company agreed to IRS adjustments and correspondingly recorded an income tax expense of \$1.9 million in the year ended December 31, 2020 which included \$1.4 million of income tax and \$0.5 million of interest and penalty expense.

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, 2021	December 31, 2020
Balance at beginning of period	\$ 171	\$ 2,677
Additions related to current period tax positions	4	171
Releases related to prior period tax positions	—	(2,677)
Balance at end of period	\$ 175	\$ 171

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 (income). Interest and penalties recognized in the consolidated statements of operations were immaterial. The release of prior period unrecognized tax positions in the year ended December 31, 2020 was due to an accounting method change which eliminated the need for an uncertain tax position.

#### **Note 18. Related Parties**

There were no related party transactions and no related expenses were recorded for the year ended December 31, 2021.

#### **Note 19. Restructuring Expenses**

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 operating expenses which were incurred in the year ended December 31, 2021. The restructuring expenses consisted of \$3.2 million 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.

## **Note 20. Shareholders' Equity and Warrant Liabilities**

### *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 our 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 underlying the Warrants were registered on the Company's Registration Statement on Form S-3 (File No. 333-260529), filed with the Securities and Exchange Commission ("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.

#### *2020 Equity Offering*

On July 16, 2020, we completed a follow-on equity offering and allotted 5,000,000 ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.6 million after deducting offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

On January 13, 2020, we completed a follow-on equity offering and allotted 6,900,000 ordinary shares at a public offering price of \$5.00 per share. The number of shares issued in this offering reflected the exercise in full of the underwriters' option to purchase 900,000 ordinary shares. The aggregate net proceeds from the follow-on offering were approximately \$31.8 million after deducting underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

#### *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. For the year ended December 31, 2020, the Company repurchased 1,435,725 ordinary shares, at a weighted-average price of \$5.62 for an aggregate of \$8.1 million. The Company did not repurchase any shares during the year ended December 31, 2021.

#### **Note 21. Financial Instruments and Fair Value Measurements**

The Company's financial instruments subject to fair value measurements include cash and cash equivalents, trade accounts receivable, 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 \$40.4 million and \$114.1 million at December 31, 2021 and 2020, respectively.

*Financial Liabilities* - The Senior Secured Notes, a material component of long-term debt at December 31, 2021 (see Note 12), and Warrants, as reflected within warrant liabilities, a material component of total liabilities, at December 31, 2021 (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,

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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):

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

Financial Instrument	At Issuance October 2021			
	Fair Value	Valuation Technique	Unobservable Inputs	
Senior Secured Notes	\$ (45,818)	Income Approach - DCF	Discount rate Term (in years)	16.3 % 5.0
Warrants	\$ (8,791)	Black-Scholes Merton	Equity volatility Term (in years)	60.0 % 3.5

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 Issuance - October 2021	\$ (45,818)	\$ (8,791)
Cash payments for interest	1,283	-
Fair value adjustments through earnings (inclusive of related accrued interest expense)	(965)	5,571
Fair value adjustments through accumulated other comprehensive income or loss	1,700	-
Balance, At December 31, 2021	\$ (43,800)	\$ (3,220)

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 exclusive of base market changes and are presented as a component of comprehensive 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.

*Assets and Liabilities for Which Fair Value is Only Disclosed*

The carrying amounts for trade accounts receivable, trade accounts payable, accrued liabilities and the residual amounts of long-term debt not otherwise measured at fair value on a recurring basis approximate their relative fair values due to their short-term nature with relevant inputs considered Level 2 measurements within the fair value hierarchy.

*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, 2021 and 2020.

**Note 22. Subsequent Events**

In January, February and March 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 (see Notes 1 and 4). In January, February, and March of 2022, the Company obtained waivers from the Purchaser 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 (see Note 12), in exchange for a consent fee of \$0.2 million, resulting in net proceeds of \$4.8 million.

On March 29, 2022, RVL Pharmaceuticals, Inc. ("RVL Pharmaceuticals"), a wholly owned subsidiary of the Company, entered into the First Amendment to License Agreement (the "Amendment") with Santen Pharmaceutical Co. Ltd. ("Santen"), amending the License Agreement dated July 28, 2020, by and between RVL Pharmaceuticals and Santen (the "License Agreement"). Under the terms of the Amendment, effective March 31, 2022, RVL Pharmaceuticals is 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. 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.

## **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 Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. 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, 2021, our Chief Executive Officer and Chief 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, 2021 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, 2021. 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, 2021, 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

<u>Exhibit No.</u>	<u>Description</u>
2.1#	<a href="#">Business Combination Agreement, dated as of December 3, 2015, among Osmotica Holdings Corp Limited, the shareholders of Osmotica Holdings Corp Limited party thereto, Altchem Limited, Vertical/Trigen Holdings, LLC, the shareholders of Vertical/Trigen Holdings, LLC party thereto, Avista Capital Partners III GP, LP, and Osmotica Holdings S.C.Sp.</a> (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
2.2	<a href="#">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)</a>
3.1	<a href="#">Memorandum and Articles of Association of RVL Pharmaceuticals plc</a> (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	<a href="#">Shareholders' Agreement</a> (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	<a href="#">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)</a>
4.3	<a href="#">Form of Ordinary Share Certificate</a> (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	<a href="#">Description of Registrant's Securities</a>
10.1†	<a href="#">License Agreement dated as of August 31, 2011 by and between VOOM, LLC and Revitalid, Inc.</a> (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†	<a href="#">Exclusive Supply Agreement, dated as of February 7, 2013, by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc.</a> (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†	<a href="#">First Amendment to Exclusive Supply Agreement, dated as October 24, 2017 by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc.</a> (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)
10.4†	<a href="#">License Agreement dated as of July 28, 2020, by and between RVL Pharmaceuticals, Inc. and Santen Pharmaceutical Co. Ltd.</a> (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on July 31, 2020, Commission File No. 001-38709)

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- 10.5+ [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)
- 10.6+ [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)
- 10.7+ [Form of Nonqualified Option Award Agreement under the RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan](#)
- 10.8+ [RVL Pharmaceuticals plc Amended and Restated 2018 Employee Share Purchase Plan](#)
- 10.9+ [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)
- 10.10+ [Amended and Restated RVL Pharmaceuticals plc 2016 Equity Incentive Plan](#)
- 10.11+ [RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan](#)
- 10.12+ [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)
- 10.13+ [Employment Agreement, dated December 3, 2015, by and between Vertical/Trigen Holdings, LLC and Brian A. Markison](#)
- 10.14+ [Amendment to Employment Agreement, dated July 29, 2021, by and between RVL Pharmaceuticals, Inc. and Brian A. Markison.](#)
- 10.15+ [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)
- 10.16+ [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)
- 10.17+ [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)
- 10.18+ [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)
- 10.19+ [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)

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10.20+	<a href="#"><u>Form of Additional Annual Retainer Agreement (In Lieu of Equity Awards) with RVL Pharmaceuticals plc Directors</u></a> (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)
10.21	<a href="#"><u>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</u></a> (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)
10.22	<a href="#"><u>Sales Agreement, dated as of September 8, 2021, by and between Osmotica Pharmaceuticals, plc and Cantor Fitzgerald &amp; Co.</u></a> (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)
10.23	<a href="#"><u>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</u></a> (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)
10.24	<a href="#"><u>Share Subscription Agreement, dated October 1, 2021, between Osmotica Pharmaceuticals plc and Athyrium Opportunities IV Acquisition LP</u></a> (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)
21.1	<a href="#"><u>Subsidiaries of RVL Pharmaceuticals plc</u></a>
23.1	<a href="#"><u>Consent of Ernst &amp; Young LLP independent registered public accounting firm</u></a>
31.1	<a href="#"><u>Principal Executive Officer Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
31.2	<a href="#"><u>Principal Financial Officer Certification Pursuant to Securities Exchange Act Rules 13a-14 and 15d-14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
32.1	<a href="#"><u>Principal Executive Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
32.2	<a href="#"><u>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</u></a>
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)

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- # 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 30, 2022

By: /s/ Brian Markison  
Brian Markison  
Chief Executive 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 30, 2022.

<u>Signatures</u>	<u>Capacity in Which Signed</u>
<u>/s/ Brian Markison</u> Brian Markison	Chief Executive Officer and Director (Chairman) (Principal Executive Officer)
<u>/s/ Andrew Einhorn</u> Andrew Einhorn	Chief Financial Officer (Principal Financial Officer and Accounting Officer)
<u>/s/Michael DeBiasi</u> Michael DeBiasi	Director
<u>/s/ David Burgstahler</u> David Burgstahler	Director
<u>/s/ Gregory L. Cowan</u> Gregory L. Cowan	Director
<u>/s/ Joaquin Benes</u> Joaquin Benes	Director
<u>/s/ Sriram Venkataraman</u> Sriram Venkataraman	Director
<u>/s/ Juan Vergez</u> Juan Vergez	Director

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

The following description sets forth certain material terms and provisions of RVL Pharmaceuticals plc (the "Company", "us", "we", or "our") securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The following is a summary of some of the terms of our ordinary shares based on our Articles of Association. The following summary is subject to, and is qualified in its entirety by reference to, the provisions of our Articles of Association, which is an exhibit to the Annual Report on Form 10-K to which this description is an exhibit.

**Organization**

We are an Irish private company with limited liability. We were organized in Ireland on July 13, 2017 under the name Lilydale Limited with registered number 607944. Effective May 1, 2018, we were renamed Osmotica Pharmaceuticals Limited. On July 31, 2018, Osmotica Pharmaceuticals Limited re-registered under the Irish Companies Act of 2014 as a public limited company and was renamed Osmotica Pharmaceuticals plc. Effective January 17, 2022, we changed our name to RVL Pharmaceuticals plc. Our affairs are governed by our Constitution, including our Articles of Association, and Irish law.

**Objective**

As provided by and described in our Memorandum of Association, our principal objective is to carry on the business of a holding company and all associated related activities and to carry on various activities associated with that objective.

**Share Capital**

Our authorized share capital is \$4,400,000 and €25,000, divided into 400,000,000 ordinary shares with a nominal value of \$0.01 per share, 40,000,000 Preferred Shares with a nominal value of \$0.01 per share and 25,000 Euro Deferred Shares with a nominal value of €1.00 per share.

We may issue shares subject to the maximum authorized share capital contained in our Constitution. The authorized share capital may be increased or reduced (but not below the number of issued ordinary shares, preferred shares and Euro deferred shares, as applicable) by a resolution approved by a simple majority of the votes of our shareholders cast at a general meeting (referred to under Irish law as an "ordinary resolution") (unless otherwise determined by the directors). The shares comprising our authorized share capital may be divided into shares of any nominal value.

The rights and restrictions to which our ordinary shares are subject are prescribed in our Articles of Association. Our Articles of Association entitle our board of directors, without shareholder approval, to determine the terms of the preferred shares issued by us. The preferred shares may be preferred as to dividends, rights upon liquidation or voting in such manner as our board of directors may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at our option, and may be convertible into or exchangeable for shares of any other class or classes of our share capital, depending on the terms of issue of such preferred shares.

Irish law does not recognize fractional shares held of record. Accordingly, our Articles of Association does not provide for the issuance of fractional shares, and our official Irish register does not reflect any fractional shares.

Whenever an alteration or reorganization of our share capital would result in any of our shareholders becoming entitled to fractions of a share, our board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, arrange for the sale of the shares representing fractions and the distribution of the net proceeds of sale in due proportion among the shareholders who would have been entitled to the fractions.

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## **Transfer and Registration of Shares**

Our share register is maintained by our transfer agent. Registration in this share register will be determinative of membership in us. Any of our shareholders who only hold ordinary shares beneficially will not be the holder of record of such ordinary shares. Instead, the depository or other nominee will be the holder of record of such shares. Accordingly, a transfer of ordinary shares from a person who holds such ordinary shares beneficially to a person who will also hold such ordinary shares beneficially through the same depository or other nominee will not be registered in our official share register, as the depository or other nominee will remain the holder of record of such ordinary shares.

A written instrument of transfer will be required under Irish law in order to register on our official share register any transfer of ordinary shares (i) from a person who holds such ordinary shares directly to any other person or (ii) from a person who holds such ordinary shares beneficially to another person who also will hold such ordinary shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred ordinary shares. An instrument of transfer will be required for a shareholder who directly holds ordinary shares to transfer those ordinary shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on our official Irish share register. However, a shareholder who directly holds ordinary shares may transfer those ordinary shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty, provided that there is no change in the beneficial ownership of the ordinary shares as a result of the transfer and the transfer is not made in contemplation of a sale of the ordinary shares.

Accordingly, we strongly recommend that shareholders hold their shares through DTC (or through a broker who holds such shares through DTC).

Any transfer of our ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless such stamp duty is paid and details of the transfer are provided to our transfer agent. We do not expect to pay any stamp duty on behalf of any acquirer of ordinary shares in our capital. We may, in our absolute discretion, pay (or cause one of our affiliates to pay) any stamp duty.

Our Articles of Association provide that, in the event of any such payment, we (i) may seek reimbursement from the transferor or transferee (at our discretion), (ii) may set-off the amount of the stamp duty against future dividends payable to the transferor or transferee (at our discretion) and (iii) will have a lien against any of our shares in respect of which we have paid stamp duty. Our Articles of Association grant our board of directors general discretion to decline to register an instrument of transfer without giving a reason. In addition, our board of directors may decline to register a transfer of shares unless a registration statement under the Securities Act is in effect with respect to the transfer or the transfer is exempt from registration.

The registration of transfers may be suspended at such times and for such periods, not exceeding 30 days in any year, as our board of directors may from time to time determine (except as may be required by law).

## **Issuance of Shares**

We have the authority, pursuant to our Articles of Association, to increase our authorized but unissued share capital by ordinary resolution by creating additional shares of any class or series. An ordinary resolution of our company requires more than 50% of the votes cast at a shareholder meeting by our shareholders entitled to vote at that meeting. As a matter of Irish law, the board of directors of a company may issue authorized but unissued new shares without shareholder approval once authorized to do so by the Articles of Association of the company or by an ordinary resolution adopted by the shareholders at a general meeting. The authority conferred can be granted for a maximum period of five years, at which point it must be renewed by the shareholders by an ordinary resolution. Because of this requirement of Irish law, our Articles of Association authorize our board of directors to issue new shares up to the amount of our authorized but unissued share capital without shareholder approval for a period of five years from the date our Articles of Association were adopted. We expect that we will seek to renew such general authority at an annual general meeting before the end of that five-year period. Our Articles of Association authorize our board of directors, without shareholder approval, to determine the terms of any class of preferred shares issued by us.

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### ***No Share Certificates***

We do not intend to issue share certificates unless (i) certificates are required by law, any stock exchange, a recognized depository, any operator of any clearance or settlement system or the terms of issue of any class or series of our shares or (ii) a holder of our ordinary shares applies for share certificates evidencing ownership of our shares.

Under our Articles of Association, holders of our ordinary shares have no right to certificates for their ordinary shares, except on request and on such terms as our board of directors, at its sole discretion, determines.

Holders' rights to request certificates for ordinary shares are subject to any resolution of our board of directors determining otherwise.

### ***No Sinking Fund***

Our ordinary shares have no sinking fund provisions.

### ***No Liability for Further Calls or Assessments***

Our ordinary shares are fully paid up and are not subject to calls for any additional payments (non-assessable).

### ***Pre-emption Rights, Share Warrants and Share Options***

Under Irish law, certain statutory pre-emption rights apply automatically in favor of our shareholders when our shares are issued for cash. However, we have opted out of these pre-emption rights in our Articles of Association as permitted under Irish law for the maximum period permitted of five years from the date of adoption of the Articles of Association. This opt-out may be renewed every five years under Irish law by a special resolution of the shareholders. A special resolution requires not less than 75% of the votes cast by our shareholders at a meeting of shareholders. We expect that we will seek renewal of the opt-out at an annual general meeting within five years from the date on which our Articles of Association were adopted. If the opt-out expires and is not renewed, shares issued for cash must be offered to our pre-existing shareholders pro rata based on their existing shareholding before the shares can be issued to any new shareholders or pre-existing shareholders in an amount greater than their pro rata entitlements. The statutory pre-emption rights:

- generally do not apply where shares are issued for non-cash consideration;
- do not apply to the issuance of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any dividend and capital distribution, which are sometimes referred to as non-participating shares); and
- do not apply to the issuance of shares pursuant to certain employee compensation plans, including the RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan.

The Irish Companies Act of 2014 (the "Irish Companies Act") provides that directors may issue share warrants or options without shareholder approval once authorized to do so by the Articles of Association or an ordinary resolution of shareholders. This authority can be granted for a maximum period of five years, after which it must be renewed by the shareholders by an ordinary resolution. Our Articles of Association provide that our board of directors is authorized to grant, upon such terms as the board deems advisable, options to purchase (or commitments to issue at a future date) our shares of any class or series, and to cause warrants or other appropriate instruments evidencing such options or commitments to be issued. This authority under the articles will lapse after five years from the date our Articles of Association were adopted. We expect that we will seek renewal of this authority at an annual general meeting before the end of that five-year period. The board of directors may issue ordinary shares upon exercise of warrants or options or other commitments without shareholder approval or authorization (up to the relevant authorized but unissued share capital). Statutory pre-emption rights will apply to the issuance of warrants and options issued by us unless an opt-out applies or shareholder approval for an opt-out is obtained in the same manner described directly above for our ordinary shares. We are subject to the Nasdaq Stock Market listing rules requiring shareholder approval of certain ordinary share issuances. The Irish Takeover Rules may be applicable in certain circumstances and can impact our ability to issue ordinary shares.

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Under Irish law, we are prohibited from allotting shares without consideration. Accordingly, at least the nominal value of the shares issued underlying any restricted share award, restricted share unit, performance share award, bonus share or any other share-based grant must be paid pursuant to the Irish Companies Act.

## **Share Repurchases and Redemptions**

### ***Overview***

Our Articles of Association provide that any share that we have agreed to acquire shall be deemed to be a redeemable share. Accordingly, for Irish law purposes, the repurchase of shares by us may technically be effected as a redemption of those shares as described below under “Repurchases and Redemptions.” If our Articles of Association did not contain such provisions, repurchases by us would be subject to many of the same rules that apply to purchases of our shares by subsidiaries described below under “Purchases by Subsidiaries,” including the shareholder approval requirements described below. Except where otherwise noted, when we refer elsewhere to repurchasing or buying back our shares, we are referring to the redemption of shares by us pursuant to the Articles of Association or the purchase of our shares by one of our subsidiaries, in each case in accordance with our Articles of Association and Irish law as described below.

### ***Repurchases and Redemptions***

Under Irish law, a company can issue redeemable shares and redeem them out of distributable reserves (which are described below under “Dividends”) or (if the company proposes to cancel the shares on redemption) the proceeds of a new issue of shares for that purpose. The redemption of redeemable shares may only be made by a public limited company where the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of the total issued share capital of the company. All redeemable shares must also be fully paid and the terms of redemption of the shares must provide for payment on redemption. Redeemable shares may, upon redemption, be cancelled or held in treasury. Shareholder approval is not required to redeem our shares.

We may also be given authority by our shareholders to purchase our shares either on or off market, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below. At an Annual General Meeting of Shareholders held on June 17, 2021, the Company’s independent shareholders (being shareholders other than Avista Capital Partners, Altchem Limited and each of their concert parties for the purposes of the Irish Takeover Rules) approved a waiver of mandatory offer obligations under Rule 37 of the Irish Takeover Rules to enable share buybacks or redemptions.

Our board of directors is also entitled to issue preferred shares that may be redeemed either at our option or the option of the shareholder, depending on the terms of such shares. See “-Share Capital.” Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. While we hold shares as treasury shares, we cannot exercise any voting rights in respect of those shares. Treasury shares may be cancelled by us or re-issued subject to certain conditions.

### ***Purchases by Subsidiaries***

Under Irish law, it may be permissible for an Irish or non-Irish subsidiary to purchase shares of a company. A general authority of the shareholders of a company is required to allow a subsidiary to make on-market purchases of the company’s shares; however, as long as this general authority has been granted, no specific shareholder authority is required for a particular on-market purchase of the company’s shares by a subsidiary. A company may elect to seek such general authority, which must expire no later than 18 months after the date on which it was granted, at the first annual general meeting of a company and at subsequent annual general meetings. For an off-market purchase by a subsidiary of a company, the proposed purchase contract must be authorized by special resolution of the shareholders of the company before the contract is entered into. The person whose shares are to be bought back cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution, the purchase contract must be on display or must be available for inspection by shareholders at the registered office of the company.

The number of shares held by the subsidiaries of a company at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of the issued share

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capital of the company. While a subsidiary holds shares of a company, it cannot exercise any voting rights in respect of those shares. The acquisition of the shares of a company by a subsidiary must be funded out of distributable reserves of the subsidiary.

### **Dividends**

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves, broadly, means the accumulated realized profits of a company, less accumulated realized losses of the company on a standalone basis. In addition, no dividend or distribution may be made unless the net assets of a company are not less than the aggregate of the company's called up share capital plus undistributable reserves and the distribution does not reduce the company's net assets below such aggregate. Undistributable reserves include a company's undenominated capital (effectively its share premium and capital redemption reserve) and the amount by which the company's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed the company's accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital. The determination as to whether or not a company has sufficient distributable reserves to fund a dividend must be made by reference to "relevant accounts" of the company. The "relevant accounts" are either the last set of unconsolidated annual audited financial statements or unaudited financial statements prepared in accordance with the Irish Companies Act, which give a "true and fair view" of a company's unconsolidated financial position in accordance with accepted accounting practice in Ireland. These "relevant accounts" must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Consistent with Irish law, our Articles of Association authorize our board of directors to declare interim dividends without shareholder approval out of funds lawfully available for the purpose, to the extent they appear justified by profits and subject always to the requirement to have distributable reserves at least equal to the amount of the proposed dividend. Our board of directors may also recommend a dividend to be approved and declared by our shareholders at a general meeting. Our board of directors may direct that the payment be made by distribution of assets, shares or cash and no dividend declared or paid may exceed the amount recommended by the directors. We may pay dividends in any currency but, if we elect to pay dividends, we intend to pay such dividends in U.S. dollars. Our board of directors may deduct from any dividend or other moneys payable to any shareholder all sums of money, if any, due from the shareholder to us in respect of our ordinary shares.

Our board of directors is also authorized to issue shares in the future with preferred rights to participate in dividends declared by us. The holders of such preference shares may, depending on their terms, rank senior to the holders of our ordinary shares with respect to dividends. The 25,000 Euro deferred shares do not have any right to receive a dividend.

### **Bonus Shares**

Under our Articles of Association, upon the recommendation of our board of directors, the shareholders by ordinary resolution may authorize the board to capitalize any amount credited to our undenominated capital, any of our profits available for distribution or any amount representing unrealized revaluation reserves, and use such amount for the issuance to shareholders of shares as fully paid bonus shares.

### **Lien on Shares, Calls on Shares and Forfeiture of Shares**

Our Articles of Association provide that we have a first and paramount lien on every share for all debts and liabilities owed by any of our shareholders to us, whether presently due or not, payable in respect of such share. Subject to the terms of their allotment, directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made within 14 days after notice demanding payment, we may sell the shares. These provisions are standard inclusions in the articles of association of an Irish company limited by shares such as ours and are only applicable to our shares that have not been fully paid up.

### **Consolidation and Division; Subdivision**

Under our Articles of Association, we may, by ordinary resolution, divide any or all of our share capital into shares of smaller nominal value than its existing shares (often referred to as a share split) or consolidate any or all of our share capital into shares of larger nominal value than its existing shares (often referred to as a reverse share split).

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## **Reduction of Share Capital**

We may, by ordinary resolution, reduce our authorized but unissued share capital. We also may, by special resolution and subject to confirmation by the Irish High Court, reduce our issued share capital and any undenominated share capital.

## **General Meetings of Shareholders**

We are required under Irish law to hold an annual general meeting within 18 months of incorporation and thereafter at intervals of no more than 15 months, provided that an annual general meeting is held in each calendar year and no more than nine months after our fiscal year-end. Any annual general meeting may be held outside Ireland, provided that technological means are provided to enable shareholders to participate in the meeting without leaving Ireland. Our Articles of Association include a provision requiring annual general meetings to be held within such time periods as required by Irish law.

The only matters that must, as a matter of Irish law, be transacted at an annual general meeting are the presentation of the annual profit and loss account, balance sheet and reports of the directors and auditors, the appointment of auditors and the fixing of the auditor's fees (or delegation of same). At any annual general meeting, only such business may be conducted as has been brought before the meeting (i) in the notice of the meeting, (ii) by or at the direction of the board of directors, (iii) in certain circumstances, at the direction of the Irish High Court, (iv) as required by law or (v) such business that the chairman of the meeting determines is properly within the scope of the meeting. In addition, subject to compliance with our Articles of Association, shareholders entitled to vote at an annual general meeting may make nominations of candidates for election to the board of directors and propose business to be considered thereat.

Our extraordinary general meetings may be convened (i) by our board of directors, (ii) on requisition of the shareholders holding the number of our shares prescribed by the Irish Companies Act (currently 10% of our paid-up share capital carrying voting rights), or (iii) in certain circumstances, on requisition of our auditors.

Extraordinary general meetings are generally held for the purposes of approving such of our shareholder resolutions as may be required from time to time. The business to be conducted at any extraordinary general meeting must be set forth in the notice of the meeting.

In the case of an extraordinary general meeting requisitioned by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice of the meeting. The requisition notice can propose any business to be considered at the meeting. Under Irish law, upon receipt of this requisition notice, the board of directors has 21 days to convene the extraordinary general meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of receipt of the requisition notice. If the board does not proceed to convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one-half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice by the board.

If the board of directors becomes aware that our net assets are half or less of the amount of our called up share capital, the board must, not later than 28 days from the date that it learns of this fact, convene an extraordinary general meeting of our shareholders to be held not later than 56 days from such date.

This meeting must be convened for the purposes of considering what measures, if any, should be taken to address the situation.

At least 21 days' notice of any annual general meeting or general meeting at which a special resolution is proposed and 14 days in all other circumstances must be given to shareholders, each director and our auditors, under our Articles of Association.

## **Quorum for Shareholder Meetings**

Our Articles of Association provide that no business shall be transacted at any general meeting unless a quorum is present. Under our Articles of Association, the presence, in person or by proxy, of one or more shareholders holding at

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least 50% of the voting power of our issued shares that carry the right to vote at the meeting constitutes a quorum for the conduct of any business at a general meeting.

The provisions of our Articles of Association relating to general meetings apply to general meetings of the holders of any class of shares except that the necessary quorum is determined by reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of shares, a quorum consists of one or more shareholders present in person or by proxy holding not less than a majority of the issued and outstanding shares of the class entitled to vote at the meeting in question.

## **Voting**

### ***Generally***

Holders of our ordinary shares are entitled to one vote per ordinary share held as of the record date for the meeting.

Our Articles of Association provide that all votes at a general meeting will be decided by way of a poll. Voting rights on a poll may be exercised by shareholders registered in our share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. All proxies must be appointed in accordance with our Articles of Association. Our Articles of Association provide that our board of directors may permit the appointment of proxies by the shareholders to be notified to us electronically.

In accordance with our Articles of Association, our board of directors may, from time to time, cause us to issue preferred shares. These shares may have such voting rights, if any, as may be specified in the terms of such shares (e.g., they may carry more votes per share or may entitle their holders to a class vote on such matters as may be specified in the terms of the shares).

Treasury shares (i.e., shares held by us) and our shares held by our subsidiaries will not entitle their holders to vote at general meetings of shareholders.

Except where a greater majority is required by Irish law or our Articles of Association, any question proposed for consideration at any of our general meetings or of any class of shareholders will be decided by an ordinary resolution passed by a simple majority of the votes cast by shareholders entitled to vote at such meeting.

Irish law requires special resolutions of the shareholders at a general meeting to approve certain matters. A special resolution requires not less than 75% of the votes cast by shareholders at a meeting of shareholders.

Examples of matters requiring special resolutions include:

- amending our objects as contained in our Memorandum of Association;
  - amending our Articles of Association (please see below in relation to an additional approval threshold for amending certain provisions of our Articles of Association);
  - approving a change of name;
  - authorizing the entry into a guarantee or the granting of security in connection with a loan, quasi loan or credit transaction in favor of a director or connected person of a director (which generally includes a family member or business partner of the director and any entity controlled by the director);
  - opting out of pre-emption rights on the issuance of new shares;
  - re-registering from a public limited company to a private company;
  - purchasing of our own shares off-market;
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- reducing issued share capital;
- resolving that we be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up;
- re-designating shares into different share classes;
- setting the re-issue price of treasury shares; and
- merging with other Irish companies or with companies incorporated in the European Economic Area (the "EEA"), as described below under "-Acquisitions."

Our Constitution requires the prior approval of holders of at least 75% in nominal value of our issued and outstanding ordinary shares which carry an entitlement to vote at a general meeting for amendments to any of the following: paragraph six of our Memorandum of Association and Articles 17, 67.1, 76, 90, 92, 112, 156-159 (inclusive), 194 and 196-198 (inclusive) of our Articles of Association.

#### ***Action by Written Consent***

Any resolution or action required or permitted to be passed or taken by our shareholders may be effected only at a duly convened annual or extraordinary general meeting of our shareholders and may not be effected by any resolution or consent in writing by such shareholders.

#### ***Variation of Rights Attaching to a Class or Series of Shares***

Under our Articles of Association and the Irish Companies Act, any variation of class rights attaching to our issued shares must be approved by an ordinary resolution passed at a general meeting of the shareholders of the affected class or series or with the consent in writing of the holders of a majority of the issued shares of that class of shares entitled to vote on such variation. The rights conferred upon the holder of any of our pre-existing issued shares shall not be deemed to be varied by the issuance of any preferred shares.

#### ***Record Dates***

Our Articles of Association provide that our board of directors may set a record date for the purposes of determining which shareholders are entitled to notice of, or to vote at, a general meeting and the record date shall not be more than sixty (60) days prior to the date of the meeting. If no record date is fixed by the board of directors, the date immediately preceding the date on which notice of the meeting is deemed given under our Articles of Association will be the record date for such determination of members.

#### ***Shareholder Proposals***

Under Irish law, there is no general right for a shareholder to put items on the agenda of an annual general meeting, other than as set out in the Articles of Association of a company. Under our Articles of Association, in addition to any other applicable requirements, for business or nominations to be properly brought by a shareholder before an annual general meeting or an extraordinary general meeting requisitioned by shareholders, such shareholder must have given timely notice thereof in proper written form to our corporate secretary.

To be timely for an annual general meeting, a shareholder's notice to our secretary as to the business or nominations to be brought before the meeting must be delivered to or mailed and received at our registered office not less than 90 days nor more than 120 days before the first anniversary of the notice convening our annual general meeting for the prior year. In the event that the date of the annual general meeting is changed by more than 30 days from the date contemplated at the time of the previous year's proxy statement, notice by the member must be so delivered by close of business on the day that is not earlier than 120 days prior to such annual general meeting and not later than the later of (a) 90 days prior to the day of the contemplated annual general meeting or (b) ten days after the day on which public announcement of the date of the contemplated annual general meeting is first made by us. In no event shall the public

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announcement of an adjournment or postponement of an annual general meeting commence a new time period (or extend any time period) for the giving of a shareholder's notice.

To be timely for business or nominations of a director at an extraordinary general meeting, notice must be delivered, or mailed and received not less than 90 days nor more than 120 days prior to the date of such extraordinary general meeting. If the first public announcement of the date of the extraordinary general meeting is less than 100 days prior to the date of the meeting, notice must be given by close of business ten days after the day on which the public announcement of the date of the extraordinary general meeting is first made by us.

For nominations to the board, the notice must include all information about the director nominee that is required to be disclosed by Securities and Exchange Commission ("SEC") rules regarding the solicitation of proxies for the election of directors pursuant to Regulation 14A under the Exchange Act. For other business that a shareholder proposes to bring before the meeting, the notice must include a brief description of the business, the reasons for proposing the business at the meeting and a discussion of any material interest of the shareholder in the business. Whether the notice relates to a nomination to the board of directors or to other business to be proposed at the meeting, the notice also must include information about the shareholder and the shareholder's holdings of our shares. The chairman of the meeting shall have the power and duty to determine whether any business proposed to be brought before the meeting was made or proposed in accordance with these procedures (as set out in our Articles of Association), and if any proposed business is not in compliance with these provisions, to declare that such defective proposal shall be disregarded.

### **Shareholders' Suits**

In Ireland, the decision to institute proceedings on behalf of a company is generally taken by the company's board of directors. In certain limited circumstances, a shareholder may be entitled to bring a derivative action on our behalf. The central question at issue in deciding whether a shareholder may be permitted to bring a derivative action is whether, unless the action is brought, a wrong committed against us would otherwise go un-redressed. The cause of action may be against a director, another person or both.

A shareholder may also bring proceedings against us in his or her own name where the shareholder's rights as such have been infringed or where our affairs are being conducted, or the powers of the board of directors are being exercised, in a manner oppressive to any shareholder or shareholders or in disregard of their interests as shareholders. Oppression connotes conduct that is burdensome, harsh or wrong. This is an Irish statutory remedy under Section 212 of the Irish Companies Act and the court can grant any order it sees fit, including providing for the purchase or transfer of the shares of any shareholder.

Our Articles of Association provide that all actions, other than those related to U.S. securities law, but including, without limitation, (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to us or any of our shareholders, (iii) any action asserting a claim against us arising pursuant to any provision of Irish law or our Articles of Association, and (iv) any action to interpret, apply, enforce or determine the validity of our Articles of Association, shall be brought in the courts of Ireland, which have sole and exclusive jurisdiction to determine such matters.

### **Inspection of Books and Records**

Under Irish law, our shareholders shall have certain rights to inspect our books and records, including the right to: (i) receive a copy of our Constitution and any act of the Irish Government that alters our Constitution; (ii) inspect and obtain copies of the minutes of general meetings of shareholders (including resolutions adopted at such meetings); (iii) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained by us; (iv) receive copies of the most recent balance sheets and directors' and auditors' reports which have previously been sent to shareholders prior to an annual general meeting; and (v) receive balance sheets of any of our subsidiary companies that have previously been sent to shareholders prior to an annual general meeting for the preceding ten years. Our auditors also have the right to inspect all of our books and records. The auditors' report must be circulated to the shareholders with our Financial Statements (as defined below) at least 21 days before the annual general meeting, and such report must (if requested) be read to the shareholders at our annual general meeting. The Financial Statements referenced above mean our balance sheet, profit and loss account and, so far as they are not incorporated in the balance sheet or profit and loss account, any group accounts and the directors'

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and auditors' reports, together with any other document required by law to be annexed to the balance sheet. Our auditors also have the right to inspect all of our books, records and vouchers.

## **Acquisitions**

There are a number of mechanisms for acquiring an Irish public limited company, including:

- a court-approved scheme of arrangement under the Irish Companies Act. A scheme of arrangement with one or more classes of shareholders requires a court order from the Irish High Court and the approval of: (i) more than 50% in number of the shareholders of each participating class or series voting on the scheme of arrangement, or (ii) representing 75% or more by value of the shares of such participating class or series held by the shareholders voting on the scheme of arrangement, in each case at the relevant meeting or meetings. A scheme of arrangement, if authorized by the shareholders of each participating class or series and the court, is binding on all of the shareholders of each participating class or series. Shares held by the acquiring party are not excluded from the tally of a vote on the scheme, but such shares may be considered to belong to a separate class for the purposes of approving the scheme, in which case the acquiring party's shares would not be voted for the purposes of the separate class approval required from the remaining, non-acquiring shareholders;
- through a tender offer by a third party pursuant to the Irish Takeover Rules. Where the holders of 80% or more in value of a class of our shares (excluding any shares already beneficially owned by the offeror) have accepted an offer for their shares, the remaining shareholders in that class may be statutorily required to also transfer their shares, unless, within one month, the non-tendering shareholders can obtain an Irish court order otherwise providing. If the offeror has acquired acceptances of 80% of all of our shares but does not exercise this "squeeze out" right, the non-accepting shareholders also have a statutory right to require the offeror to acquire their shares on the same terms as the original offer, or such other terms as the offeror and the non-tendering shareholders may agree or on such terms as an Irish court, on application of the offeror or non-tendering shareholder, may order. If our shares were listed on the Euronext Dublin or another regulated stock exchange in the EU, this 80% threshold would be increased to 90%; and
- by way of a merger with a company incorporated in the EEA under the EU Cross-Border Mergers Directive (EU) 2019/2121 and the Irish European Communities (Cross-Border Mergers) Regulations 2008, (as amended), or with another Irish company under the Irish Companies Act. Such a merger must be approved by a special resolution and the Irish High Court. Shareholders also may be entitled to have their shares acquired for cash. See "-Appraisal Rights."

The approval of the board of directors, but not shareholder approval, is required for a sale, lease or exchange of all or substantially all of our assets, except that such a transaction between us and one of our directors or a person or entity connected to such a director may require shareholder approval.

## **Appraisal Rights**

Generally, under Irish law, shareholders of an Irish company do not have statutory appraisal rights. If we are being merged as the transferor company with another EEA company under the EU Cross-Border Mergers Directive (EU) 2019/2121 and the Irish European Communities (Cross-Border Mergers) Regulations 2008 (as amended) or if we are being merged with another Irish company under the Irish Companies Act, (i) any of our shareholders who voted against the special resolution approving the merger or (ii) if 90% of our shares are held by the successor company, any other of our shareholders, may be entitled to require that the successor company acquire its shares for cash. In addition, a dissenting shareholder in a successful tender offer for an Irish company may, by application to the Irish High Court, object to the compulsory squeeze out provisions.

## **Disclosure of Interests in Shares**

Under the Irish Companies Act, our shareholders must notify us if, as a result of a transaction, (i) the shareholder will be interested in 3% or more of our ordinary shares that carry voting rights or (ii) the shareholder who was interested in 3% or more of the shares will cease to be interested in our ordinary shares that carry voting rights. In addition, where a shareholder is interested in 3% or more of our ordinary shares, the shareholder must notify us of any alteration of its interest that brings its total holding through the nearest whole percentage number, whether an increase or

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a reduction. All such disclosures must be notified to us within two days of the event that gave rise to the requirement to notify. Where a person fails to comply with the notification requirements described above, no right or interest of any kind whatsoever in respect of any of our ordinary shares held by such person will be enforceable by such person, whether directly or indirectly, by action or legal proceeding. However, such person may apply to the Irish High Court to have the rights attaching to its ordinary shares reinstated. In addition to the disclosure requirement described above, under the Irish Companies Act, we may, by notice in writing, and must, on the requisition of shareholders holding 10% or more of our paid-up capital carrying voting rights, require a person whom we know or have reasonable cause to believe is, or at any time during the three years immediately preceding the date on which such notice is issued was, interested in shares comprised in our relevant share capital to: (i) indicate whether or not it is the case and (ii) where such person holds or has during that time held an interest in our ordinary shares, to give certain further information as may be required by us including particulars of such person or beneficial owner's past or present interests in our ordinary shares.

Any information given in response to the notice is required to be given in writing within such reasonable time as may be specified in the notice.

Where such a notice is served by us on a person who is or was interested in our ordinary shares and that person fails to give us any information required within the reasonable time specified, we may apply to a court for an order directing that the affected ordinary shares be subject to certain restrictions. Under the Irish Companies Act, the restrictions that may be placed on the ordinary shares by the court are as follows:

- any transfer of those ordinary shares or, in the case of unissued shares, any transfer of the right to be issued with ordinary shares and any issue of such ordinary shares, shall be void;
- no voting rights shall be exercisable in respect of those ordinary shares;
- no further shares shall be issued in respect of those ordinary shares or in pursuance of any offer made to the holder of those ordinary shares; and
- no payment shall be made of any sums due from us on those ordinary shares, whether in respect of capital or otherwise.

Where our ordinary shares are subject to these restrictions, the court may order the ordinary shares to be sold and may also direct that the ordinary shares shall cease to be subject to these restrictions.

In addition, persons or groups (within the meaning of the Exchange Act) beneficially owning 5% or more of our ordinary shares must comply with the reporting requirements under Section 13 of the Exchange Act.

#### **Anti-Takeover Provisions**

##### ***Shareholder Rights Plans and Share Issuances***

Irish law does not expressly prohibit companies from issuing share purchase rights or adopting a shareholder rights plan as an anti-takeover measure. However, there is no directly relevant case law on the validity of such plans under Irish law.

Our Articles of Association allow our board of directors to adopt any shareholder rights plan upon such terms and conditions as the board deems expedient and in our best interest, subject to applicable law, including the Irish Takeover Rules and Substantial Acquisition Rules described below and the requirement for shareholder authorization for the issue of shares described above.

Subject to the Irish Takeover Rules described below and the Irish Companies Act, the board of directors also has the power to issue any of our authorized and unissued shares on such terms and conditions as it may determine to be in our best interest. It is possible that the terms and conditions of any issue of shares could discourage a takeover or other transaction that holders of some or a majority of our ordinary shares might believe to be in their best interest or in which holders of our ordinary shares might receive a premium for their shares over the then-market price of the shares.

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## ***Irish Takeover Rules and Substantial Acquisition Rules***

A tender offer by which a third party makes an offer generally to our shareholders or a class of shareholders to acquire shares of any class conferring voting rights will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder and will be regulated by the Irish Takeover Panel (as well as being governed by the Exchange Act and the regulations promulgated thereunder). The “General Principles” of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below. Takeovers by means of a scheme of arrangement are also generally subject to these regulations.

*General Principles.* The Irish Takeover Rules are based on the following General Principles that will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all classes of shareholders of the target company should be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to allow them to make an informed decision regarding the offer. If the board of directors of the target company advises the holders of the securities with respect to the offer, it must advise on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company’s places of business;
- the board of a target company must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- an offeror can only announce an offer after ensuring that it can fulfill in full any cash consideration offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs for longer than is reasonable by an offer for its securities. This is a recognition that an offer will disrupt the day-to-day running of a target company, particularly if the offer is hostile and the board of the target company must divert its attention to resist the offer; and
- a “substantial acquisition” of securities (whether such acquisition is to be effected by one transaction or a series of transactions) will only be allowed to take place at an acceptable speed and shall be subject to adequate and timely disclosure.

*Mandatory Offer.* If an acquisition of shares were to increase the aggregate holding of an acquirer and its concert parties (which generally mean persons acting in concert with the acquirer) to shares carrying 30% or more of the voting rights in our shares, the acquirer and, depending on the circumstances, its concert parties would be mandatorily required (except with the consent of the Irish Takeover Panel) to make a cash tender offer for the remaining outstanding shares at a price not less than the highest price paid for the shares by the acquirer or its concert parties during the previous twelve months.

This requirement would also be triggered by an acquisition of shares by a person holding (together with its concert parties) shares carrying between 30% and 50% of the voting rights in us if the effect of such acquisition were to increase the percentage of the voting rights held by that person (together with its concert parties) by 0.05% within a twelve month period.

*Voluntary Offer; Requirements to Make a Cash Offer and Minimum Price Requirements.* A voluntary offer is a tender offer that is not a mandatory offer. If an offeror or any of its concert parties acquires any of our shares of the same class as the shares that are the subject of the voluntary offer within the period of three months prior to the commencement of the offer period, the offer price must be not less than the highest price paid for our shares of that class

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by the offeror or its concert parties during that period. The Irish Takeover Panel has the power to extend the “look back” period to twelve months if the Panel, having regard to the General Principles, believes it is appropriate to do so.

If the offeror or any of its concert parties has acquired our shares of the same class as the shares that are the subject of the voluntary offer (i) during the period of twelve months prior to the commencement of the offer period which represent 10% or more of the nominal value of the issued shares of that class or (ii) at any time after the commencement of the offer period, the offer shall be in cash (or accompanied by a full cash alternative) and the price per share shall be not less than the highest price paid by the offeror or its concert parties for shares (of that class) during, in the case of (i), the period of twelve months prior to the commencement of the offer period and, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to an offeror who, together with its concert parties, has acquired less than 10% of the nominal value of the issued shares of the class of shares that is the subject of the offer in the twelve-month period prior to the commencement of the offer period if the Panel, having regard to the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of an offer or proposed offer.

*Substantial Acquisition Rules.* The Irish Takeover Rules also contain rules governing substantial acquisitions of shares which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights in our shares. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights in our shares is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights in our shares and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of certain other acquisitions of shares or rights over shares relating to such holdings.

*Frustrating Action.* Under the Irish Takeover Rules, the board of directors is not permitted to take any action that might frustrate an offer for our shares during the course of an offer or at any earlier time at which the board has reason to believe an offer is or may be imminent, except as noted below. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material 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 the frustration of an offer, are prohibited during the course of an offer or at any time during which the board has reason to believe that an offer is or may be imminent. Exceptions to this prohibition are available where:

- the action is approved by our shareholders at a general meeting; or
- with the consent of the Irish Takeover Panel, where:
- the Irish Takeover Panel is satisfied that the action would not constitute a frustrating action;
- the holders of at least 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
- the action is in accordance with a contract entered into prior to the announcement of the offer (or prior to a time at which the board has reason to believe that an offer is or may be imminent); or
- the decision to take such action was made before the announcement of the offer (or prior to a time at which the board has reason to believe that an offer is or may be imminent) and has been either at least partially implemented or is in the ordinary course of business.

*Insider Dealing.* The Irish Takeover Rules also provide that no person, other than the offeror who is privy to confidential price-sensitive information concerning an offer made in respect of the acquisition of a company (or a class of its securities) or a contemplated offer, shall deal in relevant securities of the offeree during the period from the time at which such person first has reason to suppose that such an offer, or an approach with a view to such an offer being made, is contemplated to the time of (i) the announcement of such offer or approach or (ii) the termination of discussions relating to such offer, whichever is earlier.

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For other provisions that could be considered to have an anti-takeover effect, see “-Transfer and Registration of Shares,” “-Issuance of Shares-Pre-emption Rights, Share Warrants and Share Options,” “-Voting-Generally,” “-Voting-Variation of Rights Attaching to a Class or Series of Shares,” “-Disclosure of Interests in Shares” and “-Corporate Governance.”

### ***Business Combinations with Interested Shareholders***

Our Articles of Association provide that, subject to certain exceptions, we may not engage in certain business combinations with any person, other than investment funds affiliated with Avista Capital Partners and affiliates of Altchem Limited and their respective affiliates, that acquires beneficial ownership of 15% or more of our outstanding voting shares for a period of three years following the date on which such person became a 15% shareholder unless: (i) a committee of our disinterested directors approves the business combination; and (ii) in certain circumstances, the business combination is authorized by a special resolution of disinterested shareholders.

### **Corporate Governance**

#### ***Generally***

Our Articles of Association allocate authority over management of our Company to our board of directors. Our board of directors may then delegate management to committees of the board or such other persons as it thinks fit. Regardless of any delegation, the board of directors will remain responsible, as a matter of Irish law, for the proper management of our affairs. The board of directors may create new committees or change the responsibilities of existing committees from time to time.

#### ***Directors: Term and Appointment***

Directors are elected or appointed at the annual general meeting or at any extraordinary general meeting called for that purpose until the next annual general meeting of the company. Each director is elected by the affirmative vote of a majority of the votes cast with respect to such director. In the event of a “contested election” of directors, directors shall be elected by the vote of a plurality of the votes cast at any meeting for the election of directors at which a quorum is present.

No person may be appointed director unless nominated in accordance with our Articles of Association. Our Articles of Association provide that, with respect to an annual or extraordinary general meeting of shareholders, nominations of persons for election to our board of directors may be made by (i) the affirmative vote of our board of directors or a committee thereof, (ii) any shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for our Articles of Association, or (iii) with respect to election at an extraordinary general meeting requisitioned in accordance with section 178 of the Irish Companies Act, by a shareholder who holds ordinary shares or other shares carrying the general right to vote at general meetings of the company and who makes such nomination in the written requisition of the extraordinary general meeting in accordance with our Articles of Association and the Irish Companies Act relating to nominations of directors and the proper bringing of special business before an extraordinary general meeting.

Under our Articles of Association, our board of directors has the authority to appoint directors to the board, either to fill a vacancy or as an additional director. A vacancy on the board of directors created by the removal of a director may be filled by an ordinary resolution of the shareholders at the meeting at which such director is removed and, in the absence of such election or appointment, the remaining directors may fill the vacancy. The board of directors may fill a vacancy by an affirmative vote of a majority of the directors constituting a quorum. If there is an insufficient number of directors to constitute a quorum, the board may nonetheless act to fill such vacancies or call a general meeting of the shareholders. Under our Articles of Association, if the board fills a vacancy, the director’s term expires at the next annual general meeting. If there is an appointment to fill a casual vacancy or an addition to the board, the total number of directors shall not at any time exceed the number of directors from time to time fixed by the board in accordance with the Articles of Association.

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## ***Removal of Directors***

The Irish Companies Act provides that, notwithstanding anything contained in the Articles of Association of a company or in any agreement between that company and a director, the shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term, provided that notice of the intention to move any such resolution be given by the requisitioning shareholders to the company not less than 28 days before the meeting at which the director is to be removed, and the director will be entitled to be heard at such meeting. The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment agreement) that the director may have against us in respect of his or her removal.

## ***Directors' Duties***

Our directors have certain statutory and fiduciary duties. All of our directors have equal and overall responsibility for our management (although directors who also serve as employees will have additional responsibilities and duties arising under their employment agreements and will be expected to exercise a greater degree of skill and diligence than non-executive directors). The principal fiduciary duties include the statutory and common law fiduciary duties of acting in good faith in the interests of our company and exercising due care and skill. Other statutory duties include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed, maintaining certain registers and making certain filings as well as the disclosure of personal interests. Particular duties also apply to directors of insolvent companies (for example, the directors could be liable to sanctions where they are deemed by the court to have carried on our business while insolvent, without due regard to the interests of creditors). For public limited companies like us, directors are under a specific duty to ensure that the corporate secretary is a person with the requisite knowledge and experience to discharge the role.

## ***Conflicts of Interest***

As a matter of Irish law, a director is under a fiduciary duty to avoid conflicts of interest. Irish law and our Articles of Association provide that: (i) a director may be a director of or otherwise interested in a company relating to us and will not be accountable to us for any remuneration or other benefits received as a result, unless we otherwise direct; (ii) a director or a director's firm may act for us in a professional capacity other than as auditor; and (iii) a director may hold an office or place of profit in us and will not be disqualified from contracting with us. If a director has a personal interest in an actual or proposed contract with us, the director must declare the nature of his or her interest and we are required to maintain a register of such declared interests that must be available for inspection by the shareholders. Such a director may vote on any resolution of the board of directors in respect of such a contract, and such a contract will not be voidable solely as a result.

## ***Indemnification of Directors and Officers; Insurance***

To the fullest extent permitted by Irish law, our Articles of Association confer an indemnity on our directors and officers. However, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or corporate secretary where judgment is given in favor of the director or corporate secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or corporate secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or corporate secretary over and above the limitations imposed by the Irish Companies Act will be void under Irish law, whether contained in its Articles of Association or any contract between the company and the director or corporate secretary. This restriction does not apply to our executives who are not directors, the corporate secretary or other persons who would be considered "officers" within the meaning of that term under the Irish Companies Act.

Our Articles of Association also contain indemnification and expense advancement provisions for persons who are not directors or our corporate secretary.

We are permitted under our Articles of Association and the Irish Companies Act to take out directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents.

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Additionally, we and certain of our subsidiaries have entered into agreements to indemnify our directors to the maximum extent allowed under applicable law. These agreements, among other things, provide that we indemnify our directors for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on our behalf or that person's status as our director.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling the registrant pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### **Duration; Dissolution; Rights upon Liquidation**

Our duration is unlimited. We may be dissolved at any time by way of either a shareholder's voluntary winding up or a creditors' winding up. In the case of a shareholder's voluntary winding up, we must be solvent and a special resolution of the shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Director of Corporate Enforcement in Ireland where our affairs have been investigated by an inspector and it appears from the report or any information obtained by the Director of Corporate Enforcement that we should be wound up.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in our Articles of Association or the terms of any shares issued by the board of directors from time to time. If the Articles of Association and terms of issue of our shares contain no specific provisions in respect of a dissolution or winding up then, subject to the shareholder priorities and the rights of any creditors, the assets will be distributed to shareholders in proportion to the paid-up nominal value of the shares held. Our Articles of Association provide that our ordinary shareholders may be entitled to participate in a winding up, and the method by which the property will be divided shall be determined by the liquidator, subject to a special resolution of the shareholders, but such rights of ordinary shareholders to participate may be subject to the rights of any preference shareholders to participate under the terms of any series or class of preference shares.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares is Computershare Trust Company, N.A.

#### **Exchange Controls**

There is no limitation imposed by Irish law or by our Articles of Association on the right of a non-resident to hold or vote our ordinary shares.

#### **Listing**

Our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "RVLP."

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Name:	[•]
Number of Shares subject to the Stock Option:	[•]
Exercise Price Per Share:	[\$•]
Date of Grant:	[•]
Vesting Commencement Date	[•]

**RVL PHARMACEUTICALS PLC  
2018 INCENTIVE PLAN**

**NON-STATUTORY STOCK OPTION AGREEMENT**

This agreement (this “**Agreement**”) evidences a stock option granted by the Company to the individual named above (the “**Optionee**”), pursuant to and subject to the terms of the RVL Pharmaceuticals plc 2018 Incentive Plan (as from time to time amended and in effect, the “**Plan**”).

1. Meaning of Certain Terms. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:

(a) “**Beneficiary**”: In the event of the Optionee’s death, the beneficiary named in the written designation (in a form acceptable to the Administrator) most recently filed with the Administrator by the Optionee prior to the Optionee’s death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Optionee’s estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Optionee’s death, of an instrument of revocation in a form acceptable to the Administrator.

(b) “**Change in Control**” means the first to occur of any of the following events following the Date of Grant:

(i) an event in which any “person” or “group” within the meaning of Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the “**1934 Act**”) (other than (A) the Company, (B) any subsidiary of the Company, (C) any trustee or other fiduciary holding securities under an employee benefit plan of the Company or of any subsidiary of the Company, (D) any company owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company and (E) any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P. or Altchem Limited or their respective affiliates), is or becomes the “beneficial owner” (as defined in Section 13(d) of the 1934 Act), directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities;

(ii) the consummation of the merger or consolidation of the Company with any other company, other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity), in combination with the ownership of any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any subsidiary of the Company, more than 50% of the combined voting



power of the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) after which no “person” or “group” (other than any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P. or Altchem Limited or their respective affiliates) “beneficially owns” (with the determination of such “beneficial ownership” on the same basis as set forth in clause (i) of this definition) securities of the Company or the surviving entity of such merger or consolidation representing more than 50% of the combined voting power of the securities of the Company or the surviving entity of such merger or consolidation; or

(iii) the sale or disposition by the Company of all or substantially all of the Company’s assets to one or more purchasers other than any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P. or Altchem Limited or their respective affiliates.

(c) **“Option Holder”**: The Optionee or, if at the relevant time the Stock Option has passed to a Beneficiary, the Beneficiary.

2. Grant of Stock Option. The Company grants to the Optionee on the date set forth above (the **“Date of Grant”**) an option (the **“Stock Option”**) to purchase, pursuant to and subject to the terms set forth in this Agreement and in the Plan, up to the number of Shares set forth above (the **“Optioned Shares”**), with an exercise price per Optioned Share as set forth above, in each case, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that does not qualify as an incentive stock option under Section 422 of the Code) and is granted to the Optionee in connection with the Optionee’s Employment.

3. Vesting; Method of Exercise; Cessation of Employment.

(a) Vesting. The term “vest” as used herein with respect to the Stock Option means to become exercisable and the term “vested” as applied to the Stock Option means that the Stock Option is then exercisable, subject, in each case, to the terms of the Plan. Unless earlier terminated, forfeited, relinquished or expired, the Stock Option will vest as follows, subject to the Optionee remaining in continuous Employment from the Date of Grant through the vesting date.

(i) Except as provided in Section 3(a)(ii) or (iii) below, the Stock Option will vest as to

(ii) In the event of a Change in Control in which no provision is made to assume or substitute the Stock Option pursuant to Section 7(a)(1) of the Plan, the Stock Option, to the extent then outstanding and unvested, will automatically vest in full immediately prior to the consummation of the Change in Control.

(iii) If provision is made to assume or substitute the Stock Option in connection with a Change in Control pursuant to Section 7(a)(1) of the Plan

and the Company terminates the Optionee's Employment without Cause or, if the Optionee is then subject to an employment or other individual agreement with the Company or a subsidiary containing a definition of "Good Reason", the Optionee terminates his or her Employment for Good Reason (as defined in such agreement) on or within the eighteen (18)-month period following the consummation of the Change in Control, the Stock Option, to the extent then unvested, will automatically vest in full upon such cessation of Employment and will remain outstanding and exercisable as provided in the Plan.

- (b) Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the Administrator, signed (including by electronic signature) by the Option Holder (or in such other form as is acceptable to the Administrator). Each such written or electronic exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full of the exercise price as provided in the Plan. The latest date on which the Stock Option or any portion thereof may be exercised is the 10<sup>th</sup> anniversary of the Date of Grant (the "**Final Exercise Date**") and, if not exercised by such date, the Stock Option or any remaining portion thereof will thereupon immediately terminate.
- (c) Cessation of Employment. Except as provided in Section 3(a)(iii) above, automatically and immediately upon the cessation of the Optionee's Employment, the Stock Option, to the extent not already vested, will be immediately forfeited, and any vested portion of the Stock Option that is then outstanding will be treated as provided in the Plan.

4. Forfeiture; Recovery of Compensation.

- (a) The Stock Option, and the proceeds from the exercise or disposition of the Stock Option or the Optioned Shares, will be subject to forfeiture and disgorgement to the Company, with interest and related earnings, if at any time the Optionee is not in compliance with all applicable provisions of this Agreement and the Plan.
- (b) By accepting, or being deemed to have accepted, the Stock Option, the Optionee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the Stock Option, under the Stock Option, including the right to any Shares acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence may be construed as limiting the general application of Section 8 of this Agreement.

5. Nontransferability. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Withholding. The exercise of the Stock Option will give rise to “wages” subject to withholding. The Optionee expressly acknowledges and agrees that the Optionee’s rights hereunder, including the right to be issued Shares upon exercise, are subject to the Optionee promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes required to be withheld. No Shares will be issued pursuant to the exercise of the Stock Option unless and until the person exercising the Stock Option has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Optionee authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Optionee, but nothing in this sentence may be construed as relieving the Optionee of any liability for satisfying his or her obligation under the preceding provisions of this Section.

7. Effect on Employment. Neither the grant of the Stock Option, nor the issuance of Shares upon exercise of the Stock Option, will give the Optionee any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to terminate the Optionee’s Employment at any time, or affect any right of the Optionee to terminate his or her Employment at any time.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished or made available to the Optionee. By accepting, or being deemed to have accepted, the Stock Option, the Optionee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

9. Acknowledgements. The Optionee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Optionee.

*[Signature page follows.]*

The Company, by its duly authorized officer, and the Participant have executed this Agreement as of the Date of Grant.

RVL PHARMACEUTICALS PLC

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Agreed and Accepted:

By \_\_\_\_\_  
[Optionee's Name]



**RVL PHARMACEUTICALS PLC  
AMENDED AND RESTATED  
2018 EMPLOYEE SHARE PURCHASE PLAN**

**1. Defined Terms**

Exhibit A, which is incorporated by reference, defines certain terms used in the Plan and sets forth certain operational rules related to those terms.

**2. Purpose of Plan**

The Plan is intended to enable Eligible Employees to use payroll deductions to purchase Shares in offerings under the Plan, and thereby acquire an interest in the future of the Company. The Plan is intended to qualify as an “employee stock purchase plan” under Section 423 and to be exempt from the application and requirements of Section 409A of the Code, and is to be construed accordingly.

**3. Options to Purchase Shares**

Subject to adjustment pursuant to Section 16 of the Plan, the aggregate number of Shares available for purchase pursuant to the exercise of Options granted under the Plan to Eligible Employees will be 1,550,000 Shares. The Shares to be delivered upon exercise of Options under the Plan may be either authorized but unissued Shares, treasury Shares, or Shares acquired in an open-market transaction. If any Option granted under the Plan expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased Shares subject to such Option will again be available for purchase pursuant to the exercise of Options under the Plan. If, on an Exercise Date, the total number of Shares that would otherwise be subject to Options granted under the Plan exceeds the number of Shares then available under the Plan (after deduction of all Shares for which Options have been exercised or are then outstanding), the Administrator shall make a pro rata allocation of the Shares remaining available for the Option grants in as uniform a manner as shall be practicable and as it shall determine to be equitable. In such event, the Administrator shall give written notice to each Participant of such reduction of the number of Options affected thereby and shall similarly reduce the rate of payroll deductions, if necessary.

**4. Eligibility**

(a) **Eligibility Requirements.** Subject to Section 13 of the Plan, and the exceptions and limitations set forth in Sections 4(b) and (c) and 6 of the Plan, or as may be provided elsewhere in the Plan, each Employee (i) who has been continuously employed by the Company or a Designated Subsidiary, as applicable, for a period of at least thirty (30) days as of the first day of an Option Period, (ii) whose customary Employment with the Company or a Designated Subsidiary, as applicable, is for more than five (5) months per calendar year, (iii) who customarily works twenty (20) hours or more per week, and (iv) who satisfies the requirements set forth in the Plan will be an Eligible Employee.

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(b) **Five Percent Shareholders.** No Employee may be granted an Option under the Plan if, immediately after the Option is granted, the Employee would own (or pursuant to Section 424(d) of the Code would be deemed to own) shares possessing five percent (5%) or more of the total combined voting power or value of all classes of shares of the Company or of its Parent or Subsidiaries, if any.

(c) **Additional Requirements.** The Administrator may, for Option Periods that have not yet commenced, establish additional or different eligibility requirements not inconsistent with Section 423.

## 5. Option Periods

The Plan will generally be implemented by a series of separate offerings referred to as “**Option Periods**”.

Unless otherwise determined by the Administrator, the Option Periods will be successive periods of approximately six (6) months commencing on the first Business Day in January and July of each year, anticipated to be on or around January 1 and July 1, and ending approximately six (6) months later on the last Business Day in June or December, as applicable, of each year, anticipated to be on or around June 30 and December 31, as applicable, of each year. The last Business Day of each Option Period will be an “**Exercise Date**”. The Administrator may change the Exercise Date and the commencement date, ending date and duration of the Option Periods to the extent permitted by Section 423, *provided, however*, that no Option may be exercised after 27 months from its grant date.

## 6. Option Grant

Subject to the limitations set forth in Sections 4 and 10 of the Plan and the Maximum Share Limit, on the first day of an Option Period, each Participant automatically will be granted an Option to purchase Shares on the Exercise Date; *provided, however*, that no Participant will be granted an Option under the Plan that permits the Participant’s right to purchase Shares under the Plan and under all other employee stock purchase plans of the Company and its Parent and Subsidiaries, if any, to accrue at a rate that exceeds \$25,000 in Fair Market Value (or such other maximum as may be prescribed from time to time by the Code) for each calendar year during which any Option granted to such Participant is outstanding at any time, as determined in accordance with Section 423(b)(8) of the Code.

## 7. Method of Participation

(a) **Payroll Deduction and Participation Authorization.** To participate in an Option Period, an Eligible Employee must execute and deliver to the Administrator a payroll deduction and participation authorization form in accordance with the procedures prescribed by and in a form acceptable to the Administrator and, in so doing, the Eligible Employee will thereby become a Participant as of the first day of such Option Period. Such an Eligible Employee will remain a Participant with respect to subsequent Option Periods until his or her participation in the Plan is terminated as provided herein. Such payroll deduction and participation authorization must be delivered not later than ten (10) Business Days immediately prior to the first day of an Option Period, or such other time as specified by the Administrator.

**(b) Changes to Payroll Deduction Authorization for Subsequent Option Periods.** A Participant's payroll deduction authorization will remain in effect for subsequent Option Periods unless the Participant files a new authorization not later than ten (10) Business Days immediately prior to the first day of the subsequent Option Period, or such other time as specified by the Administrator, or the Participant's Option is cancelled pursuant to Section 13 or 14 of the Plan.

**(c) Changes to Payroll Deduction Authorization for Current Option Period.** During an Option Period, a Participant's payroll deduction authorization may be reduced once, but may not be increased. Any reduction to a Participant's payroll deduction authorization must be delivered to the Administrator in accordance with the procedures prescribed by, and in a form acceptable to, the Administrator and will be effective as soon as administratively practicable. If a Participant's payroll deduction authorization is reduced to zero percent (0%) during an Option Period, the Participant will be deemed to have canceled his or her Option and terminated his or her payroll deduction authorization. Upon such termination and cancellation, the balance in the Participant's Account will be returned to the Participant, without interest, as soon as administratively practicable thereafter and the Participant's participation in the Plan will thereupon terminate, unless the Participant has delivered a new payroll deduction authorization for the subsequent Option Period in accordance with the rules of Section 7(b) above. A Participant may also terminate his or her payroll deduction authorization during an Option Period by canceling his or her Option in accordance with Section 13 of the Plan.

**(d) Payroll Deduction Authorization.** Each payroll deduction authorization will request payroll deductions as a whole dollar amount from ten dollars (\$10) to two thousand dollars (\$2,000) per payroll period.

**(e) Payroll Deduction Account.** All payroll deductions made pursuant to this Section 7 will be credited to the Participant's Account. Amounts credited to a Participant's Account will not be required to be set aside in trust or otherwise segregated from the Company's general assets.

## **8. Method of Payment**

A Participant must pay for Shares purchased upon the exercise of an Option with accumulated payroll deductions credited to the Participant's Account.

## **9. Purchase Price**

The Purchase Price of Shares issued pursuant to the exercise of an Option on each Exercise Date will be eighty-five percent (85%) (or such greater percentage specified by the Administrator to the extent permitted under Section 423) of the lesser of (a) the Fair Market Value of a Share on the date on which the Option was granted pursuant to Section 6 of the Plan (*i.e.*, the first day of the Option Period) and (b) the Fair Market Value of a Share on the date on which the Option is deemed exercised pursuant to Section 10 of the Plan (*i.e.*, the Exercise Date).

## **10. Exercise of Options**

**(a) Purchase of Shares.** Subject to the limitations set forth in Section 6 of the Plan and this Section 10, with respect to each Option Period, on the applicable Exercise Date, each Participant will be deemed to have exercised his or her Option and the accumulated payroll

deductions in the Participant's Account will be applied to purchase the greatest number of Shares (rounded down to the nearest whole share) that can be purchased with such Account balance at the applicable Purchase Price; *provided, however*, that no more than 5,000 Shares may be purchased by a Participant on any Exercise Date, or such lesser number as the Administrator may prescribe in accordance with Section 423 (the "**Maximum Share Limit**"). As soon as practicable thereafter, Shares so purchased will be placed, in book-entry form, into a record keeping account in the name of the Participant. No fractional shares will be purchased pursuant to the exercise of an Option under the Plan; any accumulated payroll deductions in a Participant's Account that are not sufficient to purchase a whole share will be retained in the Participant's Account for the subsequent Option Period, subject to earlier withdrawal by the Participant as provided in Section 13 hereof.

**(b) Return of Account Balance.** Except as provided in Section 10(a) with respect to fractional shares, any amount of payroll deductions in a Participant's Account that is not used for the purchase of Shares, whether because of the Participant's withdrawal from participation in an Option Period or for any other reason, will be returned to the Participant (or his or her designated beneficiary or legal representative, as applicable), without interest, as soon as administratively practicable after such withdrawal or other event, as applicable. If the Participant's accumulated payroll deductions on the Exercise Date of an Option Period would otherwise enable the Participant to purchase Shares in excess of the Maximum Share Limit or the maximum Fair Market Value set forth in Section 6 of the Plan, the excess of the amount of the accumulated payroll deductions over the aggregate Purchase Price of the Shares actually purchased will be returned to the Participant, without interest, as soon as administratively practicable after such Exercise Date.

#### **11. Interest**

No interest will be payable on any amount held in the Account of any Participant.

#### **12. Taxes**

Payroll deductions will be made on an after-tax basis. The Administrator will have the right, as a condition to exercising an Option, to make such provision as it deems necessary to satisfy its obligations to withhold federal, state, local income or other taxes incurred by reason of the purchase or disposition of Shares under the Plan. In the Administrator's discretion and subject to applicable law, such tax obligations may be paid in whole or in part by delivery of Shares to the Company, including Shares purchased under the Plan, valued at Fair Market Value, but not in excess of the maximum withholding amount consistent with the Option being subject to equity accounting treatment under the Accounting Rules.

#### **13. Cancellation and Withdrawal**

**(a) Cancellation of Payroll Deduction Authorization.** A Participant who holds an Option under the Plan may cancel all (but not less than all) of his or her Option and terminate his or her payroll deduction authorization by notice delivered to the Administrator in accordance with the procedures prescribed by, and in a form acceptable to, the Administrator. To be effective with respect to an upcoming Exercise Date, such cancellation notice must be delivered not later than ten (10) Business Days prior to such Exercise Date (or such other time as specified by the Administrator). Upon such termination and cancellation, the balance in the Participant's Account



will be returned to the Participant, without interest, as soon as administratively practicable thereafter.

**(b) 401(k) Hardship Withdrawal.** To the extent a suspension of contribution is required by a 401(k) Plan or otherwise by applicable law, a Participant who makes a hardship withdrawal from such 401(k) Plan will be deemed to have terminated his or her payroll deduction authorization for subsequent payroll dates relating to the then current Option Period as of the date of such hardship withdrawal and amounts accumulated in the Participant's Account as of such date will be returned to the Participant, without interest, as soon as administratively practicable thereafter. An Employee who has made a hardship withdrawal from a 401(k) Plan will not be permitted to participate in Option Periods commencing after the date of his or her hardship withdrawal until the first Option Period commencing after the suspension of contributions ceases to apply to the Participant or as otherwise required by applicable law.

#### **14. Termination of Employment or Death of Participant**

Upon the termination of a Participant's employment with the Company or a Designated Subsidiary, as applicable, for any reason or the death of a Participant during an Option Period prior to an Exercise Date or in the event the Participant ceases to qualify as an Eligible Employee, the Participant will cease to be a Participant, any Option held by him or her under the Plan will be deemed canceled, the balance in the Participant's Account will be returned to the Participant (or his or her estate or designated beneficiary in the event of the Participant's death), without interest, as soon as administratively practicable thereafter, and the Participant will have no further rights under the Plan.

#### **15. Equal Rights; Participant's Rights Not Transferable**

All Participants granted Options in an offering under the Plan will have the same rights and privileges, consistent with the requirements set forth in Section 423. Any Option granted under the Plan will be exercisable during the Participant's lifetime only by him or her and may not be sold, pledged, assigned, or transferred in any manner. In the event any Participant violates or attempts to violate the terms of this Section 15, as determined by the Administrator in its sole discretion, any Options held by him or her may be terminated by the Company and, upon the return to the Participant of the balance of his or her Account, without interest, all of the Participant's rights under the Plan will terminate.

#### **16. Change in Capitalization; Corporate Transaction**

**(a) Change in Capitalization.** In the event of any change in the outstanding Shares by reason of a share dividend, share split, reverse share split, split-up, recapitalization, merger, consolidation, reorganization, or other capital change, the aggregate number and type of Shares available under the Plan, the number and type of Shares granted under any outstanding Options, the maximum number and type of Shares purchasable under any outstanding Option, and the purchase price per Share under any outstanding Option will be appropriately adjusted; *provided*, that any such adjustment shall be made in a manner that complies with Section 423.

**(b) Corporate Transaction.** In the event of a Corporate Transaction, the Administrator may, in its discretion, (i) if the Company is merged with or acquired by another

corporation, provide that each outstanding Option will be assumed or exchanged for a substitute Option granted by the acquiror or successor corporation or by a parent or subsidiary of the acquiror or successor corporation, (ii) cancel each outstanding Option and return the balances in Participants' Accounts to the Participants, and/or (iii) pursuant to Section 18 of the Plan, terminate the Option Period on or before the date of the proposed sale, merger or similar transaction.

#### **17. Administration of Plan**

The Plan will be administered by the Administrator, which will have the authority to interpret the Plan, determine eligibility under the Plan, prescribe forms, rules and procedures relating to the Plan and otherwise do all things necessary or appropriate to carry out the purposes of the Plan. All determinations and decisions by the Administrator regarding the interpretation or application of the Plan will be final and binding on all Participants and all persons.

The Administrator may specify the manner in which the Company and/or Employees are to provide notices and forms under the Plan, and may require that such notices and forms be submitted electronically.

#### **18. Amendment and Termination of Plan; Separate Offerings; Sub-Plans**

(a) **Amendment.** The Board reserves the right at any time or times to amend the Plan to any extent and in any manner it may deem advisable; *provided, however*, that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 will have no force or effect unless approved by the shareholders of the Company within 12 months before or after its adoption.

(b) **Termination.** The Board reserves the right at any time or times to suspend or terminate the Plan. In connection therewith, the Board may provide, in its sole discretion, either that outstanding Options will be exercisable either at the Exercise Date for the applicable Option Period or on such earlier date as the Board may specify (in which case such earlier date will be treated as the Exercise Date for the applicable Option Period), or that the balance of each Participant's Account will be returned to the Participant, without interest.

(c) **Separate Offerings; Sub-Plans.** Notwithstanding the foregoing or any provision of the Plan to the contrary, consistent with the requirements of Section 423, the Administrator may, in its sole discretion, amend the terms of the Plan, or an offering, and/or provide for separate offerings under the Plan in order to, among other things, reflect the impact of local law outside of the United States as applied to one or more Eligible Employees of a Designated Subsidiary and may, where appropriate, establish one or more sub-plans to reflect such amended provisions.

#### **19. Approvals**

Shareholder approval of the Plan was obtained prior to the date that is 12 months after the date of Board approval.

Notwithstanding anything herein to the contrary, the obligation of the Company to issue and deliver Shares under the Plan will be subject to the approval required of any governmental authority in connection with the authorization, issuance, sale or transfer of such Shares and to any

requirements of any national securities exchange applicable thereto, and to compliance by the Company with other applicable legal requirements in effect from time to time.

## **20. Participants' Rights as Shareholders and Employees**

A Participant will have no rights or privileges as a shareholder of the Company and will not receive any dividends in respect of any Shares covered by an Option granted hereunder until such Option has been exercised, full payment has been made for such Shares, and the Shares have been issued to the Participant.

Nothing contained in the provisions of the Plan will be construed as giving to any Employee the right to be retained in the employ of the Company or any Designated Subsidiary or as interfering with the right of the Company or any Designated Subsidiary to discharge, promote, demote or otherwise re-assign any Employee from one position to another within the Company or any Designated Subsidiary at any time.

## **21. Restrictions on Transfer; Information Regarding Disqualifying Dispositions.**

Shares purchased under the Plan by a Participant may be subject to such restrictions on transfer, sale, pledge or alienation of such Shares as determined by the Administrator from time to time.

By electing to participate in the Plan, each Participant agrees to provide such information about any transfer of Shares acquired under the Plan that occurs within two years after the first day of the Option Period in which such Shares were acquired and within one year after the acquisition of such Shares as may be requested by the Company or any Designated Subsidiary in order to assist it in complying with applicable tax laws.

## **22. Governing Law**

The Plan will be governed by and administered in accordance with the Irish Companies Act 2014 (as may be amended, replaced and/or consolidated in the future), and with the applicable requirements of the stock exchanges or other trading systems on which the Shares are listed or entered for trading and the Code, in each case as determined by the Administrator. Except as otherwise provided under a sub-plan described in Section 18(c) or as provided in the first sentence of this Section 22, the domestic substantive laws of Delaware govern the provisions of the Plan and of Options under the Plan and all claims or disputes arising out of or based upon the Plan or any Options under the Plan or relating to the subject matter hereof or thereof without giving effect to any choice or conflict of laws provision or rule that would cause the application of the domestic substantive laws of any other jurisdiction.

## **23. Effective Date and Term**

The Plan, as amended and restated, will become effective upon adoption of the Plan by the Board. No rights will be granted hereunder after the earliest to occur of (a) the Plan's termination by the Company, (b) the issuance of all Shares available for issuance under the Plan or (c) August 13, 2028.

**EXHIBIT A**  
**Definition of Terms**

The following terms, when used in the Plan, will have the meanings and be subject to the provisions set forth below:

**“401(k) Plan”:** A savings plan qualifying under Section 401(k) of the Code that is sponsored by the Company or one of its Subsidiaries for the benefit of its employees.

**“Account”:** A payroll deduction account maintained in the Participant’s name on the books of the Company.

**“Accounting Rules”:** Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor provision.

**“Administrator”:** The Compensation Committee, except that the Compensation Committee may delegate (i) to one or more of its members (or one or more other members of the Board, including the full Board) such of its duties, powers and responsibilities as it may determine and (ii) to such Employees or other persons as it determines such ministerial tasks as it deems appropriate. In the event of any delegation described in the preceding sentence, the term “Administrator” will include the person or persons so delegated to the extent of such delegation.

**“Affiliate”** Any corporation or other entity that stands in a relationship to the Company that would result in the Company and such corporation or other entity being treated as a single employer under Sections 414(b) or 414(c) of the Code, except that such sections shall be applied by substituting “at least 50%” for “at least 80%” wherever applicable. The Company may at any time by amendment provide that different ownership thresholds apply.

**“Board”:** The Board of Directors of the Company.

**“Business Day”:** Any day on which the national stock exchange on which the Shares are traded is available and open for trading.

**“Code”:** The U.S. Internal Revenue Code of 1986, as from time to time amended and in effect, or any successor statute as from time to time in effect.

**“Company”:** RVL Pharmaceuticals plc, a public limited company registered under the Irish Companies Act 2014.

**“Corporate Transaction”:** A (i) a consolidation, merger or similar transaction or series of related transactions, including a sale or other disposition of Shares, in which the Company is not the surviving corporation or which results in the acquisition of all or substantially all of the Company’s then-outstanding Shares by a single person or entity or by a group of persons and/or entities acting in concert, including by way of a court ordered scheme of arrangement; (ii) a sale or transfer of all or substantially all of the Company’s assets; (iii) a dissolution or liquidation of the Company; or (iv) a “change in control event” as that term is defined in the regulations under

Section 409A of the Code. For the avoidance of doubt, an initial public offering shall not constitute a Change in Control. Where a Corporate Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) as determined by the Administrator, the Corporate Transaction shall be deemed to have occurred upon consummation of the tender offer.

**“Designated Subsidiary”:** A Subsidiary of the Company that has been designated by the Board or the Compensation Committee of the Board from time to time as eligible to participate in the Plan as set forth on Exhibit B to the Plan. For the avoidance of doubt, any Subsidiary of the Company shall be eligible to be designated as a Designated Subsidiary hereunder.

**“Effective Date”:** The date set forth in Section 23 of the Plan.

**“Eligible Employee”:** Any Employee who meets the eligibility requirements set forth in Section 4 of the Plan.

**“Employee”:** Any person who is employed by the Company or a Designated Subsidiary. For the avoidance of doubt, independent contractors and consultants are not “Employees”.

**“Exercise Date”:** The date set forth in Section 5 of the Plan or otherwise designated by the Administrator with respect to a particular Option Period on which a Participant will be deemed to have exercised the Option granted to him or her for such Option Period.

**“Fair Market Value”:** As of a particular date, (i) the closing price for a Share reported on the Nasdaq Global Market (or any other national securities exchange on which the Shares are then listed) for that date or, if no closing price is reported for that date, the closing price on the immediately preceding date on which a closing price was reported or (ii) in the event that the Shares are not traded on a national securities exchange, the fair market value of a Share determined by the Administrator consistent with the rules of Section 422 and Section 409A of the Code to the extent applicable.

**“Maximum Share Limit”:** The meaning set forth in Section 10 of the Plan.

**“Option”:** An option granted pursuant to the Plan entitling the holder to acquire Shares upon payment of the Purchase Price per Share.

**“Option Period”:** An offering period established in accordance with Section 5 of the Plan.

**“Parent”:** A “parent corporation” as defined in Section 424(e) of the Code.

**“Participant”:** An Eligible Employee who elects to enroll in the Plan.

**“Plan”:** The Amended and Restated RVL Pharmaceuticals plc 2018 Employee Share Purchase Plan, as from time to time amended and in effect.

**“Purchase Price”:** The price per Share with respect to an Option Period determined in accordance with Section 9 of the Plan.

**“Section 423”:** Section 423 of the Code and the regulations thereunder.

**“Share”:** An ordinary share of the Company, nominal value \$0.01 per share.

**“Subsidiary”:** On and after the date the Plan is operated as a plan intended to qualify as an “employee stock purchase plan” under Section 423, a “Subsidiary” shall be limited to a “subsidiary corporation” as defined in Section 424(f) of the Code. Prior to such date, a “Subsidiary” may also include a subsidiary of the Company that would be described in the first sentence of Section 1.409A-1(b)(5)(iii)(E) of the Treasury Regulations.

**EXHIBIT B**  
**Designated Subsidiaries**

Designated Subsidiaries as of July 1, 2020 are listed below:

Osmotica Pharmaceutical Corp.

RVL Pharmaceuticals, Inc.

**AMENDED AND RESTATED RVL PHARMACEUTICALS PLC  
2016 EQUITY INCENTIVE PLAN**

**AMENDED AND RESTATED EFFECTIVE AS OF AUGUST 14, 2018**





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# AMENDED AND RESTATED RVL PHARMACEUTICALS PLC

## 2016 EQUITY INCENTIVE PLAN

### INTRODUCTION

The Plan has been amended and restated by the Board in connection with the Reorganization (as such term is defined in the Company's Form S-1 filed on May 9, 2018). In connection with the Reorganization, options to purchase common units of RVL Holdings S.C.Sp. were converted into options to purchase Shares.

#### SECTION 1. PURPOSE.

The purpose of the Plan is to attract and retain the best available personnel, to provide additional incentive to persons who provide services to the Company's Subsidiaries, and to promote the success of the business operated by the Company's Subsidiaries. Unless the context otherwise requires, capitalized terms used herein are defined in Section 17. The Plan is a "compensatory benefit plan" within the meaning of Rule 701 under the Securities Act, and all Awards granted under the Plan are intended to qualify for an exemption from the registration requirements under the Securities Act, including, without limitation, pursuant to Rule 701 of the Securities Act or Regulation D.

#### SECTION 2. ADMINISTRATION.

The Plan shall be administered by the Board. The Board shall have full authority and sole discretion to take any actions it deems necessary or advisable for the administration and operation of the Plan, subject to the terms and conditions of the Plan, including, without limitation, the right to construe and interpret the provisions of the Plan or any Award, to provide for any omission in the Plan, to resolve any ambiguity or conflict under the Plan or any Award, to accelerate vesting of or otherwise waive any requirements applicable to any Award, to extend the term or any period of exercisability of any Award, to modify the purchase price or Exercise Price under any Award, to establish terms or conditions applicable to any Award and to review any decisions or actions made or taken by the Board. All decisions, interpretations and other actions of the Board shall be final and binding on all Participants and other persons deriving their rights from a Participant. Notwithstanding anything to the contrary herein, no action taken by the Board shall adversely affect in any material respect the rights granted to any Participant under any outstanding Award without such Participant's written consent.

#### SECTION 3. ELIGIBILITY.

The Board is authorized to grant Awards to directors (including, non-employee directors) and consultants of the Company or any of its Subsidiaries and to employees, directors (including non-employee directors) and managers (including non-employee managers) of any Subsidiaries of the Company; provided, that Options and Stock Appreciation Rights may only be granted to those employees, directors and consultants with respect to whom the Company is an "eligible issuer"

within the meaning of Section 409A. Employees, managers, directors and consultants who have been granted Awards shall be Participants in the Plan with respect to such Awards. The designation of an individual as a Participant in any year shall not require that the Board designate such individual to receive an Award in any other year or to receive the same type or amount of Award in any other year.

#### SECTION 4. SHARES SUBJECT TO PLAN.

a. **Basic Limitation.** Subject to Section 13, the maximum number of Shares that may be issued pursuant to Awards under the Plan is 3,212,607 Shares (the “Basic Limitation”). Where an Award is granted in tandem, the number of Shares charged against the Basic Limitation shall be the maximum number of Shares that may be issued pursuant to the Award.

b. **Additional Shares.** In the event that any outstanding Award expires, is cancelled or otherwise terminated without consideration (i.e., Shares or cash) therefor, any rights to acquire Shares allocable to the unexercised or unvested portion of such Award shall not be available for re-issuance under the Plan. Subject to compliance with applicable law, in the event that Shares issued under the Plan are reacquired by the Company pursuant to any forfeiture provision without consideration (i.e., Shares or cash) therefor, such Shares shall not be available for re-issuance under the Plan.

#### SECTION 5. AWARDS.

a. **Types of Awards.** The Board may, in its sole discretion, make Awards of one or more of the following: Options, Stock Appreciation Rights, Restricted Stock, Phantom Shares and Other Share-Based Awards. The Company shall make Awards directly or cause one or more of its Subsidiaries to make Awards; provided, however, that the Company shall be responsible for causing any such Subsidiary to comply with the terms of any Award and the Plan. Awards may be granted singly or in tandem.

b. **Award Agreements.** Each Award made under the Plan shall be evidenced by an Award Agreement (which need not be identical) in a form approved by the Board, and no Award shall be valid without any such agreement. An Award shall be subject to all applicable terms and conditions of the Plan and to any other terms and conditions which the Board in its sole discretion deems appropriate for inclusion in the Award Agreement, provided such terms and conditions are not inconsistent with the Plan. Accordingly, in the event of any conflict between the provisions of the Plan and any such Award Agreement, the provisions of the Plan shall prevail. Each Award Agreement shall provide, in addition to any terms and conditions required to be provided in such agreement pursuant to any other provision of this Plan, the following terms:

- (i) **Number of Shares.** The number of Shares subject to the Award, if any, which number shall be subject to adjustment in accordance with Section 13.
- (ii) **Price.** Where applicable, each Award Agreement shall designate the price, if any, to acquire any Shares underlying the Award, which price shall be payable in a form described in Section 11 and subject to adjustment pursuant to Section 13.

(iii) Vesting. Each Award Agreement shall specify the dates and events on which all or any installment of the Award shall be vested and nonforfeitable.

c. **No Rights as a Shareholder.** A Participant, or a transferee of a Participant, shall have no rights as a shareholder with respect to any Shares covered by an Award until Shares are actually issued in the name of such person (or if Shares will be held in street name, to a broker who will hold such Shares on behalf of such person), except as set forth in Section 8(c) or as may be set forth in the Award Agreement.

## SECTION 6. OPTIONS.

a. **Grant of Options.** The Board may, in its sole discretion, grant Options. All Options shall be nonqualified stock options. The Plan does not provide for the grant of “incentive stock options” within the meaning of Section 422 of the Code.

b. **Option Award Agreements.** Each agreement evidencing an Award of an Option shall contain the following information, which shall be determined by the Board in its sole discretion:

(i) Exercise Price. Each Award Agreement shall state the per Share exercise price (the “Exercise Price”), which shall not be less than 100% of the Fair Market Value of a Share on the date of grant unless such Option otherwise would satisfy Section 409A, and except in the case provided by Section 13.

(ii) Exercisability. Each Award Agreement shall specify the dates and events when all or any installment of the Option becomes exercisable.

(iii) Term. Each Award Agreement shall state the term of each Option (including the circumstances under which such Option will expire prior to the stated term thereof), which shall not exceed 10 years from the date of grant.

c. **Method of Exercise.** Options shall be exercised by the delivery of a notice of exercise to the Company or an agent designated by the Company in a form specified or accepted by the Board, or by complying with any alternative procedures which may be authorized by the Board, setting forth the number of Shares with respect to which the Option is to be exercised, accompanied by full payment for the Shares (including satisfaction of any applicable tax withholding). As soon as practicable after receipt of written notification of exercise, full payment (including satisfaction of any applicable tax withholding) and satisfaction of any other conditions set forth in the applicable Award Agreement, the Company shall deliver to the Participant evidence of issuance of the Shares. The Company, at the Board’s election and in its sole discretion, may settle any Options requested to be exercised in Shares or cash.

## SECTION 7. STOCK APPRECIATION RIGHTS.

a. **Generally.** The Board may, in its sole discretion, grant “Stock Appreciation Rights”. A Stock Appreciation Right means a right to receive a payment in cash, Shares or a combination thereof, in the sole discretion of the Board, in an amount equal to the excess of (i) the Fair Market Value, or other specified valuation, of a number of Shares on the date the right is exercised over (ii) the base value (as determined by the Board and specified in any Award Agreement). If a Stock

Appreciation Right is granted in tandem with or in substitution for an Option, the designated Fair Market Value in the Award Agreement shall reflect the Fair Market Value of the Shares underlying the Awards on the date the Option is granted.

b. **Stock Appreciation Rights Award Agreements.** Each agreement evidencing an Award of Stock Appreciation Rights shall contain the following information, which shall be determined by the Board in its sole discretion:

- (i) **Base Value.** Each Award Agreement shall specify the base value of the Shares above which a Participant shall be entitled to share in the appreciation in the value of such Shares. The per Share initial base value shall not be less than 100% of the Fair Market Value of a Share on the date of grant unless such Stock Appreciation Right otherwise would satisfy Section 409A, and except in the case provided by Section 13.
- (ii) **Exercisability.** Each Award Agreement shall specify how all or any portion of a Stock Appreciation Right shall be exercisable.
- (iii) **Term.** Each Award Agreement shall state the term of each Stock Appreciation Right (including the circumstances under which such Stock Appreciation Right will expire prior to the stated term thereof), which shall not exceed 10 years from the date of grant.

## SECTION 8. RESTRICTED STOCK

a. **Generally.** The Board is hereby authorized to grant Shares that are subject to a risk of forfeiture and, subject to compliance with applicable law, that contain such other restrictions, including restrictions on transferability, as the Board shall determine. Such Awards shall be known as a “Restricted Stock”.

b. **Restricted Stock Award Agreement.** Each agreement evidencing an Award of Restricted Stock shall specify the Restriction Period and such other terms, including vesting, term and transfer restrictions, as determined by the Board in its sole discretion. If Restricted Stock will be granted or the restrictions shall have lapsed upon the achievement of performance goals over a performance period, such Award of Restricted Stock shall be referred to as “Performance Stock”.

c. **Voting Rights.** Unless otherwise determined by the Board and set forth in a Participant’s Award Agreement, to the extent permitted or required by law, as determined by the Board, Participants holding Restricted Stock granted hereunder shall not have the right to exercise voting rights with respect to Restricted Stock during the Restriction Period.

d. **Section 83(b) Election.** The Board may provide in an Award Agreement that the Award of Restricted Stock is conditioned upon the Participant making or refraining from making an election with respect to the Award under Section 83(b) of the Code. If a Participant makes an election pursuant to Section 83(b) of the Code concerning an Award of Restricted Stock, the Participant shall be required to file promptly a copy of such election with the Company.

## SECTION 9. PHANTOM SHARES.

- a. **Generally.** The Board may, in its sole discretion, grant Phantom Shares, where in each case one Phantom Share shall be a notional account representing one Share.
- b. **Settlement of Phantom Shares.** Phantom Shares shall be settled in Shares unless the Award Agreement expressly provides for settlement of all or a portion of the Phantom Shares in cash equal to the Fair Market Value of the Shares that would otherwise be issued in settlement of such Phantom Shares. Shares issued to settle a Phantom Share may be issued with or without payment or consideration therefor, except as may be required by applicable law or the Board, in its sole discretion, as set forth in the Award Agreement. The Board may, in its sole discretion, establish a program to permit participants to defer payments and dividends made in respect of Phantom Shares.

## SECTION 10. OTHER SHARE-BASED AWARDS.

The Board may, in its sole discretion, grant Awards of Shares and Awards that are valued, in whole or in part, by reference to, or are otherwise based on the Fair Market Value of, Shares, including, without limitation, dividend equivalent rights and other phantom awards (an “Other Share-Based Award”). Such Other Share-Based Awards shall be in such form and dependent on such conditions as the Board shall determine, including, without limitation, the right to receive one or more Shares (or the equivalent cash value of such Shares) upon the completion of a specified period of Service, the occurrence of an event and/or the attainment of performance objectives. The Board shall determine to whom and when Other Share-Based Awards will be made, the number of Shares to be awarded under (or otherwise related to) such Other Share-Based Awards, whether such Other Share-Based Awards shall be settled in cash, Shares, additional Awards or other securities or property and all other terms and conditions of such Awards (including, without limitation, the vesting provisions thereof and provisions ensuring that all Shares so awarded and issued shall be fully paid and non-assessable). Each Other Share-Based Award grant shall be evidenced by an Award Agreement, which shall conform to the requirements of the Plan.

## SECTION 11. PAYMENT FOR SHARES.

- a. **General Rule.** The Exercise Price of Options and/or the purchase price (if any) of Shares issuable under the Plan shall be payable in cash or personal check at the time when such Shares are purchased, except as otherwise provided in this Section 11.
- b. **Surrender of Shares.** Only to the extent permitted by the Board, in its sole discretion, with respect to Participant who is an employee of a Subsidiary of the Company, all or any part of the Exercise Price, the purchase price or any applicable withholding requirements may be paid by surrendering, or attesting to the ownership of, Shares that have fully vested, and are already owned by the Participant. Such Shares shall be surrendered to the Company in good form for transfer and shall be valued at their Fair Market Value on the date when the Option is exercised or payment is made (or, in the case of any applicable withholding requirements, Fair Market Value on the date the tax is to be determined). The Participant shall not surrender, or attest to the ownership of, Shares in payment of any portion of the purchase price (or withholding) if such action would cause the Company or any Subsidiary thereof to recognize a compensation expense (or additional

compensation expense) with respect to the applicable Award for financial reporting purposes, unless the Board consents thereto.

c. **Discretion of Board.** The Board may authorize any other method of payment for the Exercise Price of Options that it determines, in its sole discretion; it being understood that, to the extent the Board permits any such other method of payment, it shall not be bound to permit such alternative method of payment for the remainder of any such Award or with respect to any other Award or Participant under the Plan.

## SECTION 12. TERMINATION OF SERVICE.

a. **Termination for Cause.** Unless otherwise provided in an Award Agreement, in the event that a Participant's Service is terminated for Cause, all Awards, including vested Options and Stock Appreciation Rights, held by the Participant shall terminate and be forfeited without consideration, effective on the date the Participant's Service is terminated for Cause.

b. **Termination Due to Death or Disability.** Unless otherwise provided in an Award Agreement, in the event that a Participant's Service is terminated due to death or Disability, (i) all unvested Awards held by the Participant shall terminate and be forfeited without consideration effective as of the date the Participant's Service is terminated and (ii) all vested Options and Stock Appreciation Rights shall terminate and be forfeited on the earlier of (a) one (1) year following the termination of Service and (b) the expiration of the term of such Options or Stock Appreciation Rights, as applicable.

c. **Termination Without Cause.** Unless otherwise provided in an Award Agreement, in the event that a Participant's Service is terminated by the applicable Subsidiary of the Company without Cause and other than as provided in Section 12.b., (i) all unvested Awards held by the Participant shall, subject to compliance with applicable law, terminate and be forfeited without consideration effective as of the date the Participant's Service is terminated and (ii) all vested Options and Stock Appreciation Rights shall terminate and be forfeited on the earlier of (a) the date the term of such Options or Stock Appreciation Rights, as applicable, expires and (b) sixty (60) days following the termination of the Participant's Service.

d. **Termination for any Other Reason.** Unless otherwise provided in an Award Agreement, in the event that a Participant's Service is terminated for any reason other than pursuant to Sections 12.a. through c. above, (i) all unvested Awards held by the Participant shall, subject to compliance with applicable law, terminate and be forfeited without consideration effective as of the date the Participant's Service is terminated and (ii) all vested Options and Stock Appreciation Rights shall terminate and be forfeited on the earlier of (a) the date the term of such Options or Stock Appreciation Rights, as applicable, expires and (b) forty-five (45) days following the termination of the Participant's Service.

e. **Leave of Absence.** For purposes of this Section 12. Service shall be deemed to continue while a Participant is on a *bona fide* leave of absence, if such leave is approved by the applicable Subsidiary of the Company in writing or if continued crediting of service for this purpose is expressly required by the terms of such leave or by applicable law (as determined by the Board).



### SECTION 13. ADJUSTMENT OF SHARES.

a. **General.** In the event of any corporate event or transaction (including, but not limited to, a change in the Shares of the Company or the capitalization of the Company) such as a merger, consolidation, reorganization, Recapitalization, separation, reverse share split, split up, spin-off, combination of Shares, exchange of Shares, dividend in kind, extraordinary cash dividend, or other like change in capital structure (other than normal cash dividends), or any similar event or transaction, the Board, to prevent dilution or enlargement of Participants' rights under the Plan, shall, in its sole discretion, (i) substitute or adjust (a) the number and kind of Shares or other securities that may be issued under the Plan or under particular forms of Awards, (b) the number and kind of Shares or other securities subject to outstanding Awards, or (c) the Exercise Price, grant price or purchase price applicable to outstanding Awards, (ii) grant a dividend right, and/or (iii) make or implement other value determinations applicable to the Plan or outstanding Awards, including making additional Awards, issuing Shares or making cash payments.

b. **Mergers and Consolidations.** In the event that the Company is a party to a merger or consolidation (including a Change of Control transaction), outstanding Awards shall be subject to the agreement effecting such merger or consolidation transaction. Subject to the terms of the applicable Award Agreement, the agreement with respect to such merger or consolidation transaction, without the Participants' consent, may provide for:

- (i) the continuation or assumption of such outstanding Awards under the Plan by the Company (if it is the surviving entity) or by the surviving entity or its direct or indirect parent;
- (ii) the substitution by the surviving entity or its direct or indirect parent of awards with substantially equivalent terms and economic value for such outstanding Awards;
- (iii) the acceleration of the vesting of, right to exercise, and/or lapse of restrictions under some or all then outstanding Awards immediately prior to or as of the date of any such merger or consolidation transaction,
- (iv) the expiration of such outstanding Awards to the extent not timely exercised or purchased by the date of any such merger or consolidation transaction or other date thereafter designated by the Board, after reasonable advance written notice thereof to the holder of each such Award; or
- (v) the cancellation of all or any portion of outstanding Awards for fair value (in the form of cash, Shares, other property or any combination thereof) as determined in the sole discretion of the Board and which value may be zero; provided, that, in the case of vested Options and Stock Appreciation Rights or similar Awards, the fair value shall equal the excess, if any, of the value of the consideration to be paid in any such merger or consolidation transaction to holders of the same number of Shares subject to such Awards (or, if no such consideration is paid, Fair Market Value of the Shares subject to such outstanding Awards or portion thereof being canceled) over the aggregate exercise price, purchase price or grant price, as applicable, with respect to such Awards or portion thereof being canceled, or if no such excess, zero.

## SECTION 14. SECURITIES LAW REQUIREMENTS.

Shares shall not be issued under the Plan unless the issuance and delivery of such Shares comply with (or are exempt from) all applicable requirements of law, including (without limitation) the Securities Act, state or foreign securities laws and regulations, and the regulations of any stock exchange or other securities market on which the Company's securities may then be traded. The Company shall not be obligated to file any registration statement under any applicable securities laws to permit the purchase or issuance of any Shares under the Plan. Each Participant and any person deriving its rights from any Participant shall, as a condition to the purchase or issuance of any Shares under the Plan, deliver to the Company an agreement or certificate containing such representations, warranties and covenants as the Company may deem necessary or appropriate to ensure that the issuance of Shares is not required to be registered under any applicable securities laws.

## SECTION 15. GENERAL TERMS.

a. **Nontransferability of Awards.** Unless otherwise permitted by the Board, in its sole discretion, no Award may be transferred, assigned, pledged or hypothecated by any Participant except in compliance with the terms of the applicable Award Agreement. The exercisability of an Option or other right to acquire Shares under the Plan by someone other than the Participant shall be governed by the agreement pursuant to which such Option or other right is granted.

b. **Restrictions on Transfer of Shares.** Subject to compliance with applicable law, any Shares issued under the Plan shall be subject to such vesting and special forfeiture conditions, repurchase rights, rights of first offer and other transfer restrictions as the Board may determine, including as set forth in any applicable shareholders or limited company agreement. Such restrictions shall be set forth in the applicable Award Agreement or the applicable shareholders or limited company agreement, as applicable, and shall apply in addition to any restrictions that may apply to holders of Shares generally.

c. **Settlement of Awards.** The Board shall determine whether cash, Awards, other securities or other property shall be issued or paid in lieu of fractional Shares or whether such fractional Shares or any rights thereto shall be issued, rounded, forfeited or otherwise eliminated.

d. **Compliance with Section 409A of the Code.**

(i) The Company intends that the Plan and all Awards be construed to avoid the imposition of additional taxes, interest and penalties pursuant to Section 409A. Notwithstanding the Company's intention, in the event that any Award is subject to such additional taxes, interest or penalties pursuant to Section 409A, the Board may, in its sole discretion and without a Participant's prior consent, amend the Plan and/or Awards, adopt policies and procedures or take any other actions (including amendments, policies, procedures and actions with retroactive effect) as are necessary or appropriate to (a) exempt the Plan and/or any Award from the application of Section 409A, (b) preserve the intended tax treatment of any such Award or (c) comply with the requirements of Section 409A, including, without limitation, any such regulations, guidance, compliance programs and other interpretative authority that may be issued after the date of the grant. In no event shall the

Company or any of its Subsidiaries or Affiliates or their respective directors, officers, agents, attorneys, employees, executives, shareholders, limited partners, members, managers, trustees, fiduciaries, representatives, principals, accountants, insurers, successors or assigns be liable for any additional tax, interest or penalties that may be imposed on a Participant under Section 409A or any damages for failing to comply with Section 409A.

- (ii) Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of “nonqualified deferred compensation” (within the meaning of Section 409A) that are otherwise required to be made under the Plan or any Award Agreement to a “specified employee” (as defined under Section 409A) as a result of his or her “separation from service” (other than a payment that is not subject to Section 409A) shall be delayed for the first six (6) months following such separation from service (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award Agreement) on the day that immediately follows the end of such six-month period or as soon as administratively practicable thereafter. Any remaining payments of nonqualified deferred compensation shall be paid without delay and at the time or times such payments are otherwise scheduled to be made.
- (iii) A termination of Service shall not be deemed to have occurred for purposes of any provision of the Plan or any Award Agreement providing for the payment of any amounts or benefits that are considered nonqualified deferred compensation under Section 409A upon or following a termination of Service (but not for purposes of determining vesting or forfeiture), unless such termination is also a “separation from service” within the meaning of Section 409A and the payment thereof prior to a “separation from service” would violate Section 409A. For purposes of any such provision of the Plan or any Award Agreement relating to any such payments or benefits, references to a “termination”, “termination of employment”, “termination of Service”, or like terms shall mean “separation from service”.

e. **Taxes.** The delivery, vesting and retention of Shares, cash or other property under an Award are conditioned upon full satisfaction by the Participant of all tax withholding requirements with respect to the Award. The Administrator shall prescribe such rules for the withholding of taxes with respect to any Award as it deems necessary. Except as otherwise determined by the Administrator or as required by law, the Participant shall be responsible for satisfying and paying all taxes arising from or due in connection with the Award and/or the delivery of Shares under the Award. Participants who are employees of a Subsidiary of the Company may elect, subject to the approval by the Board, in its sole discretion, to satisfy the withholding requirement, in whole or in part, by having the Company withhold Shares having a Fair Market Value on the date the tax is determined equal to the minimum statutory total tax that could be imposed in connection with any such taxable event. The Company shall have no liability or obligation related to any of the foregoing.

f. **No Guarantees Regarding Tax Treatment.** Participants (or their beneficiaries) shall be responsible for all taxes with respect to any Awards under the Plan. The Board and the Company make no guarantees to any Person regarding the tax treatment of Awards or payments made under the Plan. Neither the Board nor the Company has any obligation to take any action to prevent the assessment of any tax on any Person with respect to any Award under Section 409A, Section 280G

or 457A of the Code or otherwise, and none of the Company, any of its Subsidiaries or Affiliates or any of their employees, directors, officers, representatives, shareholders, limited partners, members or Affiliates shall have any liability to a Participant with respect thereto.

g. **No Retention Rights or Right to Awards.** Nothing in the Plan or in any Award granted under the Plan shall confer upon a Participant any right to continue in Service for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Company (or any Subsidiary thereof employing or retaining the Participant) or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her Service at any time and for any reason, with or without cause. No Participant or other Person shall have any claim to be granted any Award, and there is no obligation for uniformity of treatment of Participants or holders or beneficiaries of Awards.

h. **Severability.** If any provision of the Plan or any Award is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction or as to any Person or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Board, such provision shall be construed or deemed amended to conform to applicable laws, or, if it cannot be so construed or deemed amended without, in the determination of the Board, materially altering the intent of the Plan or the Award, such provision shall be stricken as to such jurisdiction, Person or Award, and the remainder of the Plan and any such Award shall remain in full force and effect.

i. **No Constraint on Corporate Action.** Nothing in the Plan shall be construed to (i) limit, impair or otherwise affect the Company's or any Subsidiaries' right or power to make adjustments, reclassifications, reorganizations or changes of its capital or business structure or to merge, consolidate, dissolve, liquidate, sell or transfer all or any part of its business or assets; or (ii) limit the right or power of the Company or any Subsidiary to take any action that it deems necessary or appropriate.

j. **Successors.** All obligations of the Company under the Plan with respect to Awards granted hereunder shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation or otherwise, of all or substantially all of the business or assets of the Company.

k. **Unfunded Plan.** Participants shall have no right, title or interest whatsoever in or to any investments which the Company may make to aid it in meeting its obligations under the Plan. Nothing contained in the Plan, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind, nor a fiduciary relationship between the Company and any Participant, beneficiary, legal representative or any other person. To the extent that any person acquires a right to receive payments from the Company under the Plan, such right shall be no greater than the rights of an unsecured general creditor of the Company. All payments to be made hereunder shall be paid from the general funds of the Company and no special or separate fund shall be established and no segregation of assets shall be made to assure payment of such amounts. The Plan is not intended to be subject to the Employee Retirement Income Security Act of 1974, as amended.

## SECTION 16. DURATION AND AMENDMENTS.

a. **Term of the Plan.** The Plan, as set forth herein, shall become effective on the date of its initial adoption by the Board. The Plan shall terminate automatically on the day preceding the 10th anniversary of its initial adoption by the Board unless earlier terminated pursuant to Section 16.b. below.

b. **Right to Amend or Terminate the Plan.** The Board may amend, alter, suspend, discontinue or terminate (each, an “Amendment”) the Plan and any Awards at any time and for any reason; provided, however, that any Amendment that adversely affects in any material respect the rights granted to any Participant under any outstanding Awards (other than pursuant to Section 15.d. or in order to implement Section 13 or Section 16.e.) shall require such Participant’s prior written consent; and provided, further, that such consent shall not be required with respect to an Amendment made to conform the Plan or any Award to applicable law or any applicable shareholders or limited company agreement (as currently in effect or as any such agreement may subsequently be amended), or with respect to changes that (a) are of an inconsequential nature and do not adversely affect any Participant in any material respect, (b) are necessary to clarify any ambiguity or to correct or supplement any provisions of the Plan or the Awards or (c) required or specifically contemplated by the Plan, including changes relating to the grant of any Awards under the Plan.

c. **Effect of Termination.** No Shares shall be issued or sold under the Plan after the termination thereof, except pursuant to an Award granted prior to such termination. The termination of the Plan shall not affect any Awards outstanding on the termination date.

d. **Modification, Extension and Assumption of Awards.** Within the limitations of the Plan, the Board may modify, extend or assume outstanding Awards or may provide for the cancellation of outstanding Awards in return for the grant of new Awards for the same or a different number of Shares and at the same or a different price. The foregoing notwithstanding, except as provided in Section 15.d., Section 16.b. or Section 13 hereof, no modification of an Award shall, without the consent of the Participant, impair the Participant’s rights or increase the Participant’s obligations under such Award or impair the economic value of any such Award.

## SECTION 17. DEFINITIONS.

a. **“Affiliate”** shall mean, with respect to any specified Person, (a) any other Person which directly or indirectly through one or more intermediaries controls, or is controlled by, or is under common control with, such specified Person (for the purposes of this definition, “control” (including, with correlative meanings, the terms “controlling,” “controlled by” and “under common control with”), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by agreement or otherwise); provided, however, that neither the Company nor any of its Subsidiaries shall be deemed an Affiliate of any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P., Altchem Limited or any of their respective Affiliates and *vice versa*, and (b) if such specified Person is an investment fund, any other investment fund the

primary investment advisor to which is the primary investment advisor to such specified Person.

- b. **“Award”** shall mean the grant of an Option, Stock Appreciation Right, Restricted Stock, Phantom Share or Other Share-Based Award under the Plan.
- c. **“Award Agreement”** shall mean either (i) a written agreement entered into by the Company and a Participant setting forth the terms and provisions applicable to an Award, or (ii) a written statement signed by an authorized officer of the Company to a Participant describing the terms and provisions of the actual grant of such Award.
- d. **“Board”** shall mean the Board of Directors of the Company, as constituted from time to time, or if such Board of Directors has appointed a Compensation Committee, such Compensation Committee.
- e. **“Business Day”** shall mean any day except a Saturday, Sunday or other day on which commercial banks in New York City are authorized by law to close.
- f. **“Cause”** shall, with respect to a Participant, have the meaning ascribed to such term in the employment, consulting or similar agreement between such Participant and the Company or one of its Subsidiaries, or, in the absence of such agreement or if not defined therein shall mean any of the following: (i) such Participant’s willful and continued failure or refusal to perform his or her employment duties after a written demand by the Board for substantial performance is delivered to such Participant, which specifically identifies the manner in which the Board believes that such Participant has not substantially performed his or her duties, which willful and continued failure is not cured by such Participant within thirty (30) days, (ii) the failure to be true and accurate of the statement that the execution and delivery of such Participant’s employment agreement by the parties thereto and the performance by such Participant of such Participant’s duties thereunder do not constitute a breach of, or otherwise contravene, or prevent, interfere with or hinder, the terms of any employment agreement or other agreement or policy to which such Participant is a party or otherwise bound, and that such Participant is not subject to any limitation on his activities on behalf of the Company or its Affiliates as a result of agreements into which such Participant has entered, (iii) such Participant’s fraud, dishonesty or gross misconduct that is materially and demonstrably injurious to the Company or its Affiliates, (iv) the violation by such Participant of any material written policies of the Company or its Affiliates known or provided to such Participant in written (including electronic) form, (v) such Participant’s breach of any confidentiality, non-solicitation or non-competition obligations to the Company or its Affiliates, (vi) such Participant’s conviction of, or a plea of guilty or no contest to, any felony or other criminal offence involving fraud, dishonesty, misappropriation or moral turpitude, (vii) making public disparaging, derogatory or detrimental comments about the Company, any of its Subsidiaries, ACP Holdco (Offshore), L.P., ACP III AIV, L.P., Altchem Limited, or any of their respective Affiliates or any of their directors, officers, managers or employees that are detrimental to the reputation of any of the foregoing, or (viii) engaging in a pattern of conduct that is detrimental to the reputation of the Company, any of its Subsidiaries, or any of their respective Affiliates.

- g. **“Change of Control”** shall mean any (a) transaction or series of related transactions, whether or not the Company is a party thereto, in which, after giving effect to such transaction or transactions, the equity securities representing in excess of fifty percent (50%) of the Shares are owned directly or indirectly through one or more entities, by any “person” or “group” (as such terms are used in Section 13(d) of the Exchange Act) of Persons, other than any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P. or Alchem Limited or their respective Affiliates, or (b) a sale, lease or other disposition of all or substantially all of the assets of the Company and its Subsidiaries on a consolidated basis (including securities of the Company’s directly or indirectly owned Subsidiaries) to one or more purchasers other than any of ACP Holdco (Offshore), L.P., ACP III AIV, L.P. or Alchem Limited or their respective Affiliates.
- h. **“Code”** shall mean the Internal Revenue Code of 1986, as amended.
- i. **“Company”** shall mean RVL Pharmaceuticals plc, a public limited company registered under the Irish Companies Act 2014.
- j. **“Disability”** shall mean, unless otherwise set forth in an Award Agreement,
  - (i) if a Participant has an effective employment agreement or service agreement with a Subsidiary of the Company that defines “Disability” or a like term, the meaning set forth in such agreement at the time of the Participant’s termination of Service; or, in the absence of such an effective employment agreement, service agreement or definition,
  - (ii) a Participant’s physical or mental illness, injury or infirmity which is reasonably likely to prevent or prevents such Participant from performing its essential job functions for a period of (A) ninety (90) consecutive calendar days or (B) an aggregate of one hundred twenty (120) calendar days out of any consecutive twelve (12) month period.
- k. **“Exchange Act”** shall mean the Securities Exchange Act of 1934, as amended.
- l. **“Fair Market Value”** shall mean, as of a particular date, (i) the closing price for a Share reported on the Nasdaq Global Market (or any other national securities exchange on which the Shares are then listed) for that date or, if no closing price is reported for that date, the closing price on the immediately preceding date on which a closing price was reported or (ii) in the event that the Shares are not traded on a national securities exchange, the fair market value of a Share determined by the Board consistent with the rules of Section 422 of the Code and Section 409A to the extent applicable.
- m. **“Option”** shall mean an Option granted under the Plan and entitling the holder to purchase Shares.
- n. **“Other Share-Based Award”** shall have the meaning described in Section 10.
- o. **“Participant”** shall mean an eligible individual to whom an Award is granted under the Plan.

- p. **“Person”** shall mean any individual, partnership, corporation, company, association, trust, joint venture, limited liability company, unincorporated organization, entity or division, or any government, governmental department or agency or political subdivision thereof.
- q. **“Plan”** shall mean this Amended and Restated RVL Pharmaceuticals plc 2016 Equity Incentive Plan.
- r. **“Recapitalization”** shall mean an event or series of events affecting the capital structure of the Company including, but not limited to, share dividends or distributions, share splits, rights offers or recapitalizations through large, non-recurring cash distributions.
- s. **“Restriction Period”** means the period during which Restricted Stock awarded under Section 8 of this Plan are restricted.
- t. **“Restricted Stock”** shall have the meaning described in Section 8(a).
- u. **“Phantom Share”** shall have the meaning described in Section 9(a).
- v. **“Section 409A”** means Section 409A of the Code together with all regulations, guidance, compliance programs, and other interpretative authority thereunder.
- w. **“Securities Act”** means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- x. **“Service”** shall mean service as a director (including a non-employee director) or consultant of the Company or as an employee, manager, (including a non-employee manager), director (including a non-employee director) or consultant of any Subsidiary of the Company; provided, that, if a Participant is both an employee and a director or manager of any Subsidiary of the Company, Service with respect to such Participant shall only mean Service as an employee of such Subsidiary; provided, further, that a termination of Service shall not occur until a termination of Service with the Company and its Subsidiaries.
- y. **“Share”** shall mean an ordinary share of the Company, nominal value \$0.01 per share.
- z. **“Stock Appreciation Right”** shall have the meaning described in Section 7(a).
- aa. **“Subsidiary”** shall mean any Person as to which the Company owns or controls, directly or indirectly, more than 50% percent of the voting securities of such Person.

## SECTION 18. MISCELLANEOUS

- a. **Choice of Law.** This Plan shall be governed by, and construed in accordance with, the Irish Companies Act 2014 (as may be amended, replaced and/or consolidated in the future), and with the applicable requirements of the stock exchanges or other trading systems on which the Shares are listed or entered for trading, in each case as determined by the Board. All claims or causes of action (whether in contract or tort) that may be based upon, arise out of, or relate to this Plan shall be heard and determined in the United States District Court for the District of Delaware and the parties hereto hereby irrevocably submit to the exclusive jurisdiction and venue of such



court in any such action or proceeding and irrevocably and unconditionally waive the defense of an inconvenient forum, or lack of jurisdiction to the maintenance of any such action or proceeding.

b. **Adoption.** This Plan was duly adopted as of February 3, 2016, and has been amended and restated as of August 14, 2018.

**RVL PHARMACEUTICALS PLC**  
**AMENDED AND RESTATED 2018 INCENTIVE PLAN**

**1. DEFINED TERMS**

The following terms, when used in the Plan (as defined below), have the meanings and are subject to the provisions set forth below:

**(a) “Accounting Rules”:** Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor provision.

**(b) “Administrator”:** The Compensation Committee, except with respect to such matters that are not delegated to the Compensation Committee by the Board (whether pursuant to committee charter or otherwise) or with respect to which the Board acts. The Compensation Committee (or the Board, with respect to such matters over which it retains authority under the Plan or otherwise) may delegate (i) to one or more of its members (or one or more other members of the Board, including the full Board) such of its duties, powers and responsibilities as it may determine; (ii) to the extent permitted by Irish law, to one or more officers of the Company the authority to (1) designate the recipients of Awards and (2) grant, issue or settle Awards subject to the Board resolution regarding such delegation specifying the total number of Shares to be granted, issued or settled; and (iii) to such Employees or other persons as it determines such ministerial tasks as it deems appropriate provided however, that such officer or Employee may not grant an Award to himself or herself. For purposes of the Plan, the term “Administrator” will include the Board, the Compensation Committee, and the person or persons delegated authority under the Plan to the extent of such delegation, as applicable.

**(c) “Award”:** Any or a combination of the following:

(1) Stock Options.

(2) SARs.

(3) Restricted Stock.

(4) Unrestricted Stock.

(5) Stock Units, including Restricted Stock Units.

(6) Performance Awards.

(7) Awards (other than Awards described in (1) through (6) above) that are convertible into or otherwise based on Shares.

**(d) “Board”:** The Board of Directors of the Company.

**(e) “Cause”:** In the case of any Participant who is party to an employment or severance-benefit agreement that contains a definition of “Cause,” the definition set forth in such agreement applies with respect to such Participant for purposes of the Plan for so long as such

agreement is in effect. In every other case, “Cause” means, as determined by the Administrator, (i) a substantial failure of the Participant to perform the Participant’s duties and responsibilities to the Company or any of its subsidiaries or substantial negligence in the performance of such duties and responsibilities; (ii) the commission by the Participant of a felony or a crime involving moral turpitude; (iii) the commission by the Participant of theft, fraud, embezzlement, material breach of trust or any material act of dishonesty involving the Company or any of its subsidiaries; (iv) a violation by the Participant of any material provision of the code of conduct or employee handbook of the Company or any of its subsidiaries, of any material policy of the Company or any of its subsidiaries, or of any statutory or common law duty of loyalty to the Company or any of its subsidiaries; (v) material breach of any of the terms of the Plan or any Award made under the Plan, or of the terms of any other agreement between, or restrictive covenant agreement in favor of, the Company or any of its subsidiaries and the Participant; or (vi) other conduct by the Participant that could be expected to be harmful to the business, interests or reputation of the Company or any of its subsidiaries.

(f) **“Code”**: The U.S. Internal Revenue Code of 1986, as from time to time amended and in effect, or any successor statute as from time to time in effect.

(g) **“Compensation Committee”**: The Compensation Committee of the Board.

(h) **“Company”**: RVL Pharmaceuticals plc, a public limited company registered under the Irish Companies Act 2014.

(i) **“Covered Transaction”**: Any of (i) a consolidation, merger or similar transaction or series of related transactions, including a sale or other disposition of Shares, in which the Company is not the surviving corporation or which results in the acquisition of all or substantially all of the Company’s then-outstanding Shares by a single person or entity or by a group of persons and/or entities acting in concert, including by way of a court ordered scheme of arrangement; (ii) a sale or transfer of all or substantially all of the Company’s assets; or (iii) a dissolution or liquidation of the Company. Where a Covered Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) (as determined by the Administrator), the Covered Transaction will be deemed to have occurred upon consummation of the tender offer.

(j) **“Director”**: A member of the Board who is not an Employee.

(k) **“Disability”**: In the case of any Participant who is party to an employment contract, service contract or severance-benefit agreement that contains a definition of “Disability” or a like term, the definition set forth in such agreement applies with respect to such Participant for purposes of the Plan for so long as such agreement is in effect. In every other case, “Disability” means, unless otherwise set forth in an Award agreement, a Participant’s physical or mental illness, injury or infirmity which is reasonably likely to prevent or prevents such Participant from performing his or her essential job or service functions for a period of 90 consecutive calendar days.

(l) **“Effective Date”**: The date the Plan, as amended and restated by the Board on April 9, 2021, is approved by shareholders of the Company.

(m) **“Employee”**: Any person who is employed by the Company or any of its subsidiaries.

(n) **“Employment”**: A Participant’s employment with the Company or any of its subsidiaries.

Employment will be deemed to continue, unless the Administrator otherwise determines at the time of grant of an Award or at any time thereafter, so long as the Participant is employed by, or otherwise is providing services in a capacity described in Section 5 to, the Company or any of its subsidiaries. If a Participant’s employment or other service relationship is with a subsidiary of the Company and that entity ceases to be a subsidiary of the Company, the Participant’s Employment will be deemed to have terminated when the entity ceases to be a subsidiary of the Company unless the Participant transfers Employment to the Company or any of its remaining subsidiaries. Notwithstanding the foregoing, in construing the provisions of any Award relating to the payment of “nonqualified deferred compensation” (subject to Section 409A) upon a termination or cessation of Employment, references to termination or cessation of employment, separation from service, retirement or similar or correlative terms will be construed to require a “separation from service” (as that term is defined in Section 1.409A-1(h) of the Treasury Regulations after giving effect to the presumptions contained therein) from the Company and from all other corporations and trades or businesses, if any, that would be treated as a single “service recipient” with the Company under Section 1.409A-1(h)(3) of the Treasury Regulations. Notwithstanding the foregoing, the Company may, but need not, elect in writing, subject to the applicable limitations under Section 409A, any of the special elective rules prescribed in Section 1.409A-1(h) of the Treasury Regulations for purposes of determining whether a “separation from service” has occurred. Any such written election will be deemed a part of the Plan.

(o) **“Fair Market Value”**: As of a particular date, (i) the closing price for a Share reported on the Nasdaq Global Market (or any other national securities exchange on which the Shares are then listed) for that date or, if no closing price is reported for that date, the closing price on the immediately preceding date on which a closing price was reported or (ii) in the event that the Shares are not traded on a national securities exchange, the fair market value of a Share determined by the Administrator consistent with the rules of Section 422 and Section 409A to the extent applicable.

(p) **“ISO”**: A Stock Option intended to be an “incentive stock option” within the meaning of Section 422. Each Stock Option granted pursuant to the Plan will be treated as providing by its terms that it is to be an NSO unless, as of the date of grant, it is expressly designated as an ISO.

(q) **“NSO”**: A Stock Option that is not intended to be an “incentive stock option” within the meaning of Section 422.

(r) **“Participant”**: A person who is granted an Award under the Plan.

(s) **“Performance Award”**: An Award subject to Performance Criteria.

(t) **“Performance Criteria”**: Specified criteria, other than the mere continuation of Employment or the mere passage of time, the satisfaction of which is a condition for the grant,

exercisability, vesting or full enjoyment of an Award. A Performance Criterion and any targets with respect thereto need not be based upon an increase, a positive or improved result or avoidance of loss and may be applied to the Participant individually, or to a business unit or division or the Company as a whole and may relate to any or any combination of the following (measured either absolutely or by reference to an index or indices or the performance of one or more companies and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; prescription volume or trends; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; share price; shareholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives based on: meeting specified market penetration or value added, product development or introduction (including, without limitation, any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, or patent application or issuance goals. The Administrator may provide that one or more of the Performance Criteria applicable to such Award will be adjusted to reflect events (including, but not limited to, the impact of charges for restructurings, discontinued operations, mergers, acquisitions, extraordinary items, and other unusual or non-recurring items, and the cumulative effects of tax or accounting changes, each as defined by U.S. generally accepted accounting principles) occurring during the applicable performance period that affect the applicable Performance Criterion or Criteria.

- (u) **“Plan”**: The RVL Pharmaceuticals plc Amended and Restated 2018 Incentive Plan, as from time to time amended and in effect.
- (v) **“Prior Plan”**: The Amended and Restated RVL Pharmaceuticals plc 2016 Equity Incentive Plan.
- (w) **“Restricted Stock”**: Shares subject to restrictions requiring that it be redelivered or offered for sale to the Company if specified service or performance-based conditions are not satisfied, subject to compliance with Irish law.
- (x) **“Restricted Stock Unit”**: A Stock Unit that is, or as to which the delivery of Shares or cash in lieu of Shares is, subject to the satisfaction of specified performance or other vesting conditions.
- (y) **“SAR”**: A right entitling the holder upon exercise to receive an amount (payable in cash or in Shares of equivalent value) equal to the excess of the Fair Market Value of the

Shares subject to the right over the base value from which appreciation under the SAR is to be measured.

(z) **“Section 409A”**: Section 409A of the Code and the regulations thereunder.

(aa) **“Section 422”**: Section 422 of the Code and the regulations thereunder.

(bb) **“Share”**: An ordinary share of the Company, nominal value \$0.01 per share.

(cc) **“Stock Option”**: An option entitling the holder to acquire Shares upon payment of the exercise price.

(dd) **“Stock Unit”**: An unfunded and unsecured promise, denominated in Shares, to deliver Shares or cash measured by the value of Shares in the future.

(ee) **“Substitute Awards”**: Awards issued under the Plan in substitution for equity awards of an acquired company that are converted, replaced or adjusted in connection with the acquisition.

(ff) **“Unrestricted Stock”**: Shares not subject to any restrictions under the terms of the Award.

## 2. PURPOSE

The Plan provides for the grant of Awards consisting of, or based on, Shares. The purposes of the Plan are to attract, retain and reward key Employees of the Company and its subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of the Company and to align their interests with the interests of the Company’s shareholders.

## 3. ADMINISTRATION

The Administrator has discretionary authority, subject only to the express provisions of the Plan, to interpret the Plan; determine eligibility for and grant Awards; determine, modify or waive the terms and conditions of any Award; determine the form of settlement of Awards (whether in cash, Shares, other Awards, or other property); prescribe forms, rules and procedures relating to the Plan and Awards; and otherwise do all things necessary or desirable to carry out the purposes of the Plan. Determinations of the Administrator made under the Plan are conclusive and bind all persons.

## 4. LIMITS ON AWARDS UNDER THE PLAN

(a) **Number of Shares**. Subject to adjustment as provided in Section 7(b), the maximum number of Shares that may be delivered in satisfaction of Awards under the Plan is 9,100,000 Shares (which, for the avoidance of doubt, shall include the 712,150 Shares that have been issued under the Plan prior to April 9, 2021, the date the Board approved the Plan). Up to 9,100,000 of the Shares set forth in the preceding sentence may be delivered in satisfaction of ISOs, but nothing in this Section 4(a) will be construed as requiring that any, or any fixed

number of, ISOs be awarded under the Plan. For purposes of this Section 4(a), the number of Shares delivered in satisfaction of Awards will be determined (i) net of Shares underlying the portion of any Award that is settled in cash or the portion of any Award that expires, becomes unexercisable without having been exercised, terminates, or is forfeited to or repurchased by the Company (subject to compliance with Irish law) due to failure to vest, (ii) by treating as having been delivered the full number of Shares covered by any portion of a SAR that is settled in Shares (and not only the number of Shares delivered in settlement) and (iii) by treating as having been delivered any Shares withheld from a Stock Option or other Award to satisfy the tax withholding obligations with respect to such Stock Option or other Award or in payment of the exercise price or purchase price of such Stock Option or other Award. For the avoidance of doubt, the number of Shares available for delivery under the Plan shall not be increased by any Shares that have been delivered under the Plan that are subsequently repurchased using proceeds directly attributable to Stock Option exercises. The limits set forth in this Section 4(a) shall be construed to comply with Section 422.

**(b) Substitute Awards.** The Administrator may grant Substitute Awards under the Plan. To the extent consistent with the requirements of Section 422 and the regulations thereunder and other applicable legal requirements (including applicable stock exchange requirements), Shares delivered under Substitute Awards will be in addition to and will not reduce the number of Shares available for Awards under the Plan set forth in Section 4(a). Notwithstanding anything in Section 4(a) to the contrary, if any Substitute Award is settled in cash or expires, becomes unexercisable, terminates or is forfeited to or repurchased by the Company, subject to compliance with Irish law, in each case, without the delivery of Shares, the Shares previously subject to such Award will not be available for future grants under the Plan. The Administrator will determine the extent to which the terms and conditions of the Plan apply to Substitute Awards, if at all, *provided, however*, that Substitute Awards will not be subject to the per-Participant Award limits described in Section 4(d) below.

**(c) Type of Shares.** Shares delivered by the Company under the Plan may be authorized but unissued Shares or previously issued Shares acquired by the Company. No fractional Shares will be delivered under the Plan.

**(d) Individual Limits.** The following additional limits apply to Awards of the specified type granted to any Participant in any calendar year:

- (1) Stock Options: 615,000 Shares.
- (2) SARs: 615,000 Shares.
- (3) Awards other than Stock Options and SARs: 615,000 Shares.

In applying the foregoing limits, (i) all Awards of the specified type granted to the same person in the same calendar year are aggregated and made subject to one limit; (ii) the limits applicable to Stock Options and SARs refer to the number of Shares underlying those Awards; and (iii) the share limit under clause (d)(3) refers to the maximum number of Shares that may be delivered, or the value of which could be paid in cash or other property, under an Award or Awards of the type specified in clause (d)(3) assuming a maximum payout.

## 5. ELIGIBILITY AND PARTICIPATION

The Administrator shall select Participants from among key Employees of the Company and its subsidiaries. Eligibility for ISOs is limited to individuals described in the first sentence of this Section 5 who are employees of the Company or of a “parent corporation” or “subsidiary corporation” of the Company as those terms are defined in Section 424 of the Code. Eligibility for Stock Options, other than ISOs, and SARs is limited to individuals described in the first sentence of this Section 5 who are providing direct services on the date of grant of the Award to the Company or to a subsidiary of the Company that would be described in the first sentence of Section 1.409A-1(b)(5)(iii)(E) of the Treasury Regulations. Non-employee directors of, and consultants and advisors to, the Company and its subsidiaries are eligible to be selected as Participants by the Administrator and to participate in the Plan under a sub-plan established by the Administrator pursuant to Section 12 of the Plan.

## 6. RULES APPLICABLE TO AWARDS

### (a) All Awards.

(1) **Award Provisions.** The Administrator shall determine the terms of all Awards, subject to the limitations provided herein. No term of an Award shall provide for automatic “reload” grants of additional Awards upon the exercise of an Option or SAR. By accepting (or, under such rules as the Administrator may prescribe, being deemed to have accepted) an Award, the Participant will be deemed to have agreed to the terms of the Award and the Plan. Notwithstanding any provision of this Plan to the contrary, Substitute Awards may contain terms and conditions that are inconsistent with the terms and conditions specified herein, as determined by the Administrator.

(2) **Term of Plan.** No Awards may be made after 10 years from the Effective Date, but previously granted Awards may continue beyond that date in accordance with their terms.

(3) **Transferability.** Neither ISOs nor, except as the Administrator otherwise expressly provides in accordance with the third sentence of this Section 6(a)(3), other Awards may be transferred other than by will or by the laws of descent and distribution. During a Participant’s lifetime, ISOs and, except as the Administrator otherwise expressly provides in accordance with the third sentence of this Section 6(a)(3), SARs and NSOs may be exercised only by the Participant. The Administrator may permit the transfer of Awards other than ISOs, subject to applicable securities and other laws and such limitations as the Administrator may impose.

(4) **Vesting, etc.** The Administrator shall determine the time or times at which an Award vests or becomes exercisable and the terms on which a Stock Option or SAR remains exercisable. Without limiting the foregoing, the Administrator may at any time accelerate the vesting or exercisability of an Award, regardless of any adverse or potentially adverse tax or other consequences resulting from such acceleration. Unless the Administrator expressly provides otherwise, however, the following rules will apply if a Participant’s Employment ceases:



(A) Except as provided in (B) and (C) below, immediately upon the cessation of the Participant's Employment each Stock Option and SAR that is then held by the Participant or by the Participant's permitted transferees, if any, will cease to be exercisable and will terminate and all other Awards that are then held by the Participant or by the Participant's permitted transferees, if any, to the extent not already vested will be forfeited.

(B) Subject to (C) and (D) below, all vested and unexercised Stock Options and SARs held by the Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment, to the extent then exercisable, will remain exercisable for the lesser of (i) a period of 90 days or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon immediately terminate.

(C) Subject to (D) below, all vested and unexercised Stock Options and SARs held by a Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment due to his or her death or Disability, to the extent then exercisable, will remain exercisable for the lesser of (i) the one-year period ending with the first anniversary of the Participant's death or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon immediately terminate.

(D) All Stock Options and SARs (whether or not vested or exercisable) held by a Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment will immediately terminate upon such cessation of Employment if the termination is for Cause or occurs in circumstances that in the determination of the Administrator would have constituted grounds for the Participant's Employment to be terminated for Cause.

(5) **Recovery of Compensation.** Subject to applicable law, the Administrator may provide in any case that any outstanding Award (whether or not vested or exercisable) and the proceeds from the exercise or disposition of any Award or Shares acquired under any Award will be subject to forfeiture and disgorgement to the Company, with interest and other related earnings, if the Participant to whom the Award was granted violates (i) a non-competition, non-solicitation, confidentiality or other restrictive covenant by which he or she is bound or (ii) any Company policy applicable to the Participant that provides for forfeiture or disgorgement with respect to incentive compensation that includes Awards under the Plan. Each Award will be subject to any policy of the Company or any of its subsidiaries that relates to trading on non-public information and permitted transactions with respect to Shares, including limitations on hedging and pledging. In addition, the Administrator may require forfeiture and disgorgement to the Company of any outstanding Award and the proceeds from the exercise or disposition of any Award or Shares acquired under any Award, with interest and other related earnings, to the extent required by law or applicable stock exchange listing standards, including, without limitation, Section 10D of the Securities Exchange Act of 1934, as amended, and any applicable Company policy. Each Participant, by accepting or being deemed to have accepted an Award

under the Plan, agrees to be bound by the forfeiture and disgorgement provisions contained herein and agrees to cooperate fully with the Administrator, and to cause any and all permitted transferees of the Participant to cooperate fully with the Administrator, to effectuate any forfeiture or disgorgement required hereunder, subject to applicable law. Neither the Administrator nor the Company nor any other person, other than the Participant and his or her permitted transferees, if any, will be responsible for any adverse tax or other consequences to a Participant or his or her permitted transferees, if any, that may arise in connection with this Section 6(a)(5).

(6) **Taxes.** The delivery, vesting and retention of Shares, cash or other property under an Award are conditioned upon full satisfaction by the Participant of all tax withholding requirements with respect to the Award. The Administrator shall prescribe such rules for the withholding of taxes with respect to any Award as it deems necessary. The Administrator may hold back Shares from an Award or permit a Participant to tender previously owned Shares in satisfaction of tax withholding requirements (but not in excess of the maximum withholding amount consistent with the Award being subject to equity accounting treatment under the Accounting Rules).

(7) **Dividend Equivalents, etc.** The Administrator may provide for the payment of amounts (on terms and subject to conditions established by the Administrator) in lieu of cash dividends or other cash distributions with respect to Shares subject to an Award whether or not the holder of such Award is otherwise entitled to share in the actual dividend or distribution in respect of such Award; *provided, however*, that (a) dividends or dividend equivalents relating to an Award that, at the dividend payment date, remains subject to a risk of forfeiture (whether service-based or performance-based) shall be subject to the same risk of forfeiture as applies to the underlying Award and (b) no dividends or dividend equivalents shall be payable with respect to Stock Options or SARs. Any entitlement to dividend equivalents or similar entitlements will be established and administered either consistent with an exemption from, or in compliance with, the requirements of Section 409A. Dividends or dividend equivalent amounts payable in respect of Awards that are subject to restrictions may be subject to such limits or restrictions as the Administrator may impose.

(8) **Rights Limited.** Nothing in the Plan may be construed as giving any person the right to be granted an Award or to continued employment or service with the Company or any of its subsidiaries, or any rights as a shareholder except as to Shares actually issued under the Plan. The loss of existing or potential profit in Awards will not constitute an element of damages in the event of termination of Employment for any reason, even if the termination is in violation of an obligation of the Company or any of its subsidiaries to the Participant.

(9) **Coordination with Other Plans.** Awards under the Plan may be granted in tandem with, or in satisfaction of or substitution for, other Awards under the Plan or awards made under other compensatory plans or programs of the Company or any of its subsidiaries. For example, but without limiting the generality of the foregoing, awards under other compensatory plans or programs of the Company or any of its subsidiaries may be settled in Shares (including, without limitation, Unrestricted Stock) under the Plan if the Administrator so determines, in which case the Shares delivered will be treated as awarded under the Plan (and

will reduce the number of Shares thereafter available under the Plan in accordance with the rules set forth in Section 4).

**(10) Section 409A.**

**(A)** Without limiting the generality of Section 11(b) hereof, each Award will contain such terms as the Administrator determines and will be construed and administered, such that the Award either qualifies for an exemption from the requirements of Section 409A or satisfies such requirements.

**(B)** Notwithstanding Section 9 of this Plan or any other provision of this Plan or any Award agreement to the contrary, the Administrator may unilaterally amend, modify or terminate the Plan or any outstanding Award, including but not limited to changing the form of the Award, if the Administrator determines that such amendment, modification or termination is necessary or advisable to avoid the imposition of an additional tax, interest or penalty under Section 409A.

**(C)** If a Participant is deemed on the date of the Participant's termination of Employment to be a "specified employee" within the meaning of that term under Section 409A(a)(2)(B), then, with regard to any payment that is considered nonqualified deferred compensation under Section 409A, to the extent applicable, payable on account of a "separation from service", such payment will be made or provided on the date that is the earlier of (i) the expiration of the six-month period measured from the date of such "separation from service" and (ii) the date of the Participant's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments delayed pursuant to this Section 6(a)(10)(C) (whether they would have otherwise been payable in a single lump sum or in installments in the absence of such delay) will be paid on the first business day following the expiration of the Delay Period in a lump sum and any remaining payments due under the Award will be paid in accordance with the normal payment dates specified for them in the applicable Award agreement.

**(D)** For purposes of Section 409A, each payment made under this Plan will be treated as a separate payment.

**(E)** With regard to any payment considered to be nonqualified deferred compensation under Section 409A, to the extent applicable, that is payable upon a change in control of the Company or other similar event, to avoid the imposition of an additional tax, interest or penalty under Section 409A, no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

**(b) Stock Options and SARs.**

**(1) Time and Manner of Exercise.** Unless the Administrator expressly provides otherwise, no Stock Option or SAR will be deemed to have been exercised until the Administrator receives notice of exercise in a form acceptable to the Administrator that is signed by the appropriate person and accompanied by any payment required under the Award. Any

attempt to exercise a Stock Option or SAR by any person other than the Participant (or a permitted transferee) will not be given effect unless the Administrator has received such evidence as it may require that the person exercising the Award has the right to do so.

(2) **Exercise Price.** The exercise price (or the base value from which appreciation is to be measured) of each Award requiring exercise must be no less than 100% (in the case of an ISO granted to a 10-percent shareholder within the meaning of subsection (b)(6) of Section 422, 110%) of the Fair Market Value of the Shares subject to the Award, determined as of the date of grant, or such higher amount as the Administrator may determine in connection with the grant, and in any event may not be less than the nominal value of a Share.

(3) **Payment of Exercise Price.** Where the exercise of an Award is to be accompanied by payment, payment of the exercise price must be by cash or check acceptable to the Administrator or, if so permitted by the Administrator and if legally permissible, (i) through the delivery of previously acquired unrestricted Shares, or the withholding of unrestricted Shares otherwise deliverable upon exercise, in either case that have a Fair Market Value equal to the exercise price; (ii) through a broker-assisted exercise program acceptable to the Administrator; (iii) by other means acceptable to the Administrator; or (iv) by any combination of the foregoing permissible forms of payment. The delivery of previously acquired Shares in payment of the exercise price under clause (i) above may be accomplished either by actual delivery or by constructive delivery through attestation of ownership, subject to such rules as the Administrator may prescribe.

(4) **Maximum Term.** The maximum term of Stock Options and SARs must not exceed 10 years from the date of grant (or five years from the date of grant in the case of an ISO granted to a 10-percent shareholder described in Section 6(b)(2) above).

(5) **Repricing.** Except in connection with a corporate transaction involving the Company (which term includes, without limitation, any share dividend, share split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares) or as otherwise contemplated by Section 7 below, the Company may not, without obtaining shareholder approval, (i) amend the terms of outstanding Stock Options or SARs to reduce the exercise price or base value of such Stock Options or SARs; (ii) cancel outstanding Stock Options or SARs in exchange for Stock Options or SARs with an exercise price or base value that is less than the exercise price or base value of the original Stock Options or SARs; or (iii) cancel outstanding Stock Options or SARs that have an exercise price or base value greater than the Fair Market Value of a Share on the date of such cancellation in exchange for cash or other consideration.

## 7. EFFECT OF CERTAIN TRANSACTIONS

(a) **Mergers, etc.** Except as otherwise expressly provided in an Award agreement or by the Administrator, the following provisions will apply in the event of a Covered Transaction:

(1) **Assumption or Substitution.** If the Covered Transaction is one in which there is an acquiring or surviving entity, the Administrator may provide for (i) the assumption or continuation of some or all outstanding Awards or any portion thereof or (ii) the grant of new

awards in substitution therefor by the acquiror or survivor or an affiliate of the acquiror or survivor.

(2) **Cash-Out of Awards.** Subject to Section 7(a)(5) below, the Administrator may provide for payment (a “cash-out”), with respect to some or all Awards or any portion thereof, equal in the case of each affected Award or portion thereof to the excess, if any, of (i) the Fair Market Value of a Share times the number of Shares subject to the Award or such portion, over (ii) the aggregate exercise or purchase price, if any, under the Award or such portion (in the case of a SAR, the aggregate base value above which appreciation is measured), in each case on such payment terms (which need not be the same as the terms of payment to holders of Shares) and other terms, and subject to such conditions, as the Administrator determines; *provided, however*, for the avoidance of doubt, that if the per Share exercise or purchase price (or base value) of an Award is equal to or greater than the Fair Market Value of a Share, the Award may be cancelled with no payment due hereunder or otherwise in respect of such Award.

(3) **Acceleration of Certain Awards.** Subject to Section 7(a)(5) below, the Administrator may provide that any Award requiring exercise will become exercisable, in full or in part, and/or that the delivery of any Shares remaining deliverable under any outstanding Award of Stock Units (including Restricted Stock Units and Performance Awards to the extent consisting of Stock Units) will be accelerated, in full or in part, in each case on a basis that gives the holder of the Award a reasonable opportunity, as determined by the Administrator, following exercise of the Award or the delivery of the Shares, as the case may be, to participate as a shareholder in the Covered Transaction.

(4) **Termination of Awards upon Consummation of Covered Transaction.** Except as the Administrator may otherwise determine in any case, each Award will automatically terminate (and in the case of outstanding shares of Restricted Stock, will automatically be forfeited) immediately upon consummation of the Covered Transaction, other than (i) any Award that is assumed or substituted pursuant to Section 7(a)(1) above and (ii) any Award that by its terms, or as a result of action taken by the Administrator, continues following the Covered Transaction.

(5) **Additional Limitations.** Any Share and any cash or other property delivered pursuant to Section 7(a)(2) or Section 7(a)(3) above with respect to an Award may, in the discretion of the Administrator, contain such restrictions, if any, as the Administrator deems appropriate to reflect any performance or other vesting conditions to which the Award was subject and that did not lapse (and were not satisfied) in connection with the Covered Transaction. For purposes of the immediately preceding sentence, a cash-out under Section 7(a)(2) above or an acceleration under Section 7(a)(3) above will not, in and of itself, be treated as the lapsing (or satisfaction) of a performance or other vesting condition. In the case of Restricted Stock that does not vest and is not forfeited in connection with the Covered Transaction, the Administrator may require that any amounts delivered, exchanged or otherwise paid in respect of such Share in connection with the Covered Transaction be placed in escrow or otherwise made subject to such restrictions as the Administrator deems appropriate to carry out the intent of the Plan.

**(b) Changes in and Distributions with Respect to Shares.**

**(1) Basic Adjustment Provisions.** In the event of a share dividend, share split or combination of shares (including a reverse share split), recapitalization or other change in the Company's capital structure that constitutes an equity restructuring within the meaning of the Accounting Rules, the Administrator shall make appropriate adjustments to the maximum number of Shares specified in Section 4(a) that may be issued under the Plan and to the maximum share limits described in Section 4(d), and shall make appropriate adjustments to the number and kind of shares or securities underlying Awards then outstanding or subsequently granted, any exercise or purchase prices (or base values) relating to Awards and any other provision of Awards affected by such change.

**(2) Certain Other Adjustments.** The Administrator may also make adjustments of the type described in Section 7(b)(1) above to take into account distributions to shareholders other than those provided for in Section 7(a) and 7(b)(1), or any other event, if the Administrator determines that adjustments are appropriate to avoid distortion in the operation of the Plan, having due regard for the qualification of ISOs under Section 422 and the requirements of Section 409A, to the extent applicable.

**(3) Continuing Application of Plan Terms.** References in the Plan to Shares will be construed to include any shares or securities resulting from an adjustment pursuant to this Section 7.

**8. LEGAL CONDITIONS ON DELIVERY OF SHARES**

The Company will not be obligated to deliver any Shares pursuant to the Plan or to remove any restriction from Shares previously delivered under the Plan until: (i) the Company is satisfied that all legal matters in connection with the issuance and delivery of such Shares have been addressed and resolved; (ii) if the outstanding Shares are at the time of delivery listed on any stock exchange or national market system, the Shares to be delivered have been listed or authorized to be listed on such exchange or system upon official notice of issuance; and (iii) all conditions of the Award have been satisfied or waived. The Company may require, as a condition to the exercise of an Award or the delivery of Shares under an Award, such representations or agreements as counsel for the Company may consider appropriate to avoid violation of the Securities Act of 1933, as amended, or any applicable state or non-U.S. securities law. Any Shares required to be issued to Participants under the Plan will be evidenced in such manner as the Administrator may deem appropriate, including book-entry registration or delivery of share certificates. In the event that the Administrator determines that share certificates will be issued to Participants under the Plan, the Administrator may require that certificates evidencing Shares issued under the Plan bear an appropriate legend reflecting any restriction on transfer applicable to such Shares, and the Company may hold the certificates pending lapse of the applicable restrictions.

**9. AMENDMENT AND TERMINATION**

The Administrator may at any time or times amend the Plan or any outstanding Award for any purpose which may at the time be permitted by law, and may at any time terminate the

Plan as to any future grants of Awards; *provided, however*, that except as otherwise expressly provided in the Plan the Administrator may not, without the Participant's consent, alter the terms of an Award so as to affect materially and adversely the Participant's rights under the Award, unless the Administrator expressly reserved the right to do so at the time the Award was granted. Any amendments to the Plan will be conditioned upon shareholder approval only to the extent, if any, such approval is required by law (including the Code) or applicable stock exchange requirements, as determined by the Administrator.

## 10. OTHER COMPENSATION ARRANGEMENTS

The existence of the Plan or the grant of any Award will not affect the Company's right to award a person bonuses or other compensation in addition to Awards under the Plan.

## 11. MISCELLANEOUS

(a) **Waiver of Jury Trial.** By accepting or being deemed to have accepted an Award under the Plan, to the maximum extent permitted by law, each Participant waives any right to a trial by jury in any action, proceeding or counterclaim concerning any rights under the Plan and any Award, or under any amendment, waiver, consent, instrument, document or other agreement delivered or which in the future may be delivered in connection therewith, and agrees that any such action, proceedings or counterclaim will be tried before a court and not before a jury. By accepting or being deemed to have accepted an Award under the Plan, each Participant certifies that no officer, representative, or attorney of the Company has represented, expressly or otherwise, that the Company would not, in the event of any action, proceeding or counterclaim, seek to enforce the foregoing waivers. Notwithstanding anything to the contrary in the Plan, nothing herein is to be construed as limiting the ability of the Company and a Participant to agree to submit disputes arising under the terms of the Plan or any Award made hereunder to binding arbitration or as limiting the ability of the Company to require any eligible individual to agree to submit such disputes to binding arbitration as a condition of receiving an Award hereunder.

(b) **Limitation of Liability.** Notwithstanding anything to the contrary in the Plan, neither the Company, nor any of its subsidiaries, nor the Administrator, nor any person acting on behalf of the Company, any of its subsidiaries, or the Administrator, will be liable to any Participant, to any permitted transferee, to the estate or beneficiary of any Participant or any permitted transferee, or to any other person by reason of any acceleration of income, or any additional tax (including any interest and penalties), asserted by reason of the failure of an Award to satisfy the requirements of Section 422 or Section 409A or by reason of Section 4999 of the Code, or otherwise asserted with respect to the Award.

(c)

## 12. ESTABLISHMENT OF SUB-PLANS

The Administrator may at any time and from time to time establish one or more sub-plans, including a Director and consultant sub-plan, under the Plan (for local-law compliance purposes or other administrative reasons determined by the Administrator) by adopting supplements to the Plan containing, in each case, such limitations on the Administrator's discretion under the Plan, and such additional terms and conditions, as the Administrator deems

necessary or desirable. Each supplement so established will be deemed to be part of the Plan but will apply only to Participants within the group to which the supplement applies (as determined by the Administrator).

### 13. GOVERNING LAW

(a) **Certain Requirements of Corporate Law.** Awards will be granted and administered in accordance with the Irish Companies Act 2014 (as may be amended, replaced and/or consolidated in the future), and with the applicable requirements of the stock exchanges or other trading systems on which the Shares are listed or entered for trading, in each case as determined by the Administrator.

(b) **Other Matters.** Except as otherwise provided by the express terms of an Award agreement, under a sub-plan described in Section 12 or as provided in Section 13(a) above, the domestic substantive laws of Delaware govern the provisions of the Plan and of Awards under the Plan and all claims or disputes arising out of or based upon the Plan or any Award under the Plan or relating to the subject matter hereof or thereof without giving effect to any choice or conflict of laws provision or rule that would cause the application of the domestic substantive laws of any other jurisdiction.

(c) **Jurisdiction.** By accepting an Award, each Participant will be deemed to (i) have submitted irrevocably and unconditionally to the jurisdiction of the federal and state courts located within the geographic boundaries of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon the Plan or any Award; (ii) agree not to commence any suit, action or other proceeding arising out of or based upon the Plan or an Award, except in the federal and state courts located within the geographic boundaries of the United States District Court for the District of Delaware; and (iii) waive, and agree not to assert, by way of motion as a defense or otherwise, in any such suit, action or proceeding, any claim that he or she is not subject personally to the jurisdiction of the above-named courts, that his or her property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that the Plan or an Award or the subject matter thereof may not be enforced in or by such court.



## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement"), is entered into this 3rd day of December, 2015, by and between Vertical/Trigen Holdings, LLC, a Delaware limited liability company, and its successors and assigns ("Vertical/Trigen" or the "Company") and Brian A. Markison (the "Executive").

WHEREAS, this Agreement is being entered into in connection with the entering into of the Business Combination Agreement, dated as of the date hereof (the "Transaction Agreement") by and among each of the persons designated as an "Osmotica Shareholder" in the Transaction Agreement, Osmotica Holdings Corp Limited, a company organized under the laws of Cyprus, Altchem Limited, solely in its capacity as representative for the Osmotica Shareholders, each of the persons designated as a "Vertical/Trigen Shareholder" in the Transaction Agreement, Vertical/Trigen, Avista Capital Partners III GP, LP, solely in its capacity as representative for the Vertical/Trigen Shareholders, and Osmotica Holdings S.C.Sp., a special limited partnership organized under the laws of Luxembourg ("New HoldCo") (the transactions contemplated by the Transaction Agreement, the "Transaction");

WHEREAS, the Executive is currently serving as the executive chairman of the Company pursuant to an appointment letter entered into between the Executive and the Company on December 13, 2013 (the "Appointment Letter"), and, in furtherance of this Agreement, the Executive and the Company desire to terminate the Appointment Letter effective as of the consummation of the transactions contemplated by the Transaction Agreement (the "Closing", and the date on which the Closing occurs, the "Effective Date");

WHEREAS, Vertical/Trigen desires that, from and after the Effective Date, the Executive be employed by the Company, and the Executive desires to be employed by the Company pursuant to the terms of this Agreement effective, subject to, and as of the Effective Date; and

WHEREAS, in connection with the execution of the Transaction Agreement and the consummation of the Transaction, New HoldCo will become the indirect parent entity of Vertical/Trigen

NOW, THEREFORE, in consideration of the covenants and agreements hereinafter set forth, the parties hereto agree as follows:

1. Employment and Duties.

(a) General. Effective as of the Effective Date, the Company hereby agrees to employ and the Executive hereby agrees to accept employment with and serve as President and Chief Executive Officer (the "CEO") of the Company and each of its parent entities, including New HoldCo and its subsidiaries, and will report to the Board of Managers of New HoldCo (the "Board"). Upon the Closing (as such term is defined in the Transaction Agreement), Avista Capital Partners III, LP, or one of its affiliated investment funds (the "Avista LP"), shall designate the Executive as one of the three initial managers on the Board that the Avista LP is entitled to designate. At the request of the Board, the Executive shall also serve as a manager or director on the Board of Managers or Board of Directors of each of New HoldCo's subsidiaries, and as chairman of the Board of Managers or Board of Directors of each of New HoldCo's subsidiaries. In these capacities, the Executive shall render such executive, managerial, administrative and other services as customarily are associated and incident to such positions, and as the Company or New HoldCo may, from time to time, reasonably require of him consistent with such position. Commensurate with the Executive performing his duties as CEO, the Executive will be expected to work at the Company's headquarters in Bridgewater or Sayreville, New Jersey as necessitated by business demands or as reasonably requested by the Board of the Company.

(b) Exclusive Services. For so long as the Executive is employed by the Company, the Executive shall devote his full time, energies and talents to serving as the CEO of New HoldCo and its subsidiaries (including the Company, collectively, the "Company Group"). Notwithstanding the forgoing, the Executive may devote reasonable time to activities other than those required under this Agreement, including activities involving professional, charitable, community, educational, religious and similar types of organizations, speaking engagements, and similar types of activities, to the extent that such activities do not individually or in the aggregate, conflict materially with the performance of the Executive's duties under this agreement; provided, however, that the Executive shall not serve on the board of any business or charitable organization, or hold any other position with any business, without the consent of the Board. Such advance Board approval has been obtained for the Executive to serve as (i) a director of the following public and private companies and not for profit organizations during his

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employment with the Company: Lantheus Medical Imaging, the College of New Jersey, Alere, Rosetta Genomics, LTD and Immunomedics, Inc., and (ii) an operating industry advisor to Avista Capital Holdings L.P. and any of its current or future affiliated investment funds (collectively, "Avista") and as a director of any portfolio company of Avista or of any other entity that is affiliated with Avista or with some or all of the partners of the ultimate general partner or management company of Avista; provided that (I) all service described in clauses (i) and (ii) shall be performed on the Executive's personal time and no such service interfere with the Executive's full-time commitment to serve as CEO of the Company Group for so long as Executive remains employed as such, and (II) the Executive shall immediately disclose to the Board any involvement with a business that reasonably might be expected to be competitive with a business of the Company Group.

2. Employment "At-Will". The Executive's employment with the Company shall commence on the Effective Date. The Executive's employment with the Company shall, at all times, be treated as "at will," meaning that the Executive's employment may be terminated by the Company and the Executive may resign for any reason or no reason at all, unless otherwise prohibited by law.

3. Compensation and Other Benefits. Subject to the terms of this Agreement, the Company shall pay and provide the following compensation and other benefits to the Executive as compensation for services rendered hereunder:

(a) Base Salary. The Company shall pay to the Executive an annual base salary of not less than \$600,000 (the "Base Salary"), subject to applicable tax withholdings, payable in accordance with the regular payroll practices of the Company. Salary increases, if any, may occur from time to time in the Company's sole discretion. Such salary increases will depend upon a number of factors, including but not limited to the Executive's performance, the Company's financial performance, and the general economic environment.

(b) Equity Participation. At or promptly following the Closing, the Executive will be granted an amount of options exercisable for units of New HoldCo representing 3% of the basic units of New HoldCo outstanding upon the Closing pursuant to grant documentation and on terms that are consistent with those described in Exhibit A hereto and, to the extent not inconsistent with such terms, are otherwise reasonably satisfactory to the Board. In addition, the Executive shall make a cash investment in accordance with that certain Reorganization Agreement entered into on the date hereof between the Executive, the Company and the other members of the Company party thereto.

(c) Annual Cash Bonus. The Executive shall be eligible to receive an annual, discretionary cash bonus ("Annual Cash Bonus") less taxes and withholdings, with a target bonus opportunity of 100% of the Executive's Base Salary for the applicable calendar year (the "Target Bonus"). Annual Cash Bonuses shall be subject to, and shall only be earned and payable upon, the achievement of one or more reasonable and objective annual performance targets established no later than March 30 of each performance year by the Board of Directors of the Company (the "Company Board"). The performance targets for Executive's first partial year of service after the Effective Date shall be established by the Company Board within ninety (90) calendar days following the Effective Date and shall be prorated for the Executive's first partial year of service. Annual Cash Bonuses, if any, are generally to be paid in the year immediately following the performance year after the finalization of the performance years' audit, on approximately the 15th of the month that such annual audit is finalized and will only be paid to the extent the same is earned and in the amount determined based on actual achievement of the performance targets, subject to the Executive's continued employment on such payment date, except as otherwise provided in Section 4 hereof.

(d) Employee Benefit Plans. The Executive shall be entitled to participate in employee benefit plans and programs of the Company, in accordance with their respective terms, as may be amended from time to time, on a basis no less favorable than those made available to other senior executives of the Company. Coverage under such plans is governed by the applicable plan documents which shall be provided to the Executive.

(e) Expenses. The Company shall reimburse the Executive for reasonable travel and other business-related expenses incurred by the Executive in connection with the fulfillment of his duties hereunder, upon presentation of proper receipts or other proof of expenditure and subject to the applicable expense reimbursement policies and procedures of the Company as in effect from time to time. The Executive shall comply with such expense reimbursement policies and procedures as may be in effect from time to time.

(f) Vacation. The Executive shall be entitled to twenty-five working days of paid vacation per year, which shall be accrued in accordance with the Company's vacation policy for senior executives (it being understood

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that vacation days accrued for the calendar in which the Effective Date occurs will be pro-rated for the Executive's first partial year of service). Such vacations shall extend for such periods and be taken at such intervals as shall be appropriate and consistent with the proper performance of the Executive's duties hereunder. Carryover of unused vacation days shall be permitted to the extent permitted by the Company's vacation policy for other senior executives, as in effect and amended from time to time.

(g) Reimbursement of Legal Fees. The Company shall promptly reimburse the Executive for all reasonable and documented legal fees and expenses incurred by the Executive in connection with the preparation and negotiation of this Agreement; provided, that, the Company shall not be required to reimburse the Executive for any such reasonable and documented legal fees and expenses in excess of \$25,000 in the aggregate.

#### 4. Termination of Employment and Change of Control.

(a) Termination By the Company Without Cause or By the Executive With Good Reason. If the Executive's employment is terminated by the Company without "Cause," as that term is defined in Section 4(d) below, or the Executive terminates his employment for "Good Reason," as that term is defined in Section 4(e) below, the Executive shall receive the following, subject to Section 4(g):

(i) a lump sum payment equal to the Executive's Base Salary on the date of termination for 12 months, less taxes and withholdings, payable on the sixtieth (60th) day following the date of Executive's termination of employment;

(ii) a lump sum payment equal to the full Target Bonus for the year of termination, less taxes and withholdings, payable on the sixtieth (60th) day following the date of the Executive's termination of employment;

(b) continued payment by the Company, for a period of 24 months, of the Company's portion of the premium for medical and dental benefits under the Company's group medical and dental plans that the Company was paying on the Executive's behalf on the date of termination (which subsidy will be treated as imputed income); provided, that the Executive elects to purchase continued healthcare coverage under COBRA, and the period of subsidized coverage shall count toward the Executive's period of COBRA coverage; and provided, further, that, in the event the Company determines that the benefits set forth in this clause (iii) would result in adverse tax consequences for the Company, any affiliate, or any individual, or otherwise violate applicable law at the time such payments are due, the Company shall provide, in lieu of such benefits, a cash payment equal to the subsidy described in this clause iii that does not result in such adverse tax consequences or otherwise violate applicable law;

(i) a lump sum payment equal to any earned, but unpaid, Annual Cash Bonus, if any, for the year prior to the year of termination, notwithstanding the failure of the Executive to be employed by the Company on such Annual Cash Bonus payment date; and

(ii) a lump sum payment equal to (A) any earned, but unpaid, Base Salary through the date of termination, (B) any accrued but unreimbursed business expenses incurred by the Executive prior to such termination, subject to compliance with the Company's expense reimbursement policy, and (C) the cash value of any unused vacation days accrued by the Executive as of the date of termination, subject to applicable tax withholding, which shall be payable on the sixtieth (60th) day following the Executive's termination of employment (the "Accrued Amounts"). In view of the benefits to which the Executive may be entitled under this Section 4(a) or Section 4(f), as applicable, the Executive may not participate in and shall not receive any benefits under any severance plan or policy of the Company (or any successor, affiliate, or similar severance plan) (a "Company Severance Policy") and the severance arrangements provided under this Section 4(a) or Section 4(f), as applicable, shall constitute the entire obligation of the Company and its affiliates to the Executive in connection with any termination by the Company without Cause or termination by the Executive for Good Reason; provided, that this paragraph shall not alter the Executive's rights or obligations he may have or be subject to in connection with or with respect to his direct or indirect equity interests in New HoldCo, and the Executive's indemnification rights shall continue to be governed in accordance with any Directors and Officers Liability Insurance Policy that New HoldCo or any of its subsidiaries may maintain and/or with New HoldCo's or any of its subsidiaries' certificate of incorporation or by-laws or similar governing document, and otherwise in accordance with Section 7; and further provided, that to the extent that any Company Severance Policy would provide the Executive with a greater severance benefit upon any applicable termination than provided hereunder, the Executive shall be entitled to participate in such Company Severance Policy to the extent of any such excess. The Executive expressly acknowledges and agrees that he shall not be entitled to receive any payments, benefits or other compensation under

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this Section 4(a) in the event he receives any payment as a result of a Change of Control circumstance as set forth in Section 4(f) below.

(c) Other Terminations. The Executive shall not be entitled to the post-termination benefits set forth in Section 4(a) above or Section 4(f) below, as and if applicable, other than the Accrued Amounts if his employment with the Company ceases for any reason other than his termination by the Company without Cause or his resignation for Good Reason; it being understood that if the Executive's employment with the Company ceases or terminates for any other reason, he will not be entitled to any severance or post-termination benefits or payments, whether hereunder or pursuant to any policy of the Company; provided, that this paragraph shall not alter the Executive's rights or obligations he may have or be subject to in connection with or with respect to his direct or indirect equity interests in New HoldCo, and the Executive's indemnification rights shall continue to be governed in accordance with any Directors and Officers Liability Insurance Policy that New HoldCo or any of its subsidiaries may maintain and/or with New HoldCo's or any of its subsidiaries' certificate of incorporation or by-laws or similar governing document, and otherwise in accordance with Section 7. In the event that the Executive's employment is terminated other than by the Company without Cause or by the Executive for Good Reason, the Executive shall be entitled to a lump sum payment equal to the Accrued Amounts, subject to applicable tax withholding, payable no later than the sixtieth (60th) day following the Executive's termination of employment. The Executive shall provide at least 90 days' advance notice of any resignation without Good Reason. During such 90-day period, the Executive shall continue to perform all duties requested of him, including but not limited to assisting in transition; provided that the Board shall have discretion to release the Executive from his responsibilities before the end of such 90-day notice period, without any obligation for the Company to provide any payments or benefits other than payment of the Accrued Amounts for service through his termination date, as described above; it being understood that such 90-day notice period shall count towards the Restriction Period.

(d) Termination Due to Death or Permanent Disability. The Executive's employment with the Company shall terminate automatically on the Executive's death. In the event of the Executive's Permanent Disability, the Company shall be entitled to terminate his employment. For purposes of this Agreement, the "Permanent Disability" of the Executive shall mean the Executive's inability, because of mental or physical illness or incapacity, whether total or partial, to perform one or more of the material functions of the Executive's position with or without reasonable accommodation, for a period of: (i) one hundred eighty (180) consecutive days; or (ii) one hundred eighty (180) days during any twelve (12) month period, and which entitles the Executive to receive benefits under a disability plan provided by the Company. In the event of a termination of employment under this section, the Executive shall be entitled to a lump sum payment equal to (A) any earned, but unpaid, Annual Cash Bonus, if any, for the year prior to the year of termination, (B) a portion of the Annual Cash Bonus for the year of termination, but only to the extent that the performance targets are achieved at year end and pro-rated for the number of days of employment during the year of termination, and (C) the Accrued Amounts in the case of each of clauses (A), (B) and (C), subject to applicable tax withholding, in the case of each of clauses (A) and (C), payable no later than the sixtieth (60th) day following the Executive's termination of employment, and in the case of clause (B), payable on the normal Annual Cash Bonus payment date following the year in which such termination occurs.

(e) Cause Definition. For purposes of this Agreement, "Cause" means (i) any material failure on the part of the Executive to perform the Executive's employment duties (not as a consequence of any illness, accident or disability and not relating to any corporate or individual performance targets), (ii) the Executive's continued failure to carry out any reasonable lawful direction of the Company or the Board that is consistent with his position as CEO, (iii) the Executive's material failure to comply with any of the applicable material rules of the Company contained in its Employee Handbook or any other Company policy, (iv) the Executive's failure to comply with any of the material terms of this Agreement, (v) the Executive's fraud, willful malfeasance, gross negligence or willful misconduct in the performance of his employment duties, which causes material injury to the Company Group or its reputation, including, but not limited to, willful or gross misconduct toward any of the Company Group's other employees and intentional falsification of Company data to be submitted to any governmental authority, and (vi) the Executive's conviction of a felony or other crime involving moral turpitude (or a pleading of guilty or nolo contendere thereto), other than one which in the reasonable opinion of the Board does not affect the Executive's position as an employee of the Company; provided, however, that, with respect to each of items (i) through (iv) in this Section 4(d), the Company must notify the Executive in writing within ten (10) days of the Board becoming aware of the occurrence of such event, delineating with specificity the facts constituting the Cause, requesting that the Executive remedy the situation, and stating that if the Executive fails to remedy the situation he will be terminated for Cause (an "Executive Notice to Cure"), and the Executive shall be given ten (10) days from

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the date of receipt of the Executive Notice to Cure to remedy the alleged occurrence, in which case if remedied within such ten (10) day period, such action or inaction shall not constitute Cause.

(f) Good Reason Definition. For purposes of this Agreement, “Good Reason” means (i) a material and adverse reduction in the nature or scope of the responsibilities of, or title held by, the Executive, including, for the avoidance of doubt, any action as a result of which the Executive no longer has the title of Chief Executive Officer of the Company or New HoldCo or, following a Change of Control, any entity that directly or indirectly owns more than fifty percent (50%) of the Company or New HoldCo; (ii) a material breach by the Company of this Agreement; (iii) the transfer or relocation of the Executive’s principal place of employment to a location that is more than 50 miles from the Company’s office in Bridgewater or Sayreville, New Jersey, without the Executive’s prior consent; or (iv) if the Company is not a public company, the removal (without the Executive’s consent or approval) of the Executive from the Board or any failure (without the Executive’s consent or approval) to elect the Executive to the Board; provided, however, that, with respect to each of items (i) - (iv) in this Section 4(e), the Executive must notify the Company in writing within ten (10) days of the occurrence of such event, delineating with specificity the facts constituting the Good Reason and requesting that the Company remedy the situation (“Company Notice to Cure”), the Company shall be given ten (10) days from the date of receipt of the Company Notice to Cure to remedy the alleged occurrence and the Executive’s employment must terminate within ten (10) days after the Company’s failure to cure. For the avoidance of doubt, (x) a change in the number of direct or indirect reports to the Executive, or upon the consummation of an IPO, a change in the Executive’s reporting relationships (including to a Chairman of the Board, but subject, however, to the Executive continuing to be the CEO of the Company, New HoldCo and the entity subject to such IPO), in each case, shall not by itself constitute a material and adverse reduction in the nature or scope of the responsibilities of the Executive, and (y) “Good Reason” shall not include if, with his consent, the Executive ceases to be the Chief Executive Officer of New HoldCo and becomes Chairman of the Board of Managers of New HoldCo.

(g) Change of Control.

a. Definitions. For purposes of this Agreement,

i. a “Sale of the Company” means (A) the acquisition by any person or entity, or any two or more persons or entities deemed to be one person or a group, as the terms “person” and “group” are used in Section 13(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) (a “Person”), (other than a Permitted Holder), of the direct or indirect “beneficial ownership” (within the meaning of Rule 13d-3 under the Exchange Act) of more than fifty percent (50%) of the voting securities of the Company (or of any member of the Company Group which beneficially owns or controls more than 50% of the voting securities of the Company) in one or a series of related transactions, (i) through a sale of securities, or (ii) a merger, consolidation or similar transaction involving the Company or New HoldCo, immediately following which, any member or members of the Company Group or a Permitted Holder fails to own, individually or collectively, more than fifty percent (50%) of the voting power of the successor entity, or (B) a sale or other disposition for value to any Person other than a Permitted Holder of all or substantially all of the assets of the Company or New HoldCo. For the avoidance of doubt, a Sale of the Company shall not be deemed to occur in connection with a sale, disposition or transfer of assets or stock (including by merger, recapitalization, consolidation or similar transaction) of any member of the Company Group (other than the Company or any member of the Company Group which beneficially owns or controls more than 50% of the voting stock of the Company).

ii. an “IPO” means the closing of the first sale of securities of any member of the Company Group, or any entity that beneficially owns more than fifty percent (50%) of any member of the Company Group, to the general public (including a public offering of the Company’s or New HoldCo’s securities) pursuant to an effective registration statement filed with the Securities and Exchange Commission, pursuant to the Securities Act of 1933, or some other some other securities regulator in another jurisdiction or is effected under otherwise applicable law.

iii. a “Change of Control” shall be deemed to have occurred once (and only once) upon a Sale of the Company. For the avoidance of doubt, following the first Sale of the Company after the date hereof, no subsequent Sale of the Company shall constitute a Change of Control.

iv. “Permitted Holder” means: (i) any entity within the Company Group, (ii) a Person or group affiliated with the Company or any member of the Company Group or (iii) any beneficial owner of

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the Company Group (including Altchem Limited and Avista Capital Holdings, L.P.) or any of such beneficial owner's affiliates.

b. Termination Without Cause or For Good Reason following a Change of Control. If, within twelve (12) months following the occurrence of a Change of Control (the "Change of Control Period"), the Executive resigns for Good Reason or the Company terminates the Executive's employment with the Company without Cause, the Executive shall receive the following, subject to Section 4(g):

i. a lump sum payment, equal to a multiple of Executive's Base Salary as of (A) the date of such of termination or (B) the day immediately prior to the date of the Change of Control, whichever is greater, subject to applicable tax withholding, payable on the sixtieth (60th) day following the date of Executive's termination of employment, which multiple shall vary based on the timing of the occurrence of the Executive's termination of employment in relation to the Change of Control as determined as specified below (such applicable multiple, the "Change of Control Multiple"):

- 1) if the Change of Control occurs within 12 months following the Effective Date, the Change of Control Multiple shall be 2,
- 2) if the Change of Control occurs between 12 and 24 months following the Effective Date, the Change of Control Multiple shall be 1.5, and
- 3) if the Change of Control occurs 24 or more months following the Effective Date, the Change of Control multiple shall be 1.

ii. a lump sum payment, equal to the greater of (A) the full Target Bonus for the year of termination or (B) the full Target Bonus applicable for the year in which the Change of Control occurred, multiplied by the applicable Change of Control Multiple, based on the timing of the occurrence of the Executive's termination of employment in relation to the Change of Control, subject to applicable tax withholding, payable on the sixtieth (60th) day following the date of Executive's termination of employment;

iii. continued payment by the Company, for a period of 24 months, of the Company's portion of the premium for medical and dental benefits under the Company's group medical and dental plans that the Company was paying on the Executive's behalf on the date of termination (which subsidy will be treated as imputed income), provided that the Executive elects to purchase continued healthcare coverage under COBRA, and the period of subsidized coverage shall count toward the Executive's period of COBRA coverage; provided, that, in the event the Company determines that the benefits set forth in this clause iii would result in adverse tax consequences for the Company, any affiliate, or any individual, or otherwise violate applicable law at the time such payments are due, the Company shall provide, in lieu of such benefits, a cash payment equal to the subsidy described in this clause iii that does not result in such adverse tax consequences or otherwise violate applicable law;

iv. a lump sum payment equal to any earned, but unpaid, Annual Cash Bonus, if any, for the year prior to the year of termination, notwithstanding the failure of the Executive to be employed by the Company on such Annual Cash Bonus payment date, subject to applicable tax withholding, payable on the sixtieth (60th) day following the date of Executive's termination of employment; and

v. a lump sum payment equal to the Accrued Amounts.

The parties agree and acknowledge that if the Executive is entitled to and receives payments and benefits under this Section 4(f), such payments and benefits are in lieu of and not in addition to any payments or benefits amounts payable or subject to Section 4(a).

(h) Separation Agreement and General Release. The payments and benefits set forth in Sections 4(a) and 4(f) above are expressly conditioned upon the Executive's execution and delivery to the Company of a General Release substantially in a form of Exhibit B, attached hereto, (the "General Release") and such General Release's becoming irrevocable within sixty (60) days following the Executive's termination of employment; provided that any payments or benefits otherwise due prior to such sixtieth (60th) day shall be paid on such sixtieth (60th) day; provided, further, that if such sixty (60) day period spans two taxable years, any payments or benefits shall be paid or commence, as applicable, in the second taxable year. For the avoidance of doubt, the payments and benefits set forth in Sections 4(a) and 4(f) above shall be forfeited if such General Release has not been executed, delivered and become irrevocable within such sixty (60) day period.

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(i) Section 280G. If, immediately prior to a “change in ownership or control” of the Company (within the meaning of Section 280G of the Code (“Section 280G”)), no stock in the Company or New HoldCo is readily tradeable on an established securities market, then as soon as reasonably practicable following the execution of any definitive agreement pursuant to which such “change in ownership or control” transaction would be effected, but in no event later than five (5) business days prior to the consummation of such change in ownership or control, the Company or New HoldCo shall (i) solicit a waiver from the Executive pursuant to which the Executive may waive his right to some or all of any payments and/or benefits payable hereunder or otherwise that as a result of or in connection with the change in ownership or control would be deemed to constitute “parachute payments” within the meaning of Section 280G (the “Waived 280G Benefits”) such that all remaining payments and/or benefits applicable to him shall not be deemed to be “excess parachute payments” (within the meaning of Section 280G), and (ii) solicit the approval of the stockholders of the Company or New HoldCo, as applicable, (to the extent and in the manner required under Sections 280G(b)(5)(A)(ii) and 280G(b)(5)(B) of the Code) for the payment of any Waived 280G Benefits, so that if so approved, such Waived 280G Benefits shall not be considered “parachute payments” within the meaning of Section 280G. To the extent any of the Waived 280G Benefits are not so approved by the stockholders as contemplated above, such Waived 280G Benefits shall not be made or provided.

#### 5. Restrictive Covenants.

(a) Confidential Information. On the Effective Date, the Executive will enter into and agree to be bound by and subject to an agreement with the Company relating to the protection of confidential information and developments and assignment of intellectual property and development rights, substantially in the form of Exhibit C, attached hereto (the “Confidentiality Agreement”). Notwithstanding the foregoing, in the event of any overlap between the terms contained in Sections 5(c) and 5(d) immediately below and any terms in the Confidentiality Agreement that relate to the same subject matter, the most restrictive of such terms shall apply.

(b) Covenant Against Competition. During the Executive’s employment with the Company and for the greater period of (i) one year following the Executive’s termination of employment with the Company, (ii) eighteen (18) months following the Executive’s termination of employment by the Company without Cause or by the Executive for Good Reason if such termination occurs within twelve (12) months following a Change of Control that occurs more than twelve (12) months following the Effective Date but prior to the beginning of the twenty-fourth (24th) month following the Effective Date, and (iii) twenty-four (24) months following the Executive’s termination of employment by the Company without Cause or by the Executive for Good Reason if such termination occurs within twelve (12) months following a Change of Control that occurs within twelve (12) months following the Effective Date (in each case, as applicable, the “Restriction Period”), the Executive will not, directly or indirectly, be involved as an owner, officer, director, employee, consultant, contractor or agent of any business, company or entity which, competes with the Company Group, which would include any company or business engaged, directly or indirectly, in the marketing, distribution, manufacturing or sale of branded and generic pharmaceutical products that compete with the branded or generic pharmaceutical products that the Company and its subsidiaries licenses, owns, markets, distributes, manufactures or sells at such time or any such products that have been presented to the Board of Managers for future development, licensing, marketing, distribution, manufacturing or sale at prior to such time (any such competing products, “Competing Products”). For the limited purpose of determining whether a business, company or entity “competes” with the Company Group following a Change of Control pursuant to the foregoing sentence, the term “Company Group” shall not include the businesses of any acquirer or successor of the Company which are different from the business of the Company Group at the time of such Change of Control. Notwithstanding the foregoing, the Executive, during the covenant not to compete period, may be employed by or otherwise work for a pharmaceutical company whose gross revenues from the sale of Competing Products for the most recent fiscal year prior to the date of the Executive’s affiliation is less than twenty (20) percent of the pharmaceutical company’s total gross revenues, provided that he is entirely screened from, and has no role or involvement in, that company’s business that relates to or is involved with any Competing Product during the restrictive covenant period. The Executive understands and acknowledges that his obligations hereunder shall apply anywhere that the Company’s or any of its subsidiaries’ products are marketed, distributed or sold because the Company and its subsidiaries are engaged in a global business.

(c) Covenant Against Solicitation of Employees. During the Restriction Period, the Executive will not, directly or indirectly, solicit, attempt to solicit, entice, encourage or induce any employee of the Company Group to terminate his or her relationship with the Company Group, or employ or attempt to employ or otherwise retain on an independent contractor basis, any person who was an employee of the Company Group during the Executive’s employment with the Company. Notwithstanding the foregoing, this covenant does not preclude any

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successor employer of the Executive from hiring any employees of the Company Group, provided the Executive has no involvement, direct or indirect, in their solicitation, recruitment or hire.

(d) Covenant Against Solicitation of Clients/Customers. During the Restriction Period, the Executive will not, directly or indirectly, solicit, contact, or have any contact, other than in connection with his employment with the Company, for the purpose of transacting business with any person or entity who is or was a customer or client of the Company Group during the Executive's employment with the Company, where such solicitation or contact interferes with or otherwise negatively impacts the Company Group.

(e) Reasonable Restrictions; Right to Equitable Relief. The Executive acknowledges and agrees that the restrictions and covenants set forth in Section 5 of this Agreement are reasonable in geographic and temporal scope and in all other respects and necessary to protect the Company and its legitimate business interests. The Executive understands and agrees that the Company will be irreparably injured by any breach of Section 5 and damages would be an inadequate remedy. Accordingly, the Executive acknowledges that, in the event of the Executive's breach or threatened breach of Section 5, the Company shall be entitled to a restraining order in addition to preliminary, temporary and permanent injunctive relief or other equitable relief, without the requirement of posting a bond or other security; provided, however, that the granting of any such injunctive relief shall not prejudice the Company's right to seek monetary damages for any breach of Section 5 of this Agreement and any damage that the Company Group has suffered thereby, and that the Company shall be entitled to attorneys' fees and costs incurred by the Company Group in enforcing the terms of Section 5 of this Agreement. Any right to obtain an injunction, restraining order, or other equitable relief under this Section 5 shall not be deemed to be a waiver of any right to any other remedy that the Company may have at law or in equity. Notwithstanding anything else to the contrary herein, in the event of any violation by the Executive of Section 5 of this Agreement, the Company shall immediately have no obligation thereafter to make any payments to or confer any benefits on the Executive that are set forth in this Agreement.

6. Confidentiality of This Agreement. The Executive agrees to keep the terms of this Agreement, to the extent permitted by law, completely confidential and to not disclose information about this Agreement to anyone other than the Executive's spouse or domestic partner, attorneys and licensed tax and/or professional investment advisors, all of whom the Executive will inform of and obtain their advance agreement to be bound by this confidentiality provision.

7. Indemnification. The Executive shall be indemnified pursuant to and in accordance with the terms and conditions set forth in New HoldCo's or its subsidiaries' Directors and Officers Liability Insurance Policy then in effect, which policy shall provide the Executive coverage, during and after his employment with the Company, on the same basis as the Company's other directors and officers.

8. Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, the Company and its successors and assigns and may be assigned by the Company without the Executive's consent in connection with any person acquiring, whether by merger, consolidation, purchase of stock, assets or otherwise, all or substantially all of the Company's assets and business, and the successor shall be substituted for the Company under this Agreement.

9. Withholding. Any payments made or benefits provided to the Executive under this Agreement shall be reduced by any applicable withholding taxes or other amounts required to be withheld by law or contract.

10. Cooperation. The Executive agrees to cooperate fully and in good faith with the Company and its legal counsel, both during and after his employment with the Company, in connection with any defense, prosecution or investigation of any and all actual, threatened, potential or pending court or administrative proceedings or other legal matters in which the Executive may be involved as a party and/or in which the Company determines, in its sole discretion, that the Executive is a relevant witness or has relevant knowledge or information; provided, that any such cooperation shall not unreasonably interfere with the Executive's employment with a future employer following the Executive's termination of employment with the Company. In connection with such matters, the Executive agrees to notify, communicate and be represented by counsel of the Company's choosing, to fully cooperate and work with such counsel with respect to, and in preparation for, any depositions, interviews, responses, appearances, or other legal matters, and to testify honestly with respect to all matters. The Executive is also entitled to appoint, at his request, his own legal counsel in addition to the Company's counsel in connection with any legal matters covered by this Agreement; provided, that, unless such legal matters relate to claims for which the Executive is seeking indemnification, in which case the relevant insurance policy or other document, agreement or instrument governing

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the Executive's to right to seek indemnification shall apply, the Company will pay the reasonable and documented expenses of the Executive's own legal counsel if it is determined that the Executive's interests are adverse to or in conflict with those of the Company and/or that providing counsel to the Executive would be a conflict of interest.

11. **Acknowledgement by the Executive.** The Executive represents and warrants that (i) he is not, and will not become, a party to any agreement, contract, arrangement, understanding, covenant or restriction contained in any agreement that in any way restricts or prohibits him from undertaking or performing his duties in accordance with this Agreement or that restricts his ability to be employed by the Company in accordance with this Agreement; (ii) his employment by the Company will not violate the terms of any policy of any prior employer of the Executive regarding competition or solicitation; and (iii) his position with the Company will not require him to improperly use any trade secrets or confidential information of any prior employer, or any other person or entity for whom he has performed services, and that he has not taken with him or disclosed to the Company any confidential information from any prior employment or any other entity for whom he has performed services.

12. **Section 409A**

(a) The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted by applicable law, this Agreement shall be interpreted to be in compliance therewith. To the extent that any provision hereof is modified in order to comply with or be exempt from Section 409A, such modification shall be made in good faith and shall, to the maximum extent reasonably possible, maintain the original intent and economic benefit to the Executive and the Company of the applicable provision without violating the provisions of Section 409A.

(b) If any payment, compensation or other benefit provided to the Executive under this Agreement in connection with the Executive's "separation from service" (within the meaning of Section 409A) is determined, in whole or in part, to constitute "nonqualified deferred compensation" (within the meaning of Section 409A) and the Executive is a specified employee (as defined in Section 409A(a)(2)(B)(i)) at the time of separation from service, no part of such payments shall be paid before the day that is six months plus one day after the date of separation or, if earlier, ten business days following the Executive's death (the "New Payment Date"). The aggregate of any payments and benefits that otherwise would have been paid and/or provided to the Executive during the period between the date of separation from service and the New Payment Date shall be paid to the Executive in a lump sum on such New Payment Date. Thereafter, any payments and/or benefits that remain outstanding as of or following the New Payment Date shall be paid without delay over the time period originally scheduled, in accordance with the terms of this Agreement.

(c) A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits subject to Section 409A upon or following a termination of employment unless such termination is also a "separation from service" (within the meaning of Section 409A), and for purposes of any such provision of this Agreement, references to a "resignation," "termination," "terminate," "termination of employment" or like terms shall mean separation from service (within the meaning of Section 409A).

(d) All expenses or other reimbursements as provided herein shall be payable in accordance with the Company's policies in effect from time to time, but in any event shall be made on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by the Executive. With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A: (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit; and (ii) the amount of expenses eligible for reimbursements or in-kind benefits provided during any taxable year shall not affect the expenses eligible for reimbursement or in-kind benefits to be provided in any other taxable year.

(e) For purposes of Section 409A, the Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., payment shall be made within 30 days following the date of termination), the actual date of payment within the specified period shall be within the sole discretion of the Company.

13. **Amendment; Waiver.** This Agreement may not be modified, amended or waived in any manner, except by an instrument in writing signed by both parties hereto. The waiver by either party of compliance with any

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provision of this Agreement by the other party shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by such party of a provision of this Agreement.

14. Governing Law and Forum Selection. This Agreement (including any, action, litigation or proceeding that may be based upon, arise out of or relate to this Agreement) shall be subject to, and governed by, the laws of the State of New York applicable to contracts made and to be performed therein, without regard to conflict of law principles. With respect to any dispute arising out of or related to this Agreement, the Executive hereby consents to the exclusive jurisdiction of the of the United States District Court for the Southern District of New York or the Supreme Court of the State of New York, New York County, and expressly agrees not to challenge venue or forum in the event of any litigation.

15. Entire Agreement. Subject to Section 5(a), this Agreement between the Company and the Executive, as amended from time to time, contains the entire agreement and understanding of the parties hereto with respect to the matters covered herein and supersedes all prior or contemporaneous negotiations, commitments, agreements and writings with respect to the subject matter hereof, all such other negotiations, commitments, agreements and writings shall have no further force or effect, and the parties to any such other negotiation, commitment, agreement or writing shall have no further rights or obligations there-under. The Appointment Letter shall be terminated effective as of the Effective Date and, notwithstanding anything to the contrary in this Section 15, any confidentiality undertakings contained in the Appointment Letter shall survive such termination.

16. Counterparts. This Agreement may be executed by either of the parties hereto in counterparts (including, by means of facsimile or PDF (portable document file)), each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument.

17. Headings. The headings of sections herein are included solely for convenience of reference and shall not control the meaning or interpretation of any of the provisions of this Agreement.

18. Severability. The invalidity or unenforceability of any provision of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, and this Agreement will be construed as if such invalid or unenforceable provision or portion of such provision were omitted (but only to the extent that such provision cannot be appropriately reformed or modified).

19. Notices. All notices or communications hereunder shall be in writing and addressed as follows:

To the Company:  
Vertical/Trigen Holdings, LLC.  
c/o Avista Capital Partners  
65 East 55th Street, 18th Floor  
New York, NY 10022  
Facsimile No.: +1 (212) 593 6959  
Attention: General Counsel  
With a copy to New HoldCo at its headquarters.  
To the Executive:  
Brian Markison  
1742 Stuart Road West  
Princeton, NJ 08540  
Email:  
Facsimile:  
or, if the Executive moves, at his last address on record with the Company.

All such notices shall be conclusively deemed to be received and shall be effective (i) if sent by hand delivery, upon receipt, or (ii) if sent by electronic mail or facsimile, upon confirmation of receipt by the sender of such transmission, or (iii) if sent by courier or certified or registered U.S. mail, upon receipt.

20. Termination of Transaction Agreement. Notwithstanding anything to the contrary set forth in this Agreement, in the event that the Transaction Agreement is terminated, this Agreement shall be void ab initio and of no force or effect.

*[Remainder of page intentionally left blank.]*

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**IN WITNESS WHEREOF**, the Company has caused this Agreement to be signed by an authorized officer pursuant to the authority of its Board of Managers, and the Executive has executed this Agreement, as of the day and year first written above.

**VERTICAL/TRIGEN HOLDINGS, LLC**

By: /s/ Chris Klein

Name: Chris Klein

Title: Secretary

ACCEPTED AND AGREED:

/s/ Brian A. Markison

Brian A. Markison

[MARKISON EMPLOYMENT AGREEMENT]

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Exhibit A

**Project Orbit - Proposed Management Equity Program**

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## Management Equity Program Terms And Conditions

### Option Program

#### **Size of Pool:**

Total options representing up to 7.5% of the basic units outstanding at Closing. Following the Closing, the CEO will recommend option allocations to the Board of Orbit Holdco, which the Board will have discretion to amend and/or approve. Brian Markison's employment agreement will provide for, and promptly following the Closing the Board shall approve, a grant of options to Brian Markison representing 40% of the pool. In addition, 0.5% of the pool (0.5% of the 7.5%) will be reserved for issuance to individuals selected by Altchem, the names of which have been communicated to Avista on or prior to the date of the Business Combination Agreement.

#### **Strike Price:**

Same cost per unit as Avista's and Altchem's equity investment at Closing and fair market value therefrom.

#### **Vesting:**

1/2 of the option grant will vest based upon achieving performance targets (the "Performance Plan"). The remaining 1/2 of the option grant will vest ratably over four (4) years based upon the passage of time (the "Time Plan").

#### **Performance Plan:**

One third of the options granted under the Performance Plan will fully vest upon the original holders of units of Orbit Holdco (collectively, the "Original Investors") having received (on a cumulative basis) aggregate net cash proceeds (excluding, for the avoidance of doubt, proceeds from the Promissory Notes to be issued by Orbit Holdco to certain Original Investors at the Closing and any transaction, advisory or monitoring fees) with respect to its equity securities in an amount equal to 2.0 times their Investment Amount (as defined below) (the "Tier 1 ROI"); one third of the options granted under the Performance Plan will fully vest upon the Original Investors having received (on a cumulative basis) aggregate net cash proceeds (excluding, for the avoidance of doubt, proceeds from the Promissory Notes to be issued by Orbit Holdco to certain Original Investors at the Closing and any transaction, advisory or monitoring fees) with respect to its equity securities in an amount equal to 2.5 times their Investment Amount (the "Tier 2 ROI"); and one third of the options granted under the Performance Plan will fully vest upon the Original Investors having received (on a cumulative basis) aggregate net cash proceeds (excluding, for the avoidance of doubt, proceeds from the Promissory Notes to be issued by Orbit Holdco to certain Original Investors at the Closing and any transaction, advisory or monitoring fees) with respect to its equity securities in an amount equal to 3.0 times their Investment Amount (the "Tier 3 ROI").

All dividends paid to the Original Investors (including in connection with any dividend recapitalization) shall be included in aggregate net proceeds (other than the dividend made to the shareholders of Osmotica Holdings Corp. Limited in connection with the Closing). The Board will have discretion to accelerate vesting in the event of an initial public offering or a transaction in which the Original Investors receive non-cash proceeds.

"Investment Amount" means an amount equal to \$640 million, increased from time to time for any cash or other consideration contributed by the Original Investors to Orbit Holdco after the date of grant and prior to the date on which a "Change of Control" (to be defined) transaction is consummated.

In the event of a "Change of Control", unvested options under the Performance Plan will accelerate immediately prior to the "Change in Control" event to the extent the "Return of Capital" thresholds set forth above are satisfied.

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<b>Time Plan:</b>	Vesting over four (4) years subject to continued employment. Options under the Time Plan granted in connection with the Closing will vest on the first anniversary of the Closing of the transaction, and in annual amounts thereafter. In the event of a “Change of Control” the unvested portion of the options under the Time Plan will accelerate immediately prior to the “Change in Control” event.
<b>Exercise of Options:</b>	Upon termination of employment, the terminated holder of options will be able to exercise his/her then vested options by delivering the exercise price in cash within agreed upon time periods. Any vested options that are not exercised within the applicable time periods following any such termination shall automatically forfeit and terminate. Unvested options automatically terminate upon any termination of employment. Orbit Holdco will have certain repurchase rights under certain circumstances upon termination of employment (see “Repurchase Rights” below and <u>Schedule A</u> ).
<b><u>Transfer Restrictions</u></b>	
<b>Transfer Restrictions:</b>	Units of Orbit Holdco held by members of management and other employees (the “ <u>Management Holders</u> ”) may not be transferred unless the transfer is (i) to a permitted transferee ( <u>i.e.</u> , for estate planning purposes), (ii) made in connection with the exercise of drag-along rights, (iii) made in connection with the exercise of a tag-along right or (iv) made to Orbit Holdco, Avista or Altchem in connection with their respective repurchase rights (see “Repurchase Rights” below and <u>Schedule A</u> ). Following an IPO, until such time as the Major Limited Partners have sold at least 50% of the equity interests they own immediately prior to the IPO, each Management Holder will be permitted to transfer common shares in an amount such that its “relative ownership percentage” (measured as the number of unrestricted shares owned after such transfer as a percentage of the sum of the number of unrestricted shares owned immediately after the consummation of the IPO and the number of unvested shares owned immediately after the consummation of the IPO which have vested as of the date of calculation) is equal to or greater than the aggregate “relative ownership percentage” of the Major Limited Partners.
<b>Tag-Along Rights:</b>	Management Holders will be afforded customary tag-along rights to sell a pro rata portion of their units (whether rolled over, purchased or issued upon exercise of vested options) in certain transfers of units by Avista and Altchem, subject to customary exceptions.
<b>Drag-Along Rights:</b>	Management Holders will be subject to customary drag-along rights in favor of Avista, pursuant to which they will be required to participate on a pro rata basis in certain transfers of units by Avista.
<b>Cooperation with Transfers:</b>	If drag-along or tag-along rights are exercised or if Avista or Altchem proposes a sale transaction, then Management Holders must take actions reasonably requested by Avista or Altchem in furtherance of such transaction.

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**Preemptive Rights:**

Management Holders who are also accredited investors (as defined in Rule 501(a) of the Securities Act) will have preemptive rights entitling them to participate pro rata (with respect to their reinvestment/purchased units and exercised vested options) in additional issuances of units or other equity securities of Orbit Holdco, subject to customary exceptions.

**Repurchase Rights:**

Orbit Holdco will have the right to repurchase (i) units issued upon the exercise of options (or similar securities or other incentive equity) and (ii) units issued after the Closing in transactions not subject to pre-emptive rights, in each case, under certain circumstances upon termination of employment of an employee shareholder or Management Holder as set forth on Schedule A. Alchem and Avista will have the right to repurchase certain units attributable to them, to the extent provided in the limited partnership agreement. Repurchase rights will also apply in the event an employee shareholder breaches restrictive covenants by which it is bound following termination (same price as termination for cause).

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Schedule A

**Repurchase Rights upon Employee Termination**

**Repurchase Rights Upon Termination for Rollover or Purchased Units**

<u>Employee Terminates</u>		<u>Company Terminates</u>		<u>Death/Disability</u>
<u>With Good Reason</u>	<u>Without Good Reason</u>	<u>Not for Cause</u>	<u>For Cause</u>	<u>Call @ FMV</u>
Call @ FMV	Call @ FMV	Call @ FMV	Call @ Lower of cost or FMV	Call @ FMV

**Repurchase Rights Upon Termination for Options**

	<u>Employee Terminates</u>		<u>Company Terminates</u>		<u>Death/Disability</u>
	<u>With Good Reason</u>	<u>Without Good Reason</u>	<u>Not for Cause</u>	<u>For Cause</u>	<u>Forfeited</u>
Unvested Options	Forfeited	Forfeited	Forfeited	Forfeited	Forfeited
Units purchased from exercise of vested options	Call @ FMV	Call @ Lower of cost or FMV	Call @ FMV	Call @ Lower of cost or FMV	Call @ FMV

**Definitions**

Definitions of “Cause” and “Good Reason” will be customary definitions set forth in the management equity plan.

“Fair Market Value” or “FMV” means a good faith determination by the board of directors through a reasonable application of a reasonable valuation method. Such determination shall be conclusive and binding on all persons.

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## Exhibit B

### Separation Agreement Release Language

**Release of Claims.** The Executive, individually and on behalf of his heirs, executors, personal representatives, administrators, agents and assigns, forever waives, releases, gives up and discharges all waivable claims, real or perceived, whether now known or unknown, against the Company, all direct and indirect parent entities, subsidiaries, and other related and affiliated companies, their employee benefit plans and trustees, fiduciaries, administrators, sponsors and parties-in-interest of those plans, and all of their past and present employees, managers, directors, officers, administrators, shareholders, members, agents, attorneys, insurers, re-insurers and contractors acting in any capacity whatsoever, and all of their respective predecessors, heirs, personal representatives, successors and assigns (collectively, the "Released Parties"), arising out of and in any way concerning the Executive's employment with the Company, any terms, conditions or privileges related to the Executive's employment with the Company, the termination of the Executive's employment by the Company, and all alleged violations of federal, state or local fair employment practices or laws by any of the Released Parties for any reason and under any legal theory including, but not limited to, Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000(e), *et seq.* ("Title VII"), the Americans with Disabilities Act, 42 U.S.C. § 12101, *et seq.* ("ADA"), the Age Discrimination in Employment Act, 29 U.S.C. § 621, *et seq.* ("ADEA"), the Older Worker Benefits Protection Act, 29 U.S.C. § 626(f), *et seq.* ("OWBPA"), the Employee Retirement Income Security Act of 1974, as amended, 29 U.S.C. 1001, *et seq.* ("ERISA"), the Civil Rights Act of 1991, 42 U.S.C. §§ 1981, 1983, 1985, 1986 and 1988, the Family and Medical Leave Act, 29 U.S.C. § 2601, *et seq.* ("FMLA"), the Equal Pay Act of 1963, 29 U.S.C. § 206, *et seq.* ("EPA"), the Lilly Ledbetter Fair Pay Act of 2009, H.R. 11 ("Fair Pay Act"), the Consolidated Omnibus Budget Reconciliation Act, 29 U.S.C. § 1161, *et seq.* ("COBRA"), the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* ("OSHA"), the New York State Civil Rights Law, N.Y. Exec. Law § 291, *et seq.*, the New York State Human Rights Law, N.Y. Exec. Law § 296(1)(a), *et seq.*, the New York City Civil Rights Law, N.Y.C. Admin. Code § 8-102(5), *et seq.*, the New York State Wage Payment Law, N.Y. Lab. Law § 190(1), *et seq.*, the New York State Whistleblower Law, N.Y. Lab. Law § 740, *et seq.*, the NJ WARN Act, N.J.S.A. §21 *et seq.*, the New Jersey Law Against Discrimination, the Conscientious Employee Protection Act, the New Jersey Wage Payment Law, the New Jersey Family Leave Act, all as amended; the common law of the States of New Jersey and New York; and all other federal or state or local laws, regulations, rules, ordinances, or orders, as they may be amended. The Executive also forever waives, releases, discharges and gives up all claims, real or perceived and now known or unknown, for breach of implied or express contract, including but not limited to breach of promise, breach of the covenant of good faith and fair dealing, misrepresentation, negligence, fraud, estoppel, defamation, libel, misrepresentation, intentional infliction of emotional distress, violation of public policy, wrongful, retaliatory or constructive discharge, assault, battery, false imprisonment, negligence, and all other claims or torts arising under any federal, state, or local law, regulation, ordinance or judicial decision, or under the United States, New York and New Jersey Constitutions. The Executive has agreed to and does waive any and all claims he may have for employment or reinstatement by the Company or any of the Released Parties and has agreed not to seek such employment or reemployment by the Company or any of the Released Parties in the future.

**Covenant Not to Sue.** The Executive warrants that he does not have any complaint, charge or grievance against any Released Party pending before any federal, state or local court or administrative or arbitral agency, and the Executive further agrees and covenants not to sue, file a lawsuit, or commence any other proceeding, arbitral, administrative or judicial, against any of the Released Parties in any court of law or equity, or before any arbitral body or administrative agency, with respect to any matter arising from or relating to the Executive's employment with the Released Parties, the Executive's separation thereof, or otherwise. Should the Executive file a lawsuit with any court or arbitration panel concerning any claim, demand, issue, or cause of action waived through this Agreement, the Executive agrees that he will be responsible to pay the legal fees and costs that the Released Parties incur defending that lawsuit. Further, the Executive agrees that nothing in this Agreement shall limit the right of a court to determine, in its sole discretion, that the Released Parties are entitled to restitution, recoupment or set off of any monies paid should the release of any claims under this Agreement subsequently be found to be invalid.

**Release of Claims and Covenant Not to Sue Carve Outs.** In connection with the foregoing release of claims and covenant not to sue, the Executive does not waive his right to file a charge with the EEOC or participate in an investigation conducted by the EEOC; however, the Executive expressly waives his right to monetary or other relief should any administrative agency, including but not limited to the EEOC, pursue any claim on his behalf. The Executive understands and agrees that nothing in this Agreement limits his or the Company's right to bring an action to enforce the terms of this Agreement. The foregoing release of claims and covenant not to sue shall not alter the

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Executive's rights or obligations he may have or be subject to in connection with or with respect to his direct or indirect equity interests in New HoldCo, and the Executive's indemnification rights shall continue to be governed in accordance with any Directors and Officers Liability Insurance Policy that New HoldCo or any of its subsidiaries may maintain and/or with New HoldCo's or any of its subsidiaries' certificate of incorporation or bylaws or similar governing document, and otherwise in accordance with Section 7 of the Employment Agreement.

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Exhibit C  
Confidentiality Agreement

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[FORM OF]  
**PROPRIETARY INFORMATION**  
**AND**

**ASSIGNMENT OF INVENTIONS AGREEMENT**

This PROPRIETARY INFORMATION AND ASSIGNMENT OF INVENTIONS AGREEMENT (this “**Agreement**”) between the undersigned (“**Employee**”) and [New HoldCo], a Luxembourg *société en commandite spéciale* (“**Holdings**”), sets forth the terms and conditions regarding Employee’s receipt, use, and disclosure of Proprietary Information (as defined below) belonging to Holdings and its direct and indirect subsidiaries (collectively, the “**Company**”).

1. **Term of Agreement.** This Agreement is in consideration of, among other things, Employee’s employment with the Company. This Agreement: (a) will survive the termination of Employee’s relationship with the Company; (b) inures to the benefit of successors and assigns of the Company; (c) is binding upon Employee’s heirs, executors, administrators, or other legal representatives; and (d) shall inure to the benefit of, and be enforceable by, all parent, subsidiary, or other affiliated entities of the Company.

2. **Protection of Proprietary Information.** Employee agrees that his or her employment creates a relationship of confidence and trust with the Company with respect to Proprietary Information of the Company learned or used by Employee during the period of Employee’s employment with the Company. “**Proprietary Information**” shall mean all trade secrets, confidential information, data, or any other proprietary information of the Company. “**Proprietary Information**” shall not include any information which is known in the industry or available to the public through lawful means; provided, however, that publicly known or available information may constitute “**Proprietary Information**” if it is being used by the Company in a fashion, manner, or in connection with other information, that is not publicly known. By way of illustration, but not limitation, “**Proprietary Information**” includes: (i) financial information provided to Employee by the Company; (ii) non-public information pertaining to the Company’s existing, future, or contemplated products; (iii) proprietary software programs or proprietary alterations to non-proprietary software programs; (iv) trade secrets as defined under [New Jersey] law; (v) non-public marketing information such as marketing strategies, pricing information, cost information and distribution strategies; (vi) future product plans or information which are treated as confidential or proprietary by the Company; (vii) personnel information including employee compensation, except where such information is publicly disclosed or where the applicable employee consents to its disclosure; and (viii) non-public information pertaining to the Company’s vendors, or third parties with whom the Company has business relationships, including the terms of those relationships.

(a) Employee agrees that during the term of his or her employment, and thereafter, Employee will keep in confidence and trust all Proprietary Information and will not directly or indirectly use or disclose any Proprietary Information without the written consent of the Company, except, during the period of Employee’s employment with the Company, as may be necessary in the ordinary course of performing Employee’s duties for the Company.

(b) All Company property, including, but not limited to, Proprietary Information, documents, data, records, equipment and other tangible or intangible property, whether or not pertaining to Proprietary Information, provided to Employee by the Company or used or produced by Employee or others in connection with Employee providing services to the Company shall be and remain the sole property of the Company, and shall be returned promptly to the Company as and when requested by the Company. Employee shall return and deliver all such property to the Company upon termination of his or her employment. Employee will not keep or remove any such property or any reproduction of such property upon such termination or at any time.

(c) Employee recognizes that the Company may receive from third parties information which is not publicly known or is private, proprietary or confidential, in each case, subject to a duty on the Company’s part to maintain the confidentiality of such information and to use it only for certain purposes. Employee agrees that during the term of his or her employment, and thereafter, Employee: (i) owes the Company and such third parties a duty to hold all such information received from third parties in confidence and not to disclose it, except as necessary in carrying out Employee’s work for the Company consistent with the Company’s agreement with such third party; and (ii) will not use it for the benefit of anyone, other than for the Company or such third party, consistent with the Company’s agreement with such third party.

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(d) The obligations of Employee with respect to Proprietary Information shall continue until such time as the Proprietary Information is publicly known, through lawful means or until such time as the Company advises Employee in writing to disclose the Proprietary Information.

3. Non-Solicitation of Employees. [Unless otherwise set forth in Employee's employment agreement with the Company,] Employee hereby agrees that during the term of Employee's employment with the Company and for a period of eighteen (18) months following the date of termination of Employee's employment, Employee shall not, individually or in conjunction with any other Person, and shall cause Employee's affiliates not to, directly or indirectly, cause, solicit or encourage any Person who is an employee or consultant of the Company and whose services relate to the Company's business or with whom Employee had contact, to leave his or her employment with the Company, or hire, employ or otherwise engage any employee of the Company. Nothing contained in this Section 3 shall prohibit Employee or its affiliates from soliciting any employee of the Company who shall have responded to a general solicitation for employment not otherwise aimed or targeted at the employees of the Company. The parties agree that, if any court of competent jurisdiction determines that a specified time period, a specified business limitation or any other relevant feature of this Section 3 is unreasonable, arbitrary or against public policy, then a lesser period of time, business limitation or other relevant feature which is determined by such court to be reasonable, not arbitrary and not against public policy may be enforced against the applicable party. As used herein, "**Person**" shall be constructed broadly and include any individual, sole proprietorship, partnership, joint venture, trust, unincorporated association, corporation, limited liability company, entity or governmental authority (whether federal, state, county, city or otherwise and including, without limitation, any instrumentality, division, agency or department thereof).

4. Non-Solicitation of Customers. [Unless otherwise set forth in Employee's employment agreement with the Company,] Employee hereby agrees that during the term of Employee's employment with the Company and for a period of eighteen (18) months following the date of termination of Employee's employment, Employee shall not, individually or in conjunction with any other Person, directly or indirectly, take any of the following actions, except if such actions are taken within the scope of Employee's employment:

(a) cause, induce or encourage, or attempt to cause, induce or encourage (i) any actual or prospective customer, client or account of the Company or (ii) any other Person who has a material business relationship with the Company or who is or was engaged in any substantive business discussion with the Company (each, a "**Customer**"), to terminate or modify any such actual or prospective relationship with the Company; and

(b) perform or attempt to perform services for any Customer, accept business from any Customer or otherwise interfere with the relationship between the Company and any Customer.

The parties agree that, if any court of competent jurisdiction determines that a specified time period, a specified business limitation or any other relevant feature of this Section 4 is unreasonable, arbitrary or against public policy, then a lesser period of time, business limitation or other relevant feature which is determined by such court to be reasonable, not arbitrary and not against public policy may be enforced against the applicable party.

5. Non-Competition. [Unless otherwise set forth in Employee's employment agreement with the Company,] Employee hereby agrees that during the term of Employee's employment with the Company and for a period of eighteen (18) months following the date of termination of Employee's employment, Employee shall not, individually or in conjunction with any other Person, directly or indirectly, take any of the following actions anywhere in [the United States], except if such actions are taken within the scope of Employee's employment:

(a) own, manage, control or participate in the ownership, management or control of, or consult with, or be a director or affiliate of, any entity, individual or group of individuals which engages in any manner in the business of providing some or all of the services that are part of the Company's business;

(b) solicit, employ, or attempt to entice away any person who is an employee or officer of the Company other than any employee that has been terminated by the Company after the date hereof; and

(c) unless compelled by applicable law, disparage, criticize, seek to embarrass or defame the Company, the members of its governing boards, its officers or employees in their capacities as such, or knowingly or willfully harm the business interests, reputation or goodwill of the Company.

Executive acknowledges that the Company distributes and sells its products throughout [the United States] and has customers located throughout [the United States], and that the scope of this restriction is appropriate and reasonable to protect the Company's business interests. The parties further agree that, if any court of competent

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jurisdiction determines that a specified time period, a specified geographical area, a specified business limitation or any other relevant feature of this Section 5 is unreasonable, arbitrary or against public policy, then a lesser period of time, geographical area, business limitation or other relevant feature which is determined by such court to be reasonable, not arbitrary and not against public policy may be enforced against the applicable party.

#### 6. Developed Information.

(a) Employee agrees to promptly disclose to the Company, or any persons designated by it, all improvements, inventions, programs, processes, techniques, or trade secrets, whether or not patentable or registrable under copyright or similar statutes, and all designs, trademarks and copyrightable works that Employee may solely or jointly make or conceive or reduce to practice or learn during the period of his or her employment with the Company which: (i) are within the scope of the services to be provided by Employee to the Company and are related to or useful in the business of the Company or to the Company's actual or demonstrably anticipated activities; or (ii) result from tasks assigned Employee by the Company; or (iii) are funded by the Company; or (iv) result from the use of premises, facilities or equipment owned, leased or contracted for by the Company (collectively, the "**Developed Information**").

(b) Employee agrees that all Developed Information shall be the sole property of the Company, its successors and its assigns. The Company, its successors and its assigns shall be the sole owner of all patents, trademarks, copyrights and other rights in connection therewith. Employee hereby assigns to the Company any rights Employee may have or acquire in all Developed Information. In addition, to the extent permitted by federal copyright law, the parties agree that any works resulting from Employee's work under this Agreement shall be "**works for hire**" as defined in the federal copyright law. Employee hereby assigns to the Company all of Employee's works of authorship and all rights of copyright and patent in such works to the extent such works result from Employee's work under this Agreement. Employee further agrees as to all Developed Information to assist the Company in every proper way (but at the Company's expense) to obtain and from time to time enforce patents, trademarks, copyrights and other rights to or in the Developed Information in any and all countries. Employee will perform any further acts and execute and deliver all documents for use in applying for and obtaining such patents and copyrights thereon and enforcing same, as the Company may desire, together with any assignments thereof to the Company or persons designated by it. Employee's obligation to assist the Company in obtaining and enforcing patents, trademarks, copyrights and other rights to or in the Developed Information in any and all countries shall continue beyond the termination of this Agreement, but the Company shall compensate Employee at a reasonable rate commensurate with rates paid by others for comparable services after such termination of this Agreement for time actually spent by Employee at the Company's request on such assistance. In the event that the Company is unable for any reason whatsoever to secure Employee's signature to any lawful and necessary document required to apply for or prosecute any patent, trademark, or copyright or other right or protection with respect to Developed Information (including renewals, extensions, continuations, divisions or continuations in part thereto), Employee hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Employee's agents and attorneys-in-fact to act for and on Employee's behalf and instead of Employee, to execute and file any such application(s) and to do all other lawfully permitted acts to further the prosecution and issuance of patents, trademarks, copyrights, or similar protections thereon with the same legal force and effect as if executed by Employee. The Company shall also have the right to keep and maintain any and all Developed Information as trade secrets.

(c) As a matter of record, Employee must notify management of the Company in writing of any and all inventions, discoveries, developments, improvements, and trade secrets which have been made or conceived or first reduced to practice by Employee alone or jointly with others prior to employment with the Company which Employee desires to remove from the operation of this Agreement. If Employee does not so notify management, Employee represents that he or she has made no inventions, improvements, developments, or improvements at or prior to the time of signing this Agreement that are to be removed from the operation of this Agreement.

#### 7. Property of Others.

(a) Employee represents that Employee's performance under this Agreement does not and will not breach any obligation to keep in confidence any proprietary or confidential information (including, without limitation, trade secrets) of others, if any, acquired by Employee in confidence or in trust prior to the date of this Agreement. Employee has not entered into, and Employee agrees Employee will not enter into, any agreement either written or oral in conflict with the terms and conditions of this Agreement.

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(b) Employee represents, as part of the consideration for entering into this Agreement, that Employee has not brought and will not bring to the Company or use in the performance of Employee's responsibilities as an employee of the Company any equipment, supplies, property or proprietary or confidential information (including, without limitation, trade secrets) of any current or former employer or other organization to which Employee previously provided services, unless Employee has obtained written authorization for their possession and use.

8. Conflict of Interest. During the term of employment with the Company, Employee shall inform the Company before accepting any employment or consulting relationship with another person or entity: (a) in any field related to the Company's line of business; or (b) in a position that requires significant time commitment. Lack of objection by the Company regarding any particular outside activities does not alter or reduce the Employee's obligations under this Agreement.

9. Equitable Relief. Employee acknowledges that any breach or threatened breach by Employee of the provisions of Sections 2, 3, 4, 5, 6 or 8 of this Agreement will result in immediate and irreparable harm to the Company, for which there will be no adequate remedy at law, and that the Company will be entitled to equitable relief to restrain or enjoin Employee from violating the terms of these sections, or to compel Employee to cease and desist all unauthorized use and disclosure of the Proprietary Information. Nothing in this section shall be construed as prohibiting the Company from pursuing any other remedies available to it for such breach or threatened breach, including recovery of damages from Employee.

10. Modifications. No modification of this Agreement shall be valid unless made in writing and signed by the parties hereto.

11. Severability. If one or more of the provisions in this Agreement is deemed unenforceable by law, the remaining provisions will nevertheless continue in full force and effect.

12. Integrated Agreement. This Agreement, together with [the Business Combination Agreement entered into by Holdings as of [ ], 2015,] the Amended and Restated Limited Partnership Agreement of the Company, dated as of [ ], 2016, and all agreements referenced herein or therein, and any schedules, exhibits and other documents referred to herein or therein (including Employee's employment agreement with the Company), constitutes the entire agreement and understanding between Employee and the Company with respect to the subject matter hereof and thereof and supersedes all prior and contemporaneous arrangements, agreements and understandings, both oral and written, whether in term sheets, presentations or otherwise among the parties hereto, or between any of them, with respect to the subject matter hereof and thereof. This Agreement, and any other written agreement signed by Employee on the subject of his or her employment, including the Employee's employment agreement, if any, shall not affect or supersede the Employee Handbook, if any, of the Company; provided, however, that in the case of any conflict between the Employee Handbook and this Agreement, the terms of this Agreement will supersede any conflicting personnel policy in the Employee Handbook.

13. Governing Law. This Agreement shall be construed in accordance with and governed by the laws of the State of [New Jersey], without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of [New Jersey] or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of [New Jersey].

*[Remainder of Page Intentionally Left Blank]*

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Please confirm your agreement with the foregoing by signing and returning to the undersigned a duplicate copy of this Agreement.

Sincerely,

**VERTICAL/TRIGEN HOLDINGS, LLC**

By: \_\_\_\_\_  
Name:  
Title:

[PROPRIETARY INFORMATION AND ASSIGNMENT OF INVENTIONS AGREEMENT]

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EMPLOYEE CERTIFIES AND ACKNOWLEDGES THAT EMPLOYEE HAS CAREFULLY READ ALL OF THE PROVISIONS OF THIS AGREEMENT AND THAT EMPLOYEE UNDERSTANDS AND WILL FULLY AND FAITHFULLY COMPLY WITH SUCH PROVISIONS.

Dated:

EMPLOYEE

By: \_\_\_\_\_

Name: \_\_\_\_\_

[PROPRIETARY INFORMATION AND ASSIGNMENT OF INVENTIONS AGREEMENT]

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Brian Markison

Dear Brian,

The purpose of this letter is to effect an assignment of the Employment Agreement by and between the Company and you dated as of December 3, 2015 (the "Employment Agreement"), effective as of July 29, 2021 (the "Effective Date") as describe more fully herein. Except as expressly provided for herein, the Employment Agreement shall remain in full force and effect. Capitalized terms used but not defined in this letter will have the meanings set forth in the Employment Agreement.

1. Assignment. As of the Effective Date, the Employment Agreement shall be assigned by Vertical/Trigen Holdings, LLC to RVL Pharmaceuticals, Inc. (as used in this letter, the "Company"). Accordingly, as of the Effective Date, (a) all references in the Employment Agreement to the Company, Vertical/Trigen or Vertical/Trigen Holdings, LLC will be read to refer to RVL Pharmaceuticals, Inc., (b) all references in the Employment Agreement (other than in the preambles to the Employment Agreement) to New HoldCo will be read to refer to Osmotica Pharmaceuticals plc and (c) all references in the Employment Agreement to the Board or the Board of Managers will be read to refer to the board of directors of Osmotica Pharmaceuticals plc.

2. Notices. Notwithstanding anything to the contrary set forth in the Employment Agreement, all notices under the Employment Agreement shall be sent to the following addresses:

If to the Company, to:

RVL Pharmaceuticals, Inc.  
400 Crossing Blvd.  
Bridgewater, NJ 08807  
Attn: General Counsel

If to Executive, to:

the last address shown on records of the Company,

or to such other address as a party may notify the other pursuant to a notice given in accordance with Section 19 of the Employment Agreement.

Except as expressly modified herein, the Employment Agreement remains in full force and effect, and is binding on you and the Company in accordance with its terms. Without limiting the generality of the foregoing, you acknowledge and agree that nothing contained herein shall constitute "Good Reason" for purposes of the Employment Agreement and that you remain bound by the restrictive covenants set forth in Section 5 of the Employment Agreement, and that the

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changes to the terms and conditions of your employment described in this Amendment do not change or limit the scope of, or your obligations to comply with, such restrictive covenants.

[Remainder of page intentionally left blank.]

RVL PHARMACEUTICALS, INC.:

/s/ Christopher Klein

By: Christopher Klein

Title: General Counsel

AGREED TO AND ACCEPTED:

/s/ Brian Markison

Brian Markison

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## RVL Pharmaceuticals plc

<b>Subsidiary</b>	<b>State or Other Jurisdiction of Organization</b>
RVL Holdings US LLC	Delaware
Osmotica Kereskedelmi es Szolgaltato Kft	Hungary
Osmotica Pharmaceutical Corp.	Delaware
RVL Pharmaceuticals, Inc.	Delaware
Osmotica Argentina, S.A.	Argentina
Valkyrie Group Holdings, Inc.	Delaware
RVL Pharmacy, LLC	Delaware

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-236193),
- (2) Registration Statement (Form S-3 No. 333-260529)
- (3) Registration Statement (Form S-8 No. 333-228045); and
- (4) Registration Statement (Form S-8 No. 333-261128);

of our report dated March 30, 2022, with respect to the consolidated financial statements of RVL Pharmaceuticals plc included in this Annual Report (Form 10-K) of RVL Pharmaceuticals plc for the year ended December 31, 2021.

/s/Ernst & Young LLP

Iselin, New Jersey  
March 30, 2022

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Brian Markison, certify that:

1. I have reviewed this annual report on Form 10-K of RVL Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2022

/s/ Brian Markison

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Name: Brian Markison

Title: Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andrew Einhorn, certify that:

1. I have reviewed this annual report on Form 10-K of RVL Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2022

/s/ Andrew Einhorn  
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Name: Andrew Einhorn  
Title: Chief Financial Officer  
(Principal Financial Officer)

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

In connection with the annual report of RVL Pharmaceuticals plc (the “Company”) on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Brian Markison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2022

/s/ Brian Markison  
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Brian Markison  
Chief Executive Officer  
(Principal Executive Officer)

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

In connection with the annual report of RVL Pharmaceuticals plc (the "Company") on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Einhorn, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2022

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/s/ Andrew Einhorn  
Andrew Einhorn  
Chief Financial Officer  
(Principal Financial Officer)

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