2021 IRISH STATUTORY ACCOUNTS

AVADEL PHARMACEUTICALS PLC

Directors' Report and Consolidated Financial Statements

For the Financial Year Ended 31 December 2021

AVADEL PHARMACEUTICALS PLC
TABLE OF CONTENTS

DIRECTORS' REPORT

For the Financial Year Ended 31 December 2021

(dollars in thousands, except share data and where indicated)

Overview

The directors present their report on the audited consolidated financial statements for the financial year ended 31 December 2021, which are set out on pages 57 to 95, and audited parent Company financial statements for the financial period ended 31 December 2021, which are set out on pages 96 to 112.

The directors have elected to prepare the Irish statutory consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent Company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

Basis of Presentation

The accompanying consolidated financial statements reflect the consolidated financial position of the parent Company ("Avadel Pharmaceuticals plc" or "the Group") and its subsidiaries (Avadel Pharmaceuticals plc and all its subsidiaries, hereinafter referred to as "Avadel", "the Group", "us", "we", or "our") as an independent, publicly-traded Group.

Trademarks and Trade Names

Avadel owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Directors' Report is "Avadel," which is a registered trademark or the subject of pending trademark applications in the United States ("U.S.") and other jurisdictions. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other Group appearing in this Directors' Report is, to our knowledge, owned by such other Group.

Forward-Looking Statements

We have made forward-looking statements in this Directors' Report that are based on the director's beliefs and assumptions and on information currently available to the directors. Forward-looking statements include, but are not limited to, information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The principal risks and uncertainties included in this Directors' Report could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the 31 December 2021. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Principal Activities

Avadel Pharmaceuticals plc and its subsidiaries (Nasdaq: AVDL) is a biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive

daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, we submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of 15 October 2021. On 15 October 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

Outside of the Group's lead product candidate, the Group continues to evaluate opportunities to expand its product portfolio. As of the date of this report, the Group does not have any approved and commercialized products in its portfolio.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Immediate release sodium oxybate is approved in the U.S. for the treatment of EDS or cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002, sodium oxybate has only been available as a formulation that must be taken twice nightly, first at bedtime, and then again 2.5 to 4 hours later.

On 16 December 2020, we announced the submission of our NDA to the FDA for FT218. On 26 February 2021, the FDA notified us of formal acceptance of the NDA and assigned a PDUFA target action date of 15 October 2021. On 15 October 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of FT218 or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on 27 April 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 orphan drug designation for the treatment of narcolepsy, which makes FT218 potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, we announced that the first patient was dosed in our open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS or cataplexy in patients with narcolepsy. The OLE/switch study is examining the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning 17 April 2021. The first poster described FT218 improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning 10 June 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 or Type 2. Additionally, a post-hoc analysis showed that FT218 was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

New data was presented at the American College of Chest Physicians annual meeting, beginning 17 October 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

New data was presented at World Sleep 2022 congress, which was held 11-16 March 11, 2022 in Rome, Italy. A total of eight posters were presented, including five new post-hoc analyses from the REST-ON trial. Most notably, the post-hoc analyses demonstrated that FT218 demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5-g starting dose, with even greater improvement at week 2 soon after starting the 6-g dose compared to placebo. Additional post-hoc analyses, stratified by narcolepsy type, as well as concomitant stimulant use, or without stimulants, demonstrated positive results that are generally consistent with previously reported positive endpoints from REST-ON and add to the existing body of evidence for FT218.

In addition, the results of a discrete choice experiment ("DCE") were presented, which confirmed that once-nightly dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-nightly) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE OLE/switch study, which showed that FT218 has generally been well-tolerated, with some patients receiving therapy for more than 18 months, and no new safety signals have been observed.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for EDS or cataplexy in patients with narcolepsy, which are twice-nightly oxybate formulations.

Micropump Drug-Delivery Technology

Our Micropump drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Previously Approved FDA Products

On 30 June 2020 ("Closing Date"), we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC ("Exela Buyer").

Corporate Information

The Group was incorporated in Ireland on 1 December 2015 as a private limited Company, and re-registered as an Irish public limited company on 21 November 2016 (Company registration number: 572535). The address of our registered office is 10 Earlsfort Terrace, Dublin 2, Ireland.

We currently have five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the

holding entity of (i) Avadel Legacy Pharmaceuticals, LLC, (ii) Avadel Management Corporation, and (iii) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation. Avadel France Holding SAS, a French *société par actions simplifiée*, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its Research and Development ("R&D") activities. A complete list of the Group's subsidiaries can be found in *Note 27: Subsidiary Undertakings* in the Notes to the consolidated financial statements.

Dividends

No dividends have been paid in the current or preceding period. We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the continued operation and expansion of our business. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends.

Share Capital

For the changes in share capital, see *Note 17: Called-up Share Capital and Reserves*.

Share Repurchase Program

As of 31 December 2021, the Group holds 0 of its own shares. During the year ended 31 December 2020, the Group cancelled all 5,407 shares previously held. No share purchases were made during the years ended 31 December 2021 and 2020.

Reconciliation:	Number of ordinary shares held/acquired	Aggregate consideration paid	% of the Share Capital
Balance at 1 January 2017	—	$ —	— %
Acquired:	2,117	22,361	5.1 %
Balance at 31 December 2017	2,117	$ 22,361	5.1 %
Acquired:	3,290	27,637	7.5 %
Balance at 31 December 2018	5,407	$ 49,998	12.6 %
Acquired:	—	—	— %
Balance at 31 December 2019	5,407	$ 49,998	12.6 %
Cancelled:	(5,407)	(49,998)	(12.6)%
Balance at 31 December 2020	—	$ —	— %

Business Review and Key Performance Indicators

The Group reported a loss after taxation of $77,329 and a profit after taxation of $7,028 for fiscal 2021 and 2020, respectively. No dividends have been paid in the current or preceding year. There were no share buybacks in 2021 or 2020 and all shares owned by the Group were cancelled during fiscal 2020. During fiscal 2020, the Group issued a total of 20,310 ordinary shares and 488 preferred shares as part of the February 2020 Private Placement and the May 2020 Public Offering, raising total net proceeds of $177,494. See N*ote 17: Called-up Share Capital and Reserves*.

	Fiscal Year		2021 vs. 2020	
	2021	2020	$	%
Turnover	$ —	$ 22,334	$ (22,334)	(100.0)%
Cost of sales	—	(5,742)	5,742	100.0 %
Gross profit	—	16,592	(16,592)	(100.0)%
Research and development costs	(17,104)	(20,442)	3,338	16.3 %
Distribution and administrative expenses	(68,495)	(32,405)	(36,090)	(111.4)%
Intangible asset amortization	—	(406)	406	100.0 %
Loss - changes in fair value of contingent consideration	—	(3,327)	3,327	100.0 %
Gain on disposal of Hospital Products	—	45,760	(45,760)	(100.0)%
Restructuring income	53	43	10	23.3 %
Total	(85,546)	(10,777)	(74,769)	(693.8)%
Operating (loss) profit	(85,546)	5,815	(91,361)	1,571.1 %
Interest income	1,489	673	816	121.2 %
Interest expense	(9,942)	(12,994)	3,052	23.5 %
Gain from release of certain liabilities	217	3,364	(3,147)	(93.5)%
Other expense - changes in fair value of contingent consideration payable	—	(435)	435	100.0 %
Foreign exchange gain (loss)	637	(487)	1,124	230.8 %
Other expense	—	(1,018)	1,018	100.0 %
Loss on ordinary activities before taxation	(93,145)	(5,082)	(88,063)	(1,732.8)%
Taxation credit	15,816	12,110	3,706	30.6 %
(Loss) profit after taxation	$ (77,329)	$ 7,028	$ (84,357)	(1,200.3)%

On 30 June 2020, we announced the sale of the Hospital Products, including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to the Exela Buyer. As a result of the sale, the Group recorded a gain on the sale of the Hospital Products of $45,760 and no longer recorded revenue, cost of sales, intangible amortization and changes to the fair value of the contingent consideration related to these products subsequent to the Closing Date.

Research and Development Cost

R&D cost decreased $3,338 or 16.3% during the year ended 31 December 2021 as compared to the same period in 2020. This decrease was driven by lower clinical studies expense due to the completion of the FT218 clinical study during the year ended December 31, 2020, offset by higher pre-NDA approval activities and higher compensation expense.

Distribution and Administrative Expenses

Distribution and administrative expenses increased $36,090 or 111.4% during the year ended 31 December 2021 as compared to the same prior year. This increase was driven primarily by the Group's continued commercial preparations and launch readiness activities for potential approval of FT218. These activities included an increase in marketing and market research costs of approximately $12,700 and an increase in other launch planning and preparation activities totaling $5,000. Compensation costs increased by approximately $11,000 due to an increase in headcount, primarily in commercial and medical affairs. Legal, technology and insurance costs increased by approximately $7,200.

Interest Income

Interest income on our marketable securities was $1,489 for the year ended 31 December 2021 as compared to $673 for the year ended 31 December 2020. The increase in interest income is driven by higher interest income of approximately $600 and lower realized losses on marketable securities of approximately $300 during the year ended 31 December 2021 compared to the year ended 31 December 2020.

Interest Expense

Interest expense of $9,942 and $12,994 for the years ended 31 December 2021 and 2020, respectively, is related to interest on the 2023 Notes that were issued in February 2018. Included in these amounts are coupon interest expense of $6,469 for each period and the amortization of debt issuance costs of $1,248 and $998 for the year ended 31 December 2021 and 2020,

respectively. Current period interest expense also included $2,225 of additional interest expense owed as a result of not removing a restrictive legend from the 2023 Notes 365 days following original issuance of the 2023 Notes on 16 February 2018. Prior period interest expense also included amortization of a debt discount of $5,527, which is no longer recognized upon our adoption of ASU 2020-06.

Gain from release of certain liabilities

Subsequent to the finalization of the bankruptcy, we recognized non-cash gains of $217 and $3,364 for the years ended 31 December 2021 and 2020, respectively, from the release of certain liabilities that had been retained following the deconsolidation of Avadel Specialty Pharmaceuticals, LLC in February 2019.

Foreign Exchange Losses

We recorded a foreign exchange gain of $637 for the year ended 31 December 2021 compared to a foreign exchange loss of $487 for the year ended 31 December 2020. The foreign exchange gain in the current year is a result of a decrease in the Euro foreign exchange rate during 2021. The foreign exchange loss in the prior year was driven by an increase in the Euro foreign exchange rate during 2020.

Other Expense

Other expense was $0 for the year ended 31 December 2021 as compared to $1,018 for the year ended 31 December 2020. Expense in the prior year was driven by an $800 legal settlement related to a bankruptcy claim.

Taxation

In 2021, the taxation benefit increased by $3,706 when compared to the same period in 2020. The increase in the income tax benefit in 2021 was primarily driven by the additional tax benefit from an increase in the net operating losses in the U.S. in 2021, when compared to the same period in 2020. This was partially offset by the nonrecurring nature of tax benefits recognized in 2020 from the sale of the Group's Hospital Products and passage of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") in the U.S. See *Note 6*: *Taxation Credit* for more discussion.

	Fiscal Year		2021 vs 2020	
Balance Sheet Data:	**2021**	**2020**	**$**	**%**
Cash in bank and in hand	$ 50,708	$ 71,722	$ (21,014)	(29.3)%
Investments	106,513	149,680	(43,167)	(28.8)%
Intangible assets, net	16,836	16,836	—	— %
Creditors	(164,824)	(144,856)	(19,968)	13.8 %
Provision for liabilities	(4,197)	(4,515)	318	(7.0)%
Shareholders' Funds	$ 78,244	$ 162,266	$ (84,022)	(51.8)%

Cash in bank and in hand

Cash in bank and in hand decreased $21,014 driven by the use of cash in operating activities of $77,310, partially offset by net proceeds from marketable securities of $40,455 and proceeds received from the disposal of the Hospital Products of $16,500.

Investments

Investments decreased $43,167 driven by sale of investments to fund operations. There was a net decrease of $26,574 to money market and mutual funds, a net decrease of $9,528 to U.S. government securities, a net decrease of $5,676 to corporate bonds, and a net decrease of $1,389 to other fixed-income securities. See *Note 9: Investments.*

Creditors

Creditors increased $19,968 due to the increase in long-term debt related to the adoption of ASU 2020-06 (see *Note 15*: *Long-Term Debt*), an increase in trade creditors, an increase in accrual compensation, an increase in the operating lease liabilities and

an increase in outsourced contract costs. These increases are partially offset by a decrease in customer allowances and accrued employee severance.

Provision for Liabilities

Provision for liabilities decreased $318, due to amortization of the Guarantee to Deerfield. See *Note 14: Provisions for Liabilities*.

Shareholders' Funds

The decrease in Shareholders' Funds is driven by the net loss of $77,329. See the Consolidated Statement of Changes in Shareholders' Equity and *Note 17: Called-up Share Capital and Reserves*.

Business Strategies

Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of EDS or cataplexy in adults with narcolepsy. We are primarily focused on the development and potential U.S. FDA approval of FT218.

Competition and Market Opportunities

Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing brand or generic specialty pharmaceutical products or drug delivery platforms. Some of these competitors may also be our business partners. There can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our products, including our drug delivery technologies, obsolete or noncompetitive.

The pharmaceutical industry has dramatically changed in recent years, largely as a function of the growing importance of generic drugs. The growth of generics (typically small molecules) and of large molecules (biosimilars) has been accelerated by the demand for less expensive pharmaceutical products. As a result, the pricing power of pharmaceutical companies will be more tightly controlled in the future.

In addition, consolidation has reduced our pool of potential partners and acquisition opportunities within the biopharmaceutical space.

Potential competition for FT218

If FT218 receives FDA approval, it will compete with the currently approved twice-nightly oxybate formulations, as well as a number of daytime wake promoting agents including lisdexamfetamine, detroamphetamine, methylphenidate, amphetamine, modafinil, and armodafinil, which are widely prescribed, as well as solriamfetol and pitolisant, all of which may be prescribed concomitantly with sodium oxybate. If approved, we anticipate FT218 may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer, which allows for entry of an authorized generic in 2023. In addition, there are other products in development that may be approved in the future that could have an impact on the narcolepsy treatment market, including, for example, reboxetine, orexin 2 receptor agonists, flecainide / modafinil combination, histamine H3 antagonists/inverse agonists, or $GABA_B$ agonists.

Intellectual Property

Parts of our product pipeline and strategic alliances utilize our drug delivery platforms and related products of which certain features are the subject of patents or patent applications. As a matter of policy, we seek patent protection of our inventions and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

- FT218 Patents. We have been awarded several FT218-related U.S. patents having expiry dates from mid-2037 to early-2040. We have a number of additional FT218-related patent applications pending at the USPTO as well as at non-U.S. patent offices.

- Drug Delivery Technology Patents. Our drug delivery technologies are the subject of certain patents, including: (i) for Micropump, patents relating to coating technologies that provide for controlled release of an active ingredient (expiring in 2025 in the U.S. and 2022 in non-U.S. jurisdictions); (ii) for LiquiTime, patents relating to film-coated microcapsules and a method comprising orally administering such microcapsules to a patient (expiring in 2023); and (iii) for Medusa, patents relating to an aqueous colloidal suspension of low viscosity based on submicronic particles of water-soluble biodegradable polymer PO (polyolefin) carrying hydrophobic groups (expiring in 2023).

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any of our licensed or owned patents will provide sufficient protection from competitors. Any of our licensed or owned patents may be challenged, circumvented, or invalidated by third parties. For more information, please see the information set forth under the caption "Risks Related to Our Intellectual Property – If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete" in the "Risk Factors".

Supplies and Manufacturing

We attempt to maintain multiple suppliers in order to mitigate the risk of shortfall and inability to supply market demand. Nevertheless, for FT218, we currently rely on one supplier for sourcing active pharmaceutical ingredients ("APIs").

The API in FT218, sodium oxybate, is a Schedule I controlled substance in the U.S., and FT218, if approved by the FDA, will be a Schedule III controlled substance in the U.S. As a result, FT218 is subject to regulation by the U.S. Drug Enforcement Administration ("DEA") under the Controlled Substances Act ("CSA"), and its manufacturing and distribution are highly restricted. Quotas from the DEA are required in order to manufacture and package sodium oxybate and FT218 in the U.S. Similar rules, restrictions and controls apply to FT218 in relevant jurisdictions outside of the U.S.

The API for FT218 is currently manufactured by a single source contract manufacturing organization ("CMO") in the U.S. The drug product for commercial lots is manufactured outside of the U.S. by a single source CMO. We will continue to outsource the production of FT218 to current good manufacturing practices ("cGMP") -compliant, DEA and FDA-audited CMOs pursuant to supply agreements and have no present plans to acquire manufacturing facilities. We are establishing, and may continue to establish, additional CMOs for the manufacture FT218, including drug product manufacturing in the U.S.

Principal Risks and Uncertainties

An investment in Avadel involves a high degree of risk. You should carefully consider the risks described below, as well as the other information included in the Directors' Report and accompanying financial statements, before making an investment decision. Avadel's business, financial condition, results of operations and cash flows could be materially adversely affected by any of these risks. The market or trading price of Avadel's securities could decline due to any of these risks.

Risks Related to Our Lead Product Candidate, Future Product Candidates Clinical Development and Commercialization

We cannot be certain that our lead product candidate or future product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our lead product candidate or future product candidates.

We have devoted significant financial resources and business efforts to the development of our lead product candidate. We cannot be certain that our lead product candidate or future product candidates will receive marketing approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the U.S. and by comparable regulatory authorities in other countries. We are not permitted to market our lead product candidate or future product candidates in the U.S. until we receive approval of a NDA by the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the

commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. For example, we submitted an NDA to the FDA for FT218 for the treatment of EDS or cataplexy in adults with narcolepsy to the FDA in December 2020 through the Section 505(b)(2) regulatory pathway. In February 2021, the FDA assigned FT218 a PDFUA target action date of 15 October 2021. In October, the FDA notified us that its review was still ongoing and action would not be taken by the PDUDFA date. Any delay or setback in the regulatory approval or commercialization of our lead product candidate will adversely affect our business.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our lead product candidate;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidate;
- may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our lead product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our lead product candidate.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

We have submitted a NDA for FT218 in the U.S. and will evaluate filing potentially elsewhere. We have determined, following FDA consultation, that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on the FDA's previous findings of safety or effectiveness and data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a FT218 NDA. There can be no assurances, however, that the 505(b)(2) approval pathway in the U.S., or similar approval pathways outside of the U.S., will be available for FT218 or that the FDA or other regulatory authorities will approve FT218 through an application based on such pathways.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the

U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidate.

Our business is significantly dependent on the successful development, regulatory approval and commercialization of FT218, our only product candidate.

We have invested substantially all of our efforts and financial resources in the development of FT218, which has not yet been approved for sale or commercial use. Currently, FT218 is our only product candidate and we have not licensed, acquired, or invented any other product candidates for preclinical or clinical evaluation. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend entirely on the regulatory approval and commercialization of FT218, which may never occur. Any failure to obtain regulatory approval of FT218 would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market FT218, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of FT218, even if approved.

The commercial success of FT218 will depend on a number of factors, including the following:

- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- our ability to raise any additional required capital to support the commercialization on acceptable terms, or at all;
- our ability to consistently manufacture FT218 on a timely basis;
- our ability to secure and maintain from the U.S. DEA our annual quota for FT218 APIs;
- our ability to successfully to develop and implement a REMS for the safe use of FT218;
- the prevalence, duration and severity of potential side effects or other safety issues that patients may experience with FT218;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to FT218;
- the differentiation of FT218 from other available approved, or investigational, drugs and treatments of excessive daytime sleepiness or cataplexy in adults with narcolepsy, and the willingness of physicians, operators of hospitals and clinics and patients to adopt and utilize FT218's once nightly formulation;
- our ability to successfully develop a commercial strategy and thereafter commercialize FT218 in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for FT218;
- patients' ability and willingness to pay out-of-pocket for FT218 in the absence of coverage and/or adequate reimbursement from third-party payor;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of FT218, if approved;
- patient demand for FT218, if approved;
- our ability to establish and enforce intellectual property rights in and to FT218; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize FT218. Even if regulatory approvals are obtained, we may never be able to successfully commercialize FT218. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of FT218 to continue our business or achieve profitability.

Our lead product candidate and future product candidates may not reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of new drugs and products that utilize our drug delivery technologies.

Even if our product candidates and current drug delivery technologies appear promising during development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the FDA, the EMA, the competent authority of an EU Member State or an IRB, or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our drug delivery technologies and drug products may be found to be ineffective or to cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find that certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce;
- we or our partners may face delays in completing our clinical trials due to circumstances outside of our control, including natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism; or
- our lead product candidate and future product candidates could fail to obtain regulatory approval or, if approved, could fail to achieve market acceptance, could fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or could be precluded from commercialization by proprietary rights of third parties.

If we are not able to use the 505(b)(2) regulatory approval pathway for the regulatory approval of FT218 or if the FDA requires additional clinical or nonclinical data to support an NDA under Section 505(b)(2) than we previously anticipated, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for FT218, and in any case may not be successful.

We submitted an NDA to the FDA for FT218 for the treatment of cataplexy or EDS in adults with narcolepsy in December 2020 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 Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or the FDCA. In general, Section 505(b)(2) allows an applicant to rely on the FDA's prior findings of safety or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares common characteristics with the listed drug, or on published literature that the applicant believes supports the safety or efficacy of its proposed product but for which it does not have a right of reference for the underlying data. The 505(b)(2) application must include sufficient data to support differences between the listed drug and the proposed drug in the 505(b)(2) application. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for FT218, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. Specifically, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. Although the active ingredient in FT218, sodium oxybate, is approved for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy, it has not previously been approved or demonstrated to be safe for once nightly administration in these indications. If we are unable to establish a bridge between FT218 and the listed drug upon which we rely to demonstrate that such reliance is justified, we may be required to show safety and efficacy through one or more additional clinical trials. In addition, if we are unable to utilize the 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for FT218 would likely increase substantially. Moreover, the inability to utilize the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than FT218, which could materially adversely impact its competitive position and prospects.

Even if we are successful in pursuing the 505(b)(2) regulatory pathway for FT218, we cannot assure you that we will receive the requisite or timely approval for commercialization of FT218. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved listed drugs or on published literature for which we do not have a right of reference, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of FT218 is insufficient or not applicable to our application or that additional studies will need to

be conducted. To the extent that we are relying on the 505(b)(2) regulatory pathway based on the approval of a listed drug for a similar indication, the FDA may require that we include in the labeling of FT218, if approved, some or all of the safety information that is included in the labeling of the approved listed drug. For example, the labels of current FDA-approved sodium oxybate products include a black box warning regarding risks of central nervous system depression and abuse and misuse. Moreover, even if FT218 is approved via the 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the product 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 product, such as a Risk Evaluation and Mitigation Strategy, or REMS, which is a risk mitigation plan which could include medication guides, physician communication plans, or elements to assure safe use, or ETASU, such as restricted distribution methods, patient registries and other risk minimization tools.

Our business depends heavily on our ability to successfully commercialize FT218 in the U.S. and in other jurisdictions where we may obtain marketing approval. There is no assurance that our commercialization efforts with respect to FT218, if approved, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.

Our business currently depends heavily on our ability to successfully commercialize FT218 for the treatment of cataplexy or EDS in adults with narcolepsy in the U.S. and in other jurisdictions where we may obtain marketing approval. Even if we obtain marketing approval for FT218, we may never be able to successfully commercialize our product or meet our expectations with respect to revenues. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we are building for the commercialization of FT218 in the U.S., or that we may build for other jurisdictions where we may obtain marketing approval, will be sufficient for us to achieve success at the levels we expect. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218, if approved. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes.

We may encounter issues and challenges in commercializing FT218, if approved, and generating sufficient revenues to result in a profit. We may also encounter challenges related to reimbursement of FT218, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering FT218. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. We may face other limitations or issues related to the price of FT218. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Other factors that may hinder our ability to successfully commercialize FT218, if approved, and generate sufficient revenues to result in a profit, include:

- the acceptance of FT218 by patients and the medical community;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of FT218 in sufficient quantities at acceptable costs, to remain in good standing with regulatory agencies, maintain applicable registrations and licenses, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with current Good Manufacturing Practices, or cGMP, regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA- or other foreign regulatory agency-mandated package insert requirements and successful completion of any related FDA or other foreign regulatory agency post-marketing requirements, including a REMS;
- the actual market size for FT218, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- the sufficiency of our drug supply to meet commercial demand which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;
- our ability to effectively complete with other therapies; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to FT218.

Any of these issues could impair our ability to successfully commercialize our product, if approved, or to generate sufficient revenues to result in a profit or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. Even if approved, there is no guarantee that we will be successful in our commercialization efforts with respect to FT218. We may also experience significant fluctuations in sales of FT218 from period to period and, ultimately,

we may never generate sufficient revenues from FT218 to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize FT218 in the U.S. and any other international markets where it may be approved or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218, if approved. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes.

Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that FT218 is safe and effective in clinical trials could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. For example, we are currently conducting an open-label extension ("OLE") switch study of FT218, RESTORE, to examine the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in our REST-ON trial, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218 regardless if they participated in REST-ON or not. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study. If any participants in the OLE/switch study report any serious adverse events that are deemed to be related to FT218 or if FT218 is not observed to have long-term efficacy, our business, financial condition, results of operations and growth prospects could be material and adversely affected.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including delay or failure in:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- obtaining clinical materials or manufacturing sufficient quantities of FT218 for use in clinical trials.

We have limited experience as a commercial drug company targeting an orphan drug disease and the marketing and sale of FT218, if approved, may be unsuccessful or less successful than anticipated.

We have limited experience as a commercial drug company targeting an orphan disease and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully obtaining marketing approval and marketing and selling FT218, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drug;
- obtain adequate pricing and reimbursement for FT218;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to marketing approvals and commercialization in multiple jurisdictions, if approved.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize FT218, raise capital, expand our business or continue our operations.

Our relationships with healthcare providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biotechnology and biopharmaceutical products. Arrangements with third-party payors and customers can expose biotechnology and biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, or AKS, and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biotechnology and biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. See the section entitled, "*Business — Government Regulation — Healthcare laws*".

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with 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 administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the sections entitled, "*Business — Government Regulation — Coverage and Reimbursement*" and "*Business — Government Regulation — Healthcare Laws*".

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party depends upon a number of factors.

In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. See the section entitled, "*Business — Government Regulation — Healthcare Reform*".

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

FT218, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to product candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.

Undesirable side effects caused by FT218, if successfully developed and approved, could limit the commercial profile of FT218 or result in significant negative consequences such as a more restrictive label or other limitations or restrictions. Undesirable side effects caused by FT218 could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of FT218 may only be uncovered with a significantly larger number of patients exposed to the drug, and those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by FT218 (or any other similar drugs), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their marketing approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;

- regulatory authorities may refuse to approve label expansions for additional indications for any approved drugs;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drugs;
- regulatory authorities may require a modification of an existing REMS to mitigate risks;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove FT218 from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking FT218; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of FT218, if approved, and could substantially increase the costs of commercializing FT218 and significantly impact our ability to successfully commercialize FT218 and generate revenues.

We may incur significant liability if governmental authorities allege or determine that we are engaging in commercial activities or promoting FT218 in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, if FT218 is approved, we may not promote FT218 in the U.S. for any indications other than its FDA-approved indication. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses, including promoting unapproved dosing regimens, may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We currently, and intend to increasingly, engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

Obtaining and maintaining regulatory approval of FT218 in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of FT218 in other jurisdictions.

Obtaining and maintaining regulatory approval of FT218 in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of FT218, comparable regulatory authorities in foreign jurisdictions must also approve FT218 in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of FT218 in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our market will be reduced and our ability to realize the full market potential of FT218 will be harmed.

Laws and regulations governing international operations we have and may expand in the future may preclude us from developing, manufacturing, and selling certain product candidates and products outside of the U.S. and require us to develop and implement costly compliance programs.

As we seek to expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that

accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Similar laws in other countries, such as the U.K. Bribery Act 2010, may apply to our operations.

Various laws, regulations, and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside of the U.S. in key European markets, we must dedicate additional resources to comply with these laws, and such laws may preclude us from developing, manufacturing, or selling certain product candidates and products outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Governments outside of the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing authorization for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If we seek approval for our lead product candidate or future product candidates outside of the U.S. and reimbursement of our lead product candidate or future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.

The costs of compliance with privacy and security laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with any compliance failures could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA and the General Data Protection Regulation (“GDPR”), (Regulation EU 2016/679). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many U.S. states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. GDPR requires Avadel to ensure personal data collected by Avadel is gathered legally and under strict conditions and to protect such personal data from misuse and exploitation. If Avadel fails to comply with HIPAA, GDPR or other similar laws, we will face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Requirements

We incurred a net loss in 2021 and we will likely incur a net loss in 2022, and if we are not able to regain profitability in the future, the value of our shares may fall.

Although we reported a net income for the year ended 31 December 2020 due to the gain on the sale of our Hospital Products, we incurred a net loss of $77,329 for the year ended 31 December 2021. We do not expect to become profitable in the near future, and may never achieve profitability. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to recognize revenues from the commercialization of FT218, if approved. We have devoted significant financial resources to research and development, including our clinical development activities, and the pursuit of regulatory approval for FT218. If we obtain marketing approval, our future revenues will depend upon the size of any markets in which FT218 and any future products have received approval, and our ability to achieve sufficient market acceptance,

reimbursement from third-party payors and adequate market share for our product and any future products in those markets. In addition, we are in the process of building a sales organization and supporting commercial infrastructure and, accordingly, we will incur significant expenses as we continue to develop a sales organization and commercial infrastructure in advance of generating any commercial product sales. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the timely receipt of necessary approvals from the FDA for the commercialization of FT218;
- our ability to obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- the effectiveness of our sales and marketing strategy;
- the demand and market size for FT218;
- the level of product and price competition for FT218;
- our ability to develop new partnerships and additional commercial applications for FT218 and any future product candidates;
- our ability to control our costs;
- the initiation of additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- our ability to acquire or in-license other product candidates and technologies;
- our ability to maintain, protect and expand our intellectual property portfolio;
- general economic conditions.

Even if the FDA approves our NDA for FT218, we may never recognize revenue in amounts sufficient to achieve and maintain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of the equity interest of the holders of ADSs.

We may require additional financing to fund the development and possible acquisition of new products and businesses. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize FT218, if approved. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery technologies, develop new products, or acquire additional products and businesses. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and drug delivery technologies;
- the progress of our research and product development programs; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, we may seek to issue additional ADSs representing our ordinary shares, or issue equity-linked debt, or we may choose to issue preferred shares, in either case through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to the holders of ADSs. We could also be required to seek funds through arrangements with collaborative partners and we may be required to relinquish rights to some of our product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

Our net loss and use of cash in operating activities may limit our ability to fully pursue our business strategy.

We reported net loss of $77,329 in 2021. We reported cash used in operating activities of $77,310. Cash and marketable securities as of 31 December 2021 totaled $157,221. Our business strategy is to primarily focus on the development and potential FDA approval of FT218 for the treatment of EDS or cataplexy in adults with narcolepsy. The successful pursuit of all

components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. We will likely incur a net loss in 2022 and, if we use existing cash and marketable securities, there is no guarantee that we would be able to generate additional cash through our operations or through financing. Failure to implement any component of our strategy may prevent us from achieving profitability in the future or may otherwise have a material adverse effect on our financial condition and results of operation.

Risks Related to Regulation

The distribution and sale of FT218, if approved, will be subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory requirements will subject us to risks and uncertainties, any of which could negatively impact sales of FT218, if approved.

The active pharmaceutical ingredient, or API, of FT218 is a form of gamma-hydroxybutyric acid, or GHB, a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, the FDA requires that sponsors of sodium oxybate products, such as FT218, if approved, maintain a REMS to help ensure that the benefits of the drug in treatment of EDS or cataplexy in adults with narcolepsy outweigh the serious risks of the drug. A REMS imposed on FT218, if approved, may impose extensive controls and restrictions on the sales and marketing of FT218 that we will be responsible for implementing. Any failure to demonstrate our substantial compliance with any REMS obligations, including as a result of business or other interruptions resulting from the evolving effects of the COVID-19 pandemic, or a determination by the FDA that the REMS is not meeting its goals, could result in enforcement action by the FDA, lead to changes in our REMS obligations, negatively affect sales of FT218, result in additional costs and expenses for us or require us to invest a significant amount of resources, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the REMS for FT218, if approved. Any modifications approved, required or rejected by the FDA could change the safety profile of FT218, and have a significant negative impact in terms of product liability, public acceptance of FT218 for treatment of cataplexy or EDS in adults with narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, FT218, any of which could have a material adverse effect on our business. Modifications approved, required or rejected by the FDA could also make it more difficult or expensive for us to distribute FT218, make distribution easier for sodium oxybate competitors, disrupt continuity of care for FT218 patients or negatively affect sales of FT218.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to the FDA. As required by the FDA, and similarly for other regulatory agencies, the adverse event information that we collect for FT218, if approved, must be regularly reported to the FDA and could result in the FDA requiring changes to FT218's labeling, including additional warnings or boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of FT218.

Any failure to demonstrate our substantial compliance with a REMS required for FT218, if approved, or any other applicable regulatory requirements to the satisfaction of the FDA or another regulatory authority could result in such regulatory authorities taking actions in the future which could have a material adverse effect on sodium oxybate product sales and therefore on our business, financial condition, results of operations and growth prospects.

Disruptions at the FDA, the DEA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, DEA and other agencies may also increase the time necessary for new product candidates to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC,

have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

As of 26 May 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical U.S. and non-U.S. inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain its current pace and approval timelines could be extended due to the ongoing COVID-19 pandemic. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. We cannot guarantee that the FDA, DEA and other agencies, as applicable, will be able to complete any required inspections or take other necessary actions in respect to our product candidate or future product candidates.

FT218, if approved by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.

Under the Orphan Drug Act, as amended, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population of 200,000 or more where there is no reasonable expectation that the cost of developing the drug for the rare disease or condition will be recovered from sales of the drug in the U.S. Generally, if a drug with orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for seven years, except in limited circumstances, such as if the FDA concludes that a subsequent same drug is clinically superior through greater safety, greater effectiveness, or a major contribution to patient care. In assessing whether a drug provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case-by-case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses and potential for self-administration.

Although FT218 obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018, there is no guarantee that we will obtain approval or orphan drug exclusivity for FT218. Orphan drug designation does not give a product candidate any advantage in, or shorten the timeline for, the FDA regulatory review and approval process. In addition, because FT218 would not be the first sodium oxybate product to be approved for the treatment of narcolepsy, we must demonstrate that FT218 is clinically superior to any previously approved same drug in order to obtain orphan drug exclusivity for FT218, and we may be required to demonstrate clinical superiority for the approval and exclusivity of other product candidates in the future. However, such a demonstration may be difficult to establish and there can be no assurance that we will be successful in these efforts. Even if we obtain orphan drug exclusivity for FT218, that exclusivity may not effectively protect FT218 from competition because different drugs can be approved for the same condition. In addition, the FDA could determine that unexpired orphan drug exclusivity for an approved product that is determined to be the same drug could delay the approval of FT218 unless we are able to demonstrate that FT218 is clinically superior to such approved product. Moreover, any orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of FT218 to meet the needs of patients with the particular rare disease or condition. The FDA may reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes, the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

The API in FT218, sodium oxybate, is a controlled substance subject to U.S. federal and state controlled substance laws and regulations and applicable controlled substance legislation in other countries, and our failure, or the failure of third-parties on whom we rely, to comply with these laws and regulations, or the cost of compliance with these laws and regulations, could materially and adversely affect our business, results of operations, financial condition and growth prospects.

FT218 contains a controlled substance as defined in the CSA. Controlled substances are subject to a number of requirements and restrictions under the CSA and implementing regulations, including certain registration, security, recordkeeping, reporting, manufacturing and procurement quotas, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, heightened security requirements and additional criteria for importation. The API of FT218, oxybate salts, are regulated by the DEA as Schedule I controlled substances, and FDA-approved products containing oxybate salts, including sodium oxybate, are currently Schedule III.

Individual states have also established controlled substance laws and regulations. Although state-controlled substances laws often mirror federal law, they may separately schedule our product candidates. We or our partners may also be required to obtain separate state registrations, permits or licenses in order to be able to manufacture, research, distribute, import, export, administer or prescribe controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

U.S. facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing of controlled substances must be registered (licensed) to perform these activities and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations and corresponding state requirements. DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations, obtaining and maintaining quotas and complying with the regulatory obligations may result in delay of the importation, export, manufacturing, distribution or research of our lead product candidate and our commercial product, if approved, and any future products candidates or products. Furthermore, failure to maintain compliance with the CSA and DEA and state regulations by us or any of our contractors, distributors or pharmacies can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. In addition, if we change any third-party upon whom we rely to conduct our research, manufacturing, distributing, importing, exporting, or dispensing activities, doing so will result in additional costs and expenses and may take a significant amount of time, and we may be unsuccessful in identifying a new, satisfactory third-party, any of which could materially and adversely affect our business, financial condition, and results of operations. DEA and state regulatory bodies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal penalties.

Because FT218 contains sodium oxybate, to conduct clinical trials with FT218 in the U.S. prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that allows those sites to handle and dispense FT218 and to obtain the product candidate. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. In the event the product candidate would be made outside the U.S., the importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import.

We and our manufacturing partners in the U.S. are subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, even though FT218, if approved, will be classified as Schedule III, the active ingredient in the final dosage form, sodium oxybate, is a Schedule I controlled substance and will continue be subject to such quotas as long as it remains classified as Schedule I. The annual quota allocated to us or our U.S. manufacturing partners for sodium oxybate may not be sufficient to complete clinical trials or meet commercial demand of FT218, if approved. Consequently, any delay or refusal by the DEA in establishing our, or U.S. manufacturing partner's, procurement and/or production quota for controlled substances could delay or stop our clinical trials or commercial activities, if approved, which could have a material adverse effect on our business, financial position and results of operations.

If approved, FT218 will be classified as a Schedule III substance and an importer can import it for commercial purposes if it obtains the appropriate registrations and licenses from the DEA, including an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. To the extent an importer is utilized for commercial purposes, failure by any current importer or future importer that we identify as an importer, if any are available, to obtain and maintain the necessary import authority from the DEA and other applicable regulatory authorities, including specific quantities, could affect the availability of FT218 and have a material adverse effect on our business, results of operations and financial condition.

Governments outside of the U.S. have similar controlled substance laws, regulations and requirements in their respective jurisdictions, and our failure, or the failure of third parties upon whom we rely, to comply with applicable controlled substance laws, regulations and requirements or secure necessary authorizations would result in similar risks to those described above.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to our Reliance on Third-Parties

We rely, and intend to continue to rely on single source providers for the development, manufacture and supply of FT218, and if we experience problems with these suppliers, or they fail to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, our business would be materially and adversely affected.

Currently, we use single source providers for the development, supply of clinical materials and supply of commercial batches for our lead product candidate, FT218. We do not own or operate manufacturing facilities for clinical or commercial manufacture of FT218. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture FT218 clinical or commercial scale. There can be no assurance that our clinical development or commercial product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable quantities or prices to meet commercial demand, if FT218 is approved. If the supplies of these products or materials were interrupted for any reason, including but not limited to, natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism, delays at the manufacturer, delays related to quality control, delays related to the supply chain and the manufacturing and supply of certain products could be delayed. If the supplies of these products or materials were interrupted for any reason, our manufacturing, clinical development or commercial activities, if approved, of FT218 could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current cGMP requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of FT218 by our contract development and manufacturing organizations ("CDMOs").

Additionally, our third-party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drug. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We contract with third parties for the manufacture of FT218 for clinical testing and expect to continue to do so throughout commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of FT218 for clinical testing, as well as for the commercial manufacture of our product if FT218 receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by CDMOs generally must be inspected by the FDA pursuant to pre-approval inspections conducted as a part of the FDA's review of an NDA. We do not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs in connection with the manufacture of our product candidate. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidate or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidate, if approved.

CDMOs upon whom we rely are also required to comply with the CSA, DEA regulations and other applicable controlled substance laws, regulations and requirements in other countries, where applicable, including and those relating to licensing and registration requirements. The inability of our CDMOs to maintain compliance with applicable controlled substance laws, regulations and requirements and obtain and maintain the necessary licenses and registrations could have a material adverse effect on our business, including our clinical trials, commercial activities, if approved, financial position and results of operations.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidate or product, if approved, may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations, including those relating to controlled substances. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate or product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop FT218 or commercialize our product, if approved, in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate or product that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidate or product. In addition, in the case of CDMOs that supply our product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;

- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current CDMOs cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We outsource important activities to consultants, advisors and outside contractors.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, advisors and outside contractors. If we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by such third parties is compromised for any reason, our development activities may be extended, delayed or terminated which would have an adverse effect on our development program and our business.

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

We are highly dependent on the expertise of Gregory J. Divis, our Chief Executive Officer, Thomas S. McHugh, our Chief Financial Officer, and Richard J. Kim, our Chief Commercial Officer, as well as the other key members of our management, scientific, clinical and commercial team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to obtain FDA approval for FT218 may make it more challenging to recruit and retain qualified personnel.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We currently employ approximately 66 full-time employees. As we mature and commercialize FT218, if approved, we expect to expand our full-time employee base. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize FT218 and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We rely on third parties to conduct our clinical trials, and if they do not properly and successfully perform their contractual, legal and regulatory duties, we may not be able to obtain regulatory approvals for or commercialize FT218 and future product candidates.

We rely on CROs and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as a high priority, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and foreign regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and foreign. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, CROs or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or foreign regulatory agencies will determine that any of our clinical trials comply with good clinical practices.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidate and future product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

If we or our partners fail to comply with these laws and regulations, the FDA, or other foreign regulatory agencies, may take actions that could significantly restrict or prohibit commercial distribution of FT218. If the FDA or other foreign regulatory authorities determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of a particular country;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- withdraw approval of marketing applications; and
- initiate criminal prosecutions.

We may rely on collaborations with third parties to commercialize FT218 outside of the U.S., if approved, and certain of our future product candidates and such strategy involves risks that could impair our prospects for realizing profits from such products.

We expect that the commercialization of FT218 outside of the U.S., if approved, or future product candidates may require collaboration with third-party partners involving strategic alliances, licenses, product divestitures or other arrangements. We may not be successful in entering into such collaborations on favorable terms, if at all, or our collaboration partners may not adequately perform under such arrangements, and as a result our ability to commercialize these products will be negatively affected and our prospects will be impaired.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for FT218 or future product candidates, the potential of competing products, the existence of uncertainty with respect to our ownership of our intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the

one with us for FT218. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our product candidates for which we are seeking to collaborate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop FT218 outside of the U.S., if approved, or future product candidates, or bring these products to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Our Intellectual Property

If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete.

Our success depends, in part, on our ability to obtain and enforce patents and other intellectual property rights for our product candidate and future product candidates and technology, including our drug delivery technologies, and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our technologies and deprive us of the ability to realize revenues and profits from our product candidate and future product candidates and technologies.

To the extent any of our product candidate and future product candidates may benefit from protections afforded by patents, we face the risk that patent law relating to the scope of claims in the pharmaceutical and biotechnology fields is continually evolving and can be the subject of uncertainty and may change in a way that would limit protection. If challenged, a court or other body may determine that our patents may not be exclusive, valid or enforceable. For example, our patents may not protect us against challenges by companies that submit drug marketing applications to the FDA, or the competent authorities of EU Member States or other jurisdictions in which we may attempt to compete, in particular where such applications rely, at least in part, on safety and efficacy data from our product candidate and future product candidates. In addition, competitors may obtain patents that may have an adverse effect on our ability to conduct business, or they may discover ways to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our product candidate and future product candidates or to exclude competing products. Any patent applications we have made or may make relating to our potential products or technologies may not result in patents being issued. Even after issuance, our patents may be challenged in the courts or patent offices in the U.S. and elsewhere. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidate and future product candidates. Further, patent protection once obtained is limited in time, after which competitors may use the covered product or technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the remaining period of effective patent protection for a marketed product is frequently substantially shorter than the full duration of the patent. While a patent term extension can be requested under certain circumstances, the grant of such a request is not guaranteed.

Our partnerships with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented products or technology confidential.

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

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position.

To protect our product candidate, trade secrets and proprietary technologies, we rely, in part, on confidentiality agreements with our employees, suppliers, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or technologies, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

If we and our partners do not adequately protect the trademarks and trade names for our products, then we and our partners may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our competitors or other third parties may challenge, infringe or circumvent the trademarks or trade names for our products. We and our partners may not be able to protect these trademarks and trade names. In addition, if the trademarks or trade names for one of our products infringe the rights of others, we or our partners may be forced to stop using the trademarks or trade names, which we need for name recognition in our markets of interest. If we cannot establish name recognition based on our trademarks and trade names, we and our partners may not be able to compete effectively and our business may be adversely affected.

Changes in U.S. or ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidate and future product candidates.

Changes in either the patent laws or interpretation thereof in the U.S. or in ex-U.S. jurisdictions could increase uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the Leahy-Smith America Invents Act of 2011 ("AIA"), changed the previous U.S. "first-to-invent" system to the current system that awards a patent to the "first-inventor-to-file" for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and limits the ability to rely on prior research to lay claim to patent rights. Under the current system, disputes are resolved through new derivation proceedings, and the AIA includes mechanisms to allow challenges to issued patents in reexamination, *inter partes* review and post grant proceedings. The AIA also includes bases and procedures that may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The AIA may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S. may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals may be particularly uncertain. Depending on future actions by the U.S. Congress, the U.S. federal courts, and the USPTO, or by similarly legislative, judicial, and regulatory authorities in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Third parties may claim that our product candidate or future product candidates infringe their rights, and we may incur significant costs resolving these claims. Additionally, legal proceedings related to such claims could materially delay or otherwise adversely affect commercialization plans related to our product candidate, if approved.

Third parties may claim infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products. For example, in connection with us seeking regulatory approval for a product candidate, a third party may allege that our product candidate infringes its patents or other intellectual property rights and file suit to delay/prevent regulatory approval and/or commercialization of such product. In response to any claim of infringement, we may choose or be forced to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court or administrative proceedings. If we cannot obtain required licenses on commercially reasonably terms, or at all, are found liable for infringement or are not able to have such patent rights declared

invalid or unenforceable, our business could be materially harmed. We may be subject to claims (and even held liable) for significant monetary damages (including enhanced damages and/or attorneys' fees), encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. Even if a license is available, it may not be available on commercially reasonable terms or may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. We may not have identified, or be able to identify in the future, U.S. or non-U.S. patents that pose a risk of potential infringement claims.

In addition to the possibility of intellectual property infringement claims, a third party could submit a citizen's petition to the FDA requesting relief that, if granted, could materially adversely affect the NDA and/or underlying product candidate. For example, such a third-party petition could, if granted, materially adversely affect the likelihood and/or timing of NDA approval, content of final product labeling, and/or resulting regulatory exclusivity (if any) for such product.

Parties making claims against us may be able to sustain the costs of patent litigation more effectively than we can because they have substantially greater resources. In addition, any claims, with or without merit, that our product candidate, future product candidates or drug delivery technologies infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our financial positions and operating results.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

FT218 was submitted under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables the applicant to reference published literature for which the applicant does not have a right of reference and the FDA's previous findings of safety and effectiveness for a previously approved drug.

For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply. Accordingly, if the applicant relies for approval on the safety or effectiveness on information for a previously approved drug, referred to as a listed drug, the applicable is required to include patent certifications in our 505(b)(2) NDA regarding any applicable patents covering the listed drug. If there are applicable patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and the applicant seeks to obtain approval prior to the expiration of one or more of those patents, the applicant is required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. While we did not submit any Paragraph IV certifications in connection with our 505(b)(2) NDA for FT218, there can be no assurance that we will not be required to submit a Paragraph IV certification in respect of FT218 or any future product candidates for which we seek approval under Section 505(b)(2).

If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner. Under the Hatch-Waxman Amendments, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) NDAs and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit a Section 505(b)(1) NDA or a Section 505(j) ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours and determines that our product is inappropriate for review through the 505(b)(2) pathway. These factors, among others, may limit our ability to commercialize our product candidates successfully.

If we or our partners are required to obtain licenses from third parties, our revenues and royalties on any future commercialized products could be reduced.

The development of certain products based on our drug delivery technologies may require the use of raw materials (*e.g.,* proprietary excipient), active ingredients, drugs (*e.g.,* proprietary proteins) or technologies developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our partners must obtain licenses from third parties, fees may be required for such licenses, which could reduce the net revenues and royalties we receive on any future commercialized products that incorporate our drug delivery technologies.

Patent terms may be inadequate to protect our competitive position on our product candidate or future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidate and future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel to coordinate payment of these fees due to patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on our product candidate and future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our product candidate and future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

advantage from the intellectual property we develop or license.

Risks Related to Acceptance, Sales, Marketing and Competition

If we are unable to establish effective sales, marketing and distribution capabilities for FT218, if approved, or enter into agreements with third parties to market, sell and distribute our product candidate, if approved, or if we are unable to achieve market acceptance for FT218, our business, results of operations, financial condition and prospects will be materially adversely affected.

We are continuing to build the systems, processes, policies, relationships and materials necessary for the launch of FT218 in the U.S. for the treatment of cataplexy or EDS in adults with narcolepsy. If we receive regulatory approval to market or sell FT218, but are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218.

We have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our medicines. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize FT218 may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in launching medicines.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for FT218 in any country or region, we will likely pursue collaborative arrangements regarding the sales and marketing of FT218. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized FT218 ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our medicines.

Any of these issues could impair our ability to successfully commercialize FT218 or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenues or profits. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to FT218, if approved, or with respect to any other product candidate that may be approved in the future.

If the market opportunities for FT218 are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

FT218 is an investigational formulation of sodium oxybate designed to be taken once at bedtime for the treatment of EDS or cataplexy in adults with narcolepsy. Our estimates of the market opportunities for FT218 are based on the estimated market size for the twice-nightly administration of sodium oxybate, which is the current standard of care for EDS or cataplexy in patients with narcolepsy, and our expectations with regard to FT218's potential to take a significant share of this market. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The potential target population for FT218 may turn out to be lower or more difficult to identify than expected. Even if we obtain significant market share for FT218 in this indication, because the potential target population for FT218 is small, we may never achieve profitability without obtaining marketing approval for additional indications.

Any of these factors may negatively affect our ability to recognize revenues from sales of FT218 and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

FT218, if approved, may not gain market acceptance.

FT218, if approved, may not gain market acceptance among physicians, patients, healthcare payor and medical communities. The degree of market acceptance of FT218, if approved, will depend on a number of factors, including, but not limited to:

- the clinical indications for which FT218 is approved and any restrictions placed upon the product in connection with its approval, such as a REMS or equivalent obligation by other regulatory authorities, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which FT218 is approved and its diagnosis;
- scheduling classification of sodium oxybate as a controlled substance regulated by the DEA;
- demonstration of the clinical safety and efficacy of the product or technology;
- the absence of evidence of undesirable side effects of the product or technology that delay or extend trials;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand;
- physicians' decisions relating to treatment practices based on availability;
- physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the FT218 REMS, if approved;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness and related access to payor coverage;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement or other assistance for patients who are uninsured or underinsured; and
- the marketing and distribution support it receives.

If FT218, if approved, fails to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

FT218, if approved, will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of FT218 from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of FT218, if approved, and ongoing regulation of our product, may limit how we manufacture and market FT218 and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

If approved, FT218, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for FT218, will be subject to continual requirements of and review by the FDA and other applicable regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

In the U.S., the FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the FDA and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary recall of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Similarly, failure to comply with applicable regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

In addition, we and our CDMOs will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, quality control and distribution. Under the DSCSA, for certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the PDMA, which regulations the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Prescription drug products must also meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. We, our CDMOs and other third parties upon whom we rely will be subject to applicable controlled substances laws, regulations and requirements. If FT218 is approved and we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for FT218 withdrawn by regulatory authorities and our ability to market FT218 could be limited, which could adversely affect our ability to achieve or sustain profitability and we could be subject to substantial penalties. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If our competitors develop and market technologies or products that are safer, more effective or less costly than ours, or obtain regulatory approval and market such products before we do, our commercial opportunity may be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with other pharmaceutical and biotechnology companies.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, FT218, if approved, would adversely affect sales of our product candidate. For example, in the future, we expect FT218 to face competition from manufacturers of generic twice-nightly sodium oxybate formulations who have reached settlement agreements with the current brand product marketer. Hikma Pharmaceuticals is expected to launch an authorized generic version of twice-nightly sodium oxybate in 2023 or earlier, depending on certain circumstances. Beyond 2023, there are other potential future competitive products that could impact the marketplace who have reached settlement agreements with the current brand product marketer, which allows for entry of other authorized generics in 2023 and other generic products in 2026, or earlier for both under certain circumstances. Beyond generics, there are other potential future competitive products that could impact the narcolepsy treatment marketplace.

If the FDA approves a competitor's application for a product candidate before our application for a similar product candidate, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for a product candidate is approved first, and we receive a period of statutory marketing exclusivity, we may still be subject to competition from other companies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by a grant of exclusivity to us.

Many of our competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may be able to develop, obtain regulatory approval and gain market share for their products more rapidly than us.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a 505(b)(2) NDA, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an ANDA or subsequent 505(b)(2) application. FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our products or product candidates, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our products or product candidates. In some cases, even this limited bioequivalence testing can be waived by the FDA. Laws have also been enacted to facilitate the development of generic drugs based off recently approved NDAs. The Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act") was enacted in 2019 requiring sponsors of approved NDAs to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs. The law establishes a private right of action allowing developers to sue listed drug holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted. Competition from generic equivalents to our products or product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products or product candidates.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our product candidates, if approved, and technologies could become obsolete or noncompetitive.

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our product candidate and future product candidates. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our product candidate and future product candidates or technologies obsolete or noncompetitive.

Risks Related to Our Business and Industry

COVID-19 may materially and adversely affect our business and our financial results.

The COVID-19 pandemic has spread globally. The continued spread of COVID-19 could adversely impact our operations, including our ability to fully enroll and complete RESTORE, our OLE/switch study of FT218, initiate and complete any future clinical trials, manufacture sufficient supply of our FT218 at sufficient scale for commercialization, if approved. We submitted our 505(b)(2) NDA for FT218 in December 2020.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily allowing employees to work remotely. We have suspended non-essential travel worldwide for our employees and are discouraging employee attendance at large gatherings. These measures could negatively affect our business. For instance, temporarily allowing employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and two of those later received marketing approval. Additional vaccines may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our OLE/switch clinical trial and future commercialization of FT218, if approved, which could lead to delays in these activities.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19, the identification of new

variations of the virus or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and CDMOs, or CROs operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

If we need to take further restructuring actions, necessary third-party consents may not be granted.

In February 2019, we announced a restructuring plan intended to achieve future cost savings through, among other actions, a reduction of our overall workforce by approximately 50 percent. Our management may determine we need to take further restructuring actions to achieve additional cost savings, to generate additional capital needed for our business strategy, or for other purposes. Certain restructuring scenarios that management consider could require obtaining the consent of third parties, such as holders of our Exchangeable Senior Notes due February 2023 (the "February 2023 Notes"). For example, the voluntary bankruptcy filing by Avadel Specialty Pharmaceuticals LLC ("Specialty Pharma") required the consent of holders of a majority in principal amount of our February 2023 Notes in order to avoid a default under the Indenture governing such February 2023 Notes. While we were successful in obtaining that consent, there can be no assurance we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be required. Failure to obtain these third-party consents would prevent us from taking additional restructuring actions, which could have a material adverse effect on our cash flow, financial resources and ability to successfully pursue our business strategy.

Risks Related to Litigation and Legal Matters

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidate or future product candidates, the defendant could counterclaim that the patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. There is risk that a court could rule in favor of the defendant with respect to such a counterclaim of patent invalidity and/or unenforceability.

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

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

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ or may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we endeavor to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or

disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying any awarded monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and/or be a distraction to management and other employees.

We and companies to which we have licensed, or will license our future products or drug delivery technologies and subcontractors we engage or may engage for services related to the development and manufacturing of our lead product candidate or future product candidates are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.

We, and companies to which we will license our future products or drug delivery technologies, as well as companies acting as subcontractors for our product developments, including but not limited to non-clinical, pre-clinical and clinical studies, and manufacturing, are subject to extensive regulation by the FDA, other U.S. authorities and equivalent non-U.S. regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including:

- warning letters or untitled letters;
- fines and civil penalties;
- delays in clearing or approving, or refusal to clear or approve, products;
- withdrawal, suspension or variation of approval of products; product recall or seizure;
- orders to the competent authorities of EU Member States to withdraw or vary national authorization;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair our ability to produce and market applicable products, which could significantly impact our revenues and royalties that we would be eligible to receive from our potential customers.

We may face product liability claims related to clinical trials for our product candidate or future product candidates or their misuse.

The testing, including through clinical trials, manufacturing and marketing, and the use of our product candidate and future product candidates may expose us to potential product liability and other claims. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from CROs or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance and product liability insurance. We cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition.

Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing, or will develop, our future products may not protect us from product liability claims from the consumers of those products or from the costs of related litigation.

If we use hazardous biological and/or chemical materials in a manner that causes injury, we may be liable for significant damages.

Our R&D activities involve the controlled use of potentially harmful biological and/or chemical materials, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental

contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain property, business interruption and casualty insurance with limits that we believe to be commercially reasonable but may be inadequate to cover any actual liability or damages.

Risks Related to Ownership of Our Securities

The price of ADSs representing our ordinary shares has been volatile and may continue to be volatile.

The trading price of ADSs has been, and is likely to continue to be, highly volatile. The market value of an investment in ADSs may fall sharply at any time due to this volatility. During the year ended 31 December 2021, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $6.49 to $11.18. During the year ended 31 December 2020, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $4.06 to $11.75. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological partnerships, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery technologies developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our product candidate or future product candidates;
- lack of efficacy of our product candidate or future product candidates;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products that may incorporate our technologies;
- the perception by the market of specialty pharma, biotechnology, and high technology companies generally;
- general market conditions, including the impact of the current financial environment; and
- the dilutive impact of any new equity or convertible debt securities we may issue or have issued.

Risks Related to the 2023 Notes

Servicing our February 2023 Notes and our October 2023 Notes (as defined below) may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of the 2023 Notes in cash, repay the Notes at maturity, or repurchase the 2023 Notes as required following a fundamental change.

In February 2018, we issued $143,750 aggregate principal amount of our February 2023 Notes. Prior to February 2023, the February 2023 Notes are convertible at the option of the holders only under certain conditions or upon the occurrence of certain events. On 5 April 2022, we completed the exchange of $117,375 of our February 2023 Notes for a new series of its Exchangeable Senior Notes due October 2, 2023 (the "October 2023 Notes", together with the February 2023 Notes, the "2023 Notes") (the "Exchange Transaction"). The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and will maintain a maturity date of 1 February 2023. We refer to the February 2023 Notes and the October 2023 Notes as the "2023 Notes".

If holders of the 2023 Notes elect to exchange their 2023 Notes, unless we elect to deliver solely our ADSs to settle such exchanges, we will be required to make cash payments in respect of the 2023 Notes being exchanged. Holders of the 2023 Notes also have the right to require us to repurchase all or a portion of their 2023 Notes upon the occurrence of a fundamental change (as defined in the applicable indenture governing the 2023 Notes) at a repurchase price equal to 100% of the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest. If the 2023 Notes have not previously been exchanged or repurchased, we will be required to repay the 2023 Notes in cash at maturity. Our ability to make cash payments in connection with exchanges of the 2023 Notes, repurchase the 2023 Notes in the event of a fundamental change, or to repay or refinance the 2023 Notes at maturity will depend on market conditions and our future performance, which is subject to economic, financial, competitive, and other factors many of which are beyond our control. We had limited net income in 2020 and incurred a net loss in 2021. As a result, we may not have enough available cash or be able to obtain financing at the time we

are required to repurchase or repay the 2023 Notes or in the event we elect to pay cash with respect to 2023 Notes being exchanged.

The conditional exchange feature of the 2023 Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional exchange feature of the 2023 Notes is triggered, holders of 2023 Notes will be entitled to exchange the 2023 Notes at any time during specified periods at their option. If one or more holders elect to exchange their 2023 Notes, unless we elect to satisfy our exchange obligation by causing to be delivered solely ADSs (other than paying cash in lieu of any fractional ADSs), we would be required to settle a portion or all of our exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to exchange their 2023 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2023 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible and exchangeable debt securities that may be settled in cash, such as the 2023 Notes, could have a material effect on our reported financial results.

In accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 470, Debt, an entity must separately account for the liability and equity components of convertible debt instruments (such as the 2023 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. ASC 470-20 requires the value of the conversion option of the 2023 Notes, representing the equity component, to be recorded as additional paid-in capital within stockholders' equity in our consolidated balance sheets and as a discount to the 2023 Notes, which reduces their initial carrying value. In addition, under the treasury stock method, if the conversion value of the 2023 Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the 2023 Notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the 2023 Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the 2023 Notes does not exceed their principal amount for a reporting period, then the shares of common stock underlying the 2023 Notes will not be reflected in our diluted earnings per share.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. This would reduce non-cash interest expense, and thereby decrease net loss (or increase net income). Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments whose principal amount may be settled using shares and the if-converted method will be required.

We elected to early adopt ASU 2020-06 beginning with our fiscal year ending 31 December 2021, including any interim periods within that fiscal year. Under ASU 2020-06, the 2023 Notes will be subject to the "if-converted" method for calculating diluted earnings per share. Accordingly, under the "if-converted" method, diluted earnings per share will be calculated assuming that all of the Convertible Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. This new method of calculating earnings per share may adversely affect our reported financial condition and results.

If any of the conditions to the convertibility of the 2023 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2023 Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their 2023 Notes and could materially reduce our reported working capital.

Exchanges of the 2023 Notes will dilute the ownership interest of our existing shareholders and holders of the ADSs, including holders who may exchange their 2023 Notes and receive ADSs upon exchange, to the extent our exchange obligation includes ADSs.

The exchange of some or all of the 2023 Notes will dilute the ownership interests of our existing shareholders and holders of the ADSs to the extent our exchange obligation includes ADSs. Any sales in the public market of the ADSs issuable upon such exchange of the 2023 Notes could adversely affect prevailing market prices of the ADSs and, in turn, the price of the 2023 Notes. In addition, the existence of the 2023 Notes may encourage short selling by market participants because the exchange of the 2023 Notes could depress the price of the ADSs.

The fundamental change repurchase feature of the 2023 Notes may delay or prevent an otherwise beneficial takeover attempt of Avadel.

The indenture governing the 2023 Notes will require us to repurchase the 2023 Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the exchange rate for a holder that exchanges its 2023 Notes in connection with a make-whole fundamental change. A takeover of Avadel may trigger the requirement that we repurchase the 2023 Notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us. Such additional costs may have the effect of delaying or preventing a takeover of Avadel that would otherwise be beneficial to investors.

If we pay dividends, the dividends may be subject to Irish dividend withholding tax

In certain circumstances, as an Irish tax resident company, we may be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to its shareholders. Shareholders that are resident in the U.S., EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of ordinary shares and the value of their 2023 Notes.

General Risk Factors

Provisions of our articles of association could delay or prevent a third-party's effort to acquire us.

Our articles of association could delay, defer or prevent a third-party from acquiring us, even where such a transaction would be beneficial to the holders of ADSs, or could otherwise adversely affect the price of ADSs. For example, certain provisions of our articles of association:

- permit our board of directors to issue preferred shares with such rights and preferences as they may designate, subject to applicable law;
- impose advance notice requirements for shareholder proposals and director nominations to be considered at annual shareholder meetings; and
- require the approval of a supermajority of the voting power of our shares entitled to vote at a general meeting of shareholders to amend or repeal any provisions of our articles of association.

We believe these provisions, if implemented in compliance with applicable law, may provide some protection to holders of ADSs from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. They will, however, apply even if some holders of ADSs consider an offer to be beneficial and could delay or prevent an acquisition that our Board of Directors determines is in the best interest of the holders of ADSs. Certain of these provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, mandatory provisions of Irish law could prevent or delay an acquisition of the Group by a third party. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. In addition, an effort to acquire us may be subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in ADSs in certain circumstances.

These provisions may discourage potential takeover attempts or bids for our ordinary shares at a premium over the market price or they may adversely affect the market price of, and the voting and other rights of the holders of, ADSs. These provisions could also discourage proxy contests and make it more difficult for holders of ADSs to elect directors other than the candidates nominated by our board of directors and could depress affect the market price of ADSs.

Irish law differs from the laws in effect in the U.S. and might afford less protection to the holders of ADSs.

Holders of ADSs could have more difficulty protecting their interests than would the shareholders of a U.S. corporation. As an Irish company, we are governed by Irish law, including the Irish Companies Act 2014 and the Irish Takeover Rules, which differs in some significant, and possibly material, respects from provisions set forth in various U.S. state laws applicable to U.S.

corporations and their shareholders, including provisions relating to interested directors, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors.

The duties of directors and officers of an Irish company are generally owed to the company only. Therefore, under Irish law shareholders of Irish companies do not generally have a right to commence a legal action against directors or officers and may only do so in limited circumstances. Directors of an Irish company must act with due care and skill, honestly and in good faith with a view to the best interests of the company. Directors must not put themselves in a position in which their duties to the company and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the company or any of our subsidiaries. A director or officer can be held personally liable to the company in respect of a breach of duty to the company.

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the U.S., may not be enforceable in Irish courts.

An investor in the U.S. may find it difficult to:

- effect service of process within the U.S. against us and our non-U.S. resident directors and officers;
- enforce U.S. court judgments based upon the civil liability provisions of the U.S. federal securities laws against us and our non-U.S. resident directors and officers in Ireland; or
- bring an original action in an Irish court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in Cayman Islands courts.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us or Avadel judgments of courts of the U.S. predicated upon the civil liability provisions of the securities laws of the U.S. or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us or Avadel predicated upon the civil liability provisions of the securities laws of the U.S. or any State, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the U.S., the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary (the "Depositary"), is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

Security breaches and other disruptions could compromise confidential information and expose us to liability and cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store on our networks various intellectual property including our proprietary business information and that of former customers, suppliers and business partners. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to disruptions such as computer hacking, phishing attacks,

ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

We could suffer financial loss or the loss of valuable confidential information. Although we develop and maintain systems and controls designed to prevent these events from occurring and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

We have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion in the use of our cash and may not apply our cash in ways that ultimately increases the value of any investment in our securities. We currently intend to use our cash to fund marketing activities for any future commercialized products, to fund certain clinical trials for product candidates, to fund research and development activities for potential new product candidates, and for working capital, capital expenditures and general corporate purposes. As in the past we expect to invest our excess cash in available-for-sale marketable securities, including corporate bonds, U.S. government securities, other fixed income securities and equities; and these investments may not yield a favorable return. If we do not invest or apply our cash effectively, our financial position and the price of ADSs may decline.

We currently do not intend to pay dividends and cannot assure the holders of our ADSs that we will make dividend payments in the future.

We have never declared or paid a cash dividend on any of our ordinary shares or ADSs and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

Our effective tax rate could be highly volatile and could adversely affect our operating results.

Our future effective tax rate may be adversely affected by a number of factors, many of which are outside of our control, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- changes in the valuation of our deferred tax assets and liabilities;
- changes in share-based compensation expense;
- changes in domestic or international tax laws or the interpretation of such tax laws;
- changes in available tax credits;
- adjustments to estimated taxes upon finalization of various tax returns; and
- the resolution of issues arising from tax audits with various tax authorities.

Any significant increase in our future effective tax rates could impact our results of operations for future periods adversely.

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

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes to applicable U.S. or foreign tax laws and regulations, or their interpretation and application (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our ordinary shares or ADSs. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in tax laws on an investment in our ordinary shares or ADSs.

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

As of 31 December 2021, we had $74,406 of net operating losses in the U.S. Of the $74,406 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC") and $64,041 are due to the losses at Avadel US Holdings, Inc. The portion due to the acquisition of FSC will expire in 2034 through 2035. The U.S. net operating losses acquired as part of the acquisition of FSC are subject to an annual limitation under Internal Revenue Code Section 382 and $1,473 of the $10,365 will not be fully utilized before they expire. The remaining $64,041 of net operating losses do not have an expiration date.

Under U.S. federal tax legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act ("Tax Act"), U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such U.S. federal net operating losses is limited. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986 (the "Code") if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage-point cumulative change (by value) in the equity ownership of certain shareholders over a rolling three-year period), the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes as a result of future issuances of our stock or as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have completed an analysis to determine that no events have been triggered in the past. If any ownership changes are determined to be triggered in the future, our ability to use our current net operating losses to offset post-change taxable income or taxes would be subject to limitation. We will be unable to use our net operating losses if we do not attain profitability sufficient to offset our available net operating losses prior to their expiration.

As of 31 December 2021, we had approximately $124,720 of net operating losses in Ireland that do not have an expiration date. While these losses do not have an expiration date, substantial changes in the activities performed in these jurisdictions could have an impact on our ability to utilize these tax attributes in the future.

U.S. Holders of ordinary shares or ADSs may suffer adverse U.S. tax consequences if we are classified as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties that are received from unrelated parties in connection with the active conduct of a trade or business. Our status as a PFIC depends on the composition of our income and the composition and value of our assets (for which purpose the total value of our assets may be determined in part by the market value of the ordinary shares or ADSs, which are subject to change) from time to time. If we are characterized as a PFIC, U.S. Holders (as defined below under "Material U.S. Federal Income Tax Considerations for U.S. Holders") of ordinary shares or ADSs may suffer materially adverse tax consequences, including having gains realized on the sale of ordinary shares or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on ordinary shares or ADSs by individuals who are U.S. Holders, and having interest charges apply to distributions by us and the proceeds of sales of ordinary shares or ADSs.

We believe that we were not a PFIC for the taxable year ending 31 December 2020 and, based on the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets, we will be a PFIC for our current taxable year. However, our status as a PFIC is a fact-intensive determination subject to various uncertainties, and we cannot provide any assurances regarding our PFIC status for the current, prior or future taxable years.

Certain U.S. Holders that own 10 percent or more of the vote or value of ordinary shares or ADSs may suffer adverse U.S. tax consequences because our non-U.S. subsidiaries are expected to be classified as controlled foreign corporations.

Each ''Ten Percent Shareholder'' (as defined below) in a non-U.S. corporation that is classified as a ''controlled foreign corporation,'' or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's ''Subpart F income'' and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Subpart F income generally includes dividends, interest, rents, royalties, ''global intangible low-taxed income,'' gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of

the stock of such corporation. A ‘‘Ten Percent Shareholder’’ is a U.S. person (as defined by the Code) who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote or 10% or more of the total value of all classes of stock of such corporation.

We believe that we were not a CFC in the 2021 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2021 taxable year. We anticipate that our non-U.S. subsidiaries will remain CFCs in the 2021 taxable year, and it is possible that we may become a CFC in the 2022 taxable year or in a subsequent taxable year. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. U.S. Holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC, including the possibility and consequences of becoming a Ten Percent Shareholder in one or more of our non-U.S. subsidiaries that are anticipated to be treated as CFCs. If we are classified as both a CFC and a PFIC, we generally will not be treated as a PFIC with respect to those U.S. Holders that meet the definition of a Ten Percent Shareholder during the period in which we are a CFC, subject to certain exceptions.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We have identified a material weakness in our internal control over financial reporting. We may be exposed to potential risks if we are unable to comply the requirements to maintain internal controls over financial reporting or if we identify additional material weaknesses.

As a public company in the United States organized, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the listing rules of the Nasdaq Stock Market ("Nasdaq"), and incur significant legal, accounting and other expenses to comply with applicable requirements. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

For example, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Such compliance may require that we incur substantial accounting expenses and expend significant management efforts.

During the Group’s fiscal 2021 financial statement close process, management identified a deficiency in the design of internal control over financial reporting related to its February 2023 Notes indenture. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, management did not have a control to identify that we were in technical default of the February 2023 Notes and owed 0.50% of additional interest on the February 2023 Notes due to not removing a restrictive legend from the February 2023 Notes 365 days following the original issuance of the February 2023 Notes on 16 February 2018.

Once the material weakness was identified, we developed and implemented a remediation plan that includes the implementation of additional control procedures surrounding timely and period evaluation of all terms of our debt agreement and the associated calculation of interest expense in accordance with the terms of such debt agreement to ensure the completeness and accuracy of the calculation and timely payment of additional interest expense. Management is committed to maintaining a strong internal control environment and have fully implemented measures designed to help ensure that the control deficiency contributing to the material weakness is remediated. However, there cannot be any assurance that these remediation efforts will be successful or that our internal control over financial reporting will be effective as a result of these efforts. The material weakness will be fully remediated when, we have determined, through testing, these controls have operated effectively for a sufficient period of time.

In the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our ADSs.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to provide research coverage or that new analysts will begin to provide research coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A transfer of ordinary shares may be subject to Irish stamp duty.

Transfers of ordinary shares (as opposed to ADSs) 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. Although transfers of ADSs are not subject to Irish stamp duty, the potential for stamp duty to arise on transfers of ordinary shares could adversely affect the price of our ordinary shares or ADSs.

Financial Risk Management

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

The Group is subject to interest rate risk as a result of our portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities.

Foreign Exchange Risk

We are exposed to foreign currency exchange risk as the functional currency financial statements of a non-U.S. subsidiary is translated to U.S. dollars. The assets and liabilities of this non-U.S. subsidiary having a functional currency other than the U.S. dollar is translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of this non-U.S. subsidiary will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to one subsidiary that has functional currencies denominated in euro. A 10% strengthening/weakening in the rates used to translate the results of our non-U.S. subsidiaries that have functional currencies

denominated in euro as of 31 December 2021 would have had an immaterial impact on net loss for the year ended 31 December 2021.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in investment and other (expense) income, net in the consolidated profit and loss account. As of 31 December 2021, our primary exposure is to transaction risk related to euro net monetary assets and liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were immaterial for the year ended 31 December 2021.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development and commercial launch plans, our cost structure, and other factors set forth in "Risk Factors" within this report. To complete the FT218 clinical development and commercial launch plans we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions concerning the outcome of certain business conditions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business. Additionally, we are unable to estimate the near or long term impact of COVID-19, which may have a material adverse impact on our business.

If available to us, raising additional capital may be accomplished through one or more public or private debt or equity financings, royalty financings or collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

Cash, cash equivalent and marketable security balances as of 31 December 2021 and unused financing sources are expected to provide us with the flexibility to meet our liquidity needs in 2022, including operating requirements related to the commercial launch of FT218.

Accounting records

The directors are responsible for ensuring that the Group and Company keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Group's and Company's obligation to keep adequate accounting records include the use of appropriate systems and procedures and the employment of competent persons. The directors have appointed a Chief Financial Officer who makes regular reports to the directors and ensures compliance with the requirements of Sections 281 to 285 of the Companies Act 2014. The Chief Financial Officer makes regular reports to the Audit Committee. The Audit Committee, in turn, briefs the directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor**.**

The accounting records of Avadel are maintained at 16640 Chesterfield Grove Rd., St. Louis, Missouri 63005, United States. In accordance with Section 283(2) of the Companies Act 2014, sufficient accounting records are also maintained in the Republic of Ireland to disclose, with reasonable accuracy, the assets, liabilities, financial position and profit or loss of the Group. The accounting records are available at 10 Earlsfort Terrace, Dublin 2, Ireland, which enable such information and returns relating to the Company to be disclosed with reasonable accuracy concerning the assets, liabilities, financial position and profit or loss at intervals not exceeding 6 months.

Directors

The remuneration of statutory directors of the Company during the year is set forth in *Note 22: Key Management Compensation* in the Notes to Consolidated Financial Statements. No director or Company secretary of the Company had an interest in shares or debentures required to be disclosed under Section 329 of the Companies Act 2014 either at the beginning of the financial year, or date of appointment if later, or at the end of the financial year. Note that where the aggregate interest in shares of any director or secretary (and his or her spouse (or civil partner) and children) represents less than 1% in nominal value of the Group's ordinary shares, the only interests of that director or secretary that are required to be disclosed constitute a right to subscribe for shares in the Company or that arise as a result of the exercise of such a right. Performance stock units where the director or secretary is an employee of the Company and does not make any payment to the Company in respect of the shares are not considered to be rights to subscribe for the purposes of this disclosure and no disclosure is required where they form part

of an aggregate less than 1% holding. No Directors or Corporate Secretary had holdings of 1% or more as of 31 December 2021.

Set forth below are the names of the individuals serving as statutory directors during fiscal 2021 through the date of this report:

Nominee	Principal Occupation or Experience	Nationality	Committees
Geoffrey M. Glass	President and Chief Executive Officer of Kiniciti, LLC	American	(1)(3)(4)
Dr. Eric J. Ende	President of Ende BioMedical Consulting Group Director at Matinas BioPharma, Inc.	American	(1)(3)
Dr. Mark A. McCamish	President, Chief Executive Officer of IconOVir Bio, Inc.	American	(1)(2)
Linda S. Palczuk	Chief Operating Officer and Director of Envara Health, Inc.	American	(2)(3)
Peter J. Thornton	President and Chief Financial Officer of Envetec Sustainable Technologies Limited	Irish	(1)(2)
Gregory J. Divis	Chief Executive Officer of the Company	American	

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Non-Executive Chairman of the Board of Directors

Set forth below is the name of the individual serving as the company secretary during fiscal 2021 through the date of this report:

Nominee	Principal Occupation or Experience	Nationality
Jerad G. Seurer	Company Secretary	American

Political Donations

No political contributions that require disclosure under Irish law were made during the year.

Subsidiary Companies and Branches

Information regarding subsidiary undertakings, including information regarding branches, is provided in *Note 27: Subsidiary Undertakings* in the Notes to Consolidated Financial Statements.

Disclosure of Information to Auditor

Each of the persons who is a director at the date of approval of this report confirms that:

- so far as that director is aware, there is no relevant audit information of which the Group's auditor is unaware, and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014.

Directors' Compliance Statement

As required by section 225 of the Companies Act 2014, the directors acknowledge that they are responsible for securing the Avadel Pharmaceuticals plc's compliance with its "relevant obligations" (as defined in that legislation). The directors further confirm that a compliance policy statement has been drawn up, and that appropriate arrangements and structures have been put in place that are, in the directors' opinion, designed to secure material compliance with the relevant obligations. A review of those arrangements and structures has been conducted in the financial year to which this report relates. In discharging their responsibilities under section 225, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise Avadel Pharmaceuticals plc on compliance with its relevant obligations.

Audit Committee

The Board has established an Audit committee that in all material respects meets the requirements of Section 167 of the Companies Act 2014.

Events Since the Balance Sheet Date

Exchange Transaction Closing

On 5 April 2022, Avadel completed the exchange of $117,375 of its February 2023 Notes for a new series of its Exchangeable Senior Notes due 2 October 2023. The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and will maintain a maturity date of 1 February 2023. The Group paid $4,800 in fees paid to note holders of the October 2023 Notes and $5,400 in fees paid to third parties as part of the completed Exchange Transaction.

Jazz Litigation

On 14 April 2022, Avadel CNS Pharmaceuticals LLC and Avadel Pharmaceuticals plc (collectively the "Avadel Plaintiffs") filed a formal complaint (the "Avadel Complaint") initiating a lawsuit in the Court against Jazz and Jazz Pharmaceuticals Ireland Ltd. (collectively, the "Jazz Parties"). In the Avadel Complaint, the Avadel Plaintiffs allege that the Jazz Parties breached certain confidential disclosure agreements and misappropriated certain of Avadel's trade secrets. The Avadel Complaint further includes typical relief requests such as injunctive relief, monetary damages and attorneys' fees, costs and expenses, as well as seeking correction of inventorship of certain Jazz patents to include former Avadel scientists.

Going Concern

The directors have a reasonable expectation that Avadel Pharmaceuticals plc and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the directors continue to adopt the going concern basis in preparing the financial statements. Please see *Note 1: Background and Basis of Presentation,* for additional information

Auditor

The auditor, Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continues in office in accordance with Section 383(2) of the Companies Act 2014.

On behalf of the Directors

/s/ Peter J. Thornton	/s/ Gregory J. Divis
Peter J. Thornton	Gregory J. Divis
Director	Director
9 May 2022	9 May 2022

AVADEL PHARMACEUTICALS PLC

DIRECTORS' RESPONSIBILITIES STATEMENT

The directors are responsible for preparing the directors' report and financial statements in accordance with the Companies Act 2014.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with U.S. GAAP, as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the group financial statements does not contravene any provision of Part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* issued by the Financial Reporting Council ("relevant financial reporting framework").

Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the group and company as at the financial year end date and of the profit or loss of the group for the financial year and otherwise comply with the Companies Act 2014.

In preparing the financial statements, the directors are required to:

- select suitable accounting policies for the group and company financial statements and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company; enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the company's website. Legislation in Ireland concerning the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Independent auditor's report to the members of Avadel Pharmaceuticals plc

Report on the audit of the financial statements

Opinion on the financial statements of Avadel Pharmaceuticals plc (the 'Group')

In our opinion the Group financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2021 and of the loss of the Group for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Consolidated Profit and Loss Account;
- the Consolidated Statement of Other Comprehensive (Loss) Income;
- the Consolidated Balance Sheet;
- the Consolidated Statement of Cash Flows;
- the Consolidated Statement of Changes in Shareholders' Equity; and
- the related notes 1 to 30, including a summary of significant accounting policies as set out in note 2.

The relevant financial reporting framework that has been applied in the preparation of the Group financial statements is the Companies Act 2014 and US Generally Accepted Accounting Principles (US GAAP), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene Part 6 of the Companies Act ("the relevant financial reporting framework").

We have reported separately on the parent company financial statements of Avadel Pharmaceuticals plc for the financial year ended 31 December 2021.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "Auditor's responsibilities for the audit of the financial statements" section of our report.

We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Summary of our audit approach

Key audit matter	The key audit matter that we identified in the current year was: • Management override of internal controls In the prior year, we identified a key audit matter related to the sale of the Hospital Products business. This matter was not relevant for the current year.
Materiality	The materiality that we used in the current year was US$2 million, which was determined on the basis of operating costs.
Scoping	We determined the scope of our audit by obtaining an understanding of the Group and its environment, including group wide controls and assessing the risks of material misstatement at the Group level.
Significant changes in our approach	No significant changes to note.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Our evaluation of the directors' assessment of the group's ability to continue to adopt the going concern basis of accounting included:

- As part of our risk assessment procedures, obtaining an understanding of the relevant controls in place regarding going concern;
- Reviewing documentation supporting the key inputs to budgets and forecasts including obtaining evidence supporting the following; exchange of February 2023 loan notes for October 2023 loan notes, fees incurred for the debt extension and the group's capital commitments;
- challenging the reasonableness of the key assumptions applied by the directors in their going concern assessment which covers a period of at least 12 months from the date of signing the financial statements;
- obtaining an understanding of the Group's controls over the development and approval of the projections and assumptions used in the cash flow forecasts to support the going concern assumption and assessing the design and determining the implementation of these controls;
- testing the clerical accuracy of the forecasts; and
- assessing the adequacy of the disclosures in the financial statements.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Key Audit Matter

Key audit matter is a matter that, in our professional judgment, is of most significance in our audit of the financial statements of the current financial period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. The matter was addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on this matter.

Management override of internal control	
Key audit matter description	Following the sale of the Group's Hospital Products in 2020, the group has not earned income and has focused on developing FT218. There have been no significant transactions during the year requiring changes to the overall audit strategy or specific area's requiring significant allocation of audit resources. We identified management override of internal control as a key audit matter as this represents the key significant risk identified as part of our risk assessment procedures. Although the level of risk of management override of controls will vary from entity to entity, the risk is nevertheless present in all entities. Management is in a unique position to perpetrate fraud because of its ability to directly or indirectly manipulate accounting records and prepare fraudulent financial statements by overriding established controls that otherwise appear to be operating effectively. When considering the risk of management override of controls, we note that it is pervasive in all entities. Because of its unpredictable nature, this risk could result in a material misstatement. This significant risk also represents a fraud risk

How the scope of our audit responded to the key audit matter	Our audit procedures related to management override of internal controls included the following, among others: • We used proprietary quantitative financial analysis and benchmarking software analysis tool, to identify unusual trends in account balances and ratios. • We engaged in periodic fraud discussions with certain members of senior management and others, including the internal auditors, internal counsel, and the audit committee. • We completed our testing of management judgment and estimates, including performing retrospective analysis of significant accounting estimates. • We evaluated whether the Group entered into any significant unusual transactions and, if so, the nature, terms, and business purpose (or lack thereof) of those transactions and whether such transactions involved related parties. • We evaluated the Group's fraud risk assessment and considered entity-level internal controls and internal controls over the closing and reporting process. • We tested journal entries that exhibit characteristics of possible management override of controls, identified using electronic data interrogation techniques. • We also tested controls over significant, unusual transactions, particularly those that result in late or unusual journal entries and controls over journal entries and adjustments made in the period-end financial reporting process.
Key observations	We have no observations to report in relation to management override of internal controls.

Our audit procedures relating to the key audit matter were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on this individual matter.

Our application of materiality

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

We determined materiality for the Group to be US$2 million which represents approximately 2.3% of operating costs. We have considered the benchmark of operating costs to be critical components for determining materiality as we determined these results to be of most importance to the principal external users of the financial statements. We have considered quantitative and qualitative factors such as our understanding of the entity and its environment, history of misstatements, complexity of the Group, and reliability of the internal control environment in our determination of materiality.

We agreed with the Audit Committee that we would report to them any audit differences in excess of $0.1 million or 5.0% of materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the Group financial statements.

An overview of the scope of our audit

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including Group-wide controls, and assessing the risks of material misstatement at the Group level. Based on that assessment, we focused our Group audit scope primarily with a full scope audit, predominately performed in the United States, on the Group's US operations which represented 70% of the operating costs and 77% of the assets. The Group's remaining Non US international components were subject to specified audit procedures, where the extent of our testing was based on our assessment of the risks of material misstatement and of the materiality of the Group's operations in those areas. Overall 98% of the groups operating costs and 77% of the group's assets were subject to direct audit procedures.

These components were selected based on coverage achieved and to provide an appropriate basis for undertaking audit work to address the risks of material misstatements identified above. Our audit work at the Non US International component was executed at levels of materiality applicable to each individual component which were lower than Group materiality at US$2 million.

Other information

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 31 December 2021, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the Group' ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.

- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the Group) to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtain sufficient appropriate audit evidence regarding the financial information of the business activities within the Group to express an opinion on the consolidated financial statements. The Group auditor is responsible for the direction, supervision and performance of the Group audit. The Group auditor remains solely responsible for the audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland) 2016, and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements
Opinion on other matters prescribed by the Companies Act 2014

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in the directors' report as specified in our review is consistent with the financial statements and has been prepared in accordance with the Companies Act 2014.

Matters on which we are required to report by exception

Based on the knowledge and understanding of the Group and its environment obtained in the course of the audit, we have not identified material misstatements in those parts of the directors' report that have been specified for our review.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Use of our report

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

/s/ Cathal Treacy
Cathal Treacy
For and on behalf of Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House, Earlsfort Terrace, Dublin 2
Date: 9 May 2022

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
(In thousands, except per share data)

	Note	Years Ended 31 December 2021	2020
Turnover	20	$ —	$ 22,334
Cost of sales		—	(5,742)
Gross profit		—	16,592
Research and development costs		(17,104)	(20,442)
Distribution and administrative expenses		(68,495)	(32,405)
Intangible asset amortization	11	—	(406)
Loss - changes in fair value of contingent consideration	16	—	(3,327)
Gain on disposal of Hospital Products	4	—	45,760
Restructuring income	29	53	43
Operating (loss) profit		(85,546)	5,815
Interest income		1,489	673
Interest expense	15	(9,942)	(12,994)
Gain from release of certain liabilities	28	217	3,364
Other expense - changes in fair value of contingent consideration payable	16	—	(435)
Foreign exchange gain (loss)		637	(487)
Other expense		—	(1,018)
Loss on ordinary activities before taxation		(93,145)	(5,082)
Taxation credit	6	15,816	12,110
(Loss) profit after taxation		$ (77,329)	$ 7,028
(Loss) profit per share - basic:		$ (1.32)	$ 0.13
(Loss) profit per share - diluted:		$ (1.32)	$ 0.13

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC

CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE (LOSS) INCOME

(In thousands)

	Years ended 31 December	
	2021	**2020**
(Loss) profit after taxation	$ (77,329)	$ 7,028
Other comprehensive profit, net of taxation:		
Foreign currency translation (loss) gain	(1,228)	1,111
Net other comprehensive (loss) profit on marketable securities, net of $214 and ($202), tax, respectively	(1,661)	644
Total other comprehensive (loss) profit, net of taxation	(2,889)	1,755
Total comprehensive (loss) income	$ (80,218)	$ 8,783

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEET
(In thousands)

	Note	31 December 2021	31 December 2020
Fixed Assets			
Intangible assets	11	$ 16,836	$ 16,836
Tangible assets	10	2,937	2,963
		19,773	19,799
Current Assets			
Debtors	8	70,271	70,436
Investments	9	106,513	149,680
Cash at bank and in hand		50,708	71,722
		227,492	291,838
Creditors (amounts falling due within one year)	12	(20,720)	(14,790)
Net Current Assets		206,772	277,048
Total Assets Less Current Liabilities		226,545	296,847
Creditors (amounts due after more than one year)	13	(144,104)	(130,066)
Provision for Liabilities	14	(4,197)	(4,515)
Net Assets		$ 78,244	$ 162,266
Capital and Reserves			
Called-up share capital presented as equity	17	$ 617	$ 614
Share premium account	17	277,127	276,865
Other reserves	17	31,639	22,769
Profit and loss account	17	(231,139)	(137,982)
Shareholders' Funds		$ 78,244	$ 162,266

Approved by the board of directors on 9 May 2022 and signed on its behalf by:

/s/ Peter J. Thornton
Peter J. Thornton
Director

/s/ Gregory J. Divis
Gregory J. Divis
Director

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands)

	Years ended 31 December	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) profit	$ (77,329)	$ 7,028
Adjustments to reconcile net (loss) profit to net cash used in operating activities:		
Depreciation and amortization	815	1,690
Remeasurement of related party acquisition-related contingent consideration	—	3,327
Remeasurement of related party financing-related royalty agreements	—	435
Amortization of debt discount and debt issuance costs	1,248	6,524
Change in deferred tax	(15,666)	(7,431)
Share-based compensation expense	8,872	2,999
Gain on the disposal of the Hospital Products	—	(45,760)
Gain from the release of certain liabilities	(217)	(3,364)
Other adjustments	1,272	142
Net changes in assets and liabilities		
Trade debtors	—	8,281
Stocks	—	(1,352)
Prepaid expenses and other current assets	(439)	1,863
Research and development tax credit receivable	2,796	2,213
Trade creditors & other current liabilities	4,232	(2,788)
Accrued expenses	895	(13,226)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	—	(5,323)
Royalty payments for related party payable in excess of original fair value	—	(866)
Other long-term assets and liabilities	(3,789)	(3,126)
Net cash used in operating activities	(77,310)	(48,734)
Cash flows from investing activities:		
Purchases of tangible assets	(26)	(98)
Proceeds from disposal of businesses, including cash acquired and other adjustments	16,500	25,500
Proceeds from turnover of marketable securities	102,224	36,284
Purchases of marketable securities	(61,769)	(131,407)
Net cash provided by (used in) investing activities	56,929	(69,721)
Cash flows from financing activities:		
Proceeds from the February 2020 private placement	—	60,570
Proceeds from the May 2020 public offering	—	116,924
Cash proceeds from issuance of ordinary shares	263	2,189
Net cash provided by financing activities	263	179,683
Effect of exchange rate changes on cash and cash equivalents	(896)	720
Net change in cash and cash equivalents	(21,014)	61,948
Cash and cash equivalents at 1 January	71,722	9,774
Cash and cash equivalents at 31 December	$ 50,708	$ 71,722
Supplemental disclosures of cash flow information:		
Income taxes paid (refund), net	$ 76	$ (1,701)
Interest paid	6,469	6,469

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

(In thousands)

	Called-up Share Capital - Ordinary		Called-up Share Capital - Preferred		Share Premium Account	Other Reserves	Profit and Loss Account	Total
	Number	Amount	Number	Amount				
Balance, 31 December 2019	42,952	$ 455	—	$ —	$ 84,866	$ 32,245	$ (146,765)	$ (29,199)
Net profit	—	—	—	—	—	—	7,028	7,028
Other comprehensive income	—	—	—	—	—	—	1,755	1,755
Exercise of stock options	403	4	—	—	2,041	—	—	2,045
February 2020 private placement	8,680	87	488	5	64,908	(4,430)	—	60,570
May 2020 public offering	11,630	116	—	—	124,906	(8,098)	—	116,924
Vesting of restricted shares	114	1	—	—	—	(1)	—	—
Employee share purchase plan issuance	49	—	—	—	144	—	—	144
Share-based compensation	—	—	—	—	—	2,999	—	2,999
Cancellation of treasury shares	(5,407)	(54)	—	—	—	54	—	—
Balance, 31 December 2020	58,421	$ 609	488	$ 5	$ 276,865	$ 22,769	$ (137,982)	162,266
Impact of accounting standard adoptions	—	—	—	—	—	—	(12,939)	(12,939)
Net loss	—	—	—	—	—	—	(77,329)	(77,329)
Other comprehensive loss	—	—	—	—	—	—	(2,889)	(2,889)
Exercise of stock options	48	1	—	—	168	—	—	169
Vesting of restricted shares	159	2	—	—	—	(2)	—	—
Employee share purchase plan issuance	17	—	—	—	94	—	—	94
Share-based compensation	—	—	—	—	—	8,872	—	8,872
Balance, 31 December 2021	58,645	$ 612	488	$ 5	$ 277,127	$ 31,639	$ (231,139)	$ 78,244

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except per share data)

NOTE 1: Background and Basis of Presentation

Going Concern Assessment. The adequacy of our cash resources primarily depends on the outcome of certain business conditions including the cost of our FT218 commercial plan and our cost structure. To complete the FT218 commercial plan, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions concerning the outcome of certain business conditions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

The directors have assessed the COVID-19 pandemic on the Group's business and do not believe the outbreak has any material impact on the financial results.

On this basis, the directors have a reasonable expectation that the Group and Company have adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis in preparing the annual financial statements.

Background. Avadel Pharmaceuticals plc and its subsidiaries (Nasdaq: AVDL) ("Avadel," the "Group," "we," "our," or "us") is a biopharmaceutical company. The Group's lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. The Group is primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, the Group submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of 15 October 2021. On 15 October 2021, the Group announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this report, the FDA's review of the Group's NDA for FT218 remains ongoing.

Outside of the Group's lead product candidate, the Group continues to evaluate opportunities to expand its product portfolio. As of the date of this report, the Group does not have any approved and commercialized products in its portfolio.

The Group was incorporated in Ireland on 1 December 2015 as a private limited Company, and re-registered as an Irish public limited Company on 21 November 2016. The address of our registered office is 10 Earlsfort Terrace, Dublin 2, Ireland. Its registered number is 572535.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses the Group's Micropump controlled release drug-delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Immediate release sodium oxybate is approved in the U.S. for the treatment of EDS or cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002, sodium oxybate has only been available as a formulation that must be taken twice nightly, first at bedtime, and then again 2.5 to 4 hours later.

On 16 December 2020, the Group announced the submission of its NDA to the FDA for FT218. On 26 February 2021, the FDA notified the Group of formal acceptance of the NDA and assigned a PDUFA target action date of 15 October 2021. On 15 October 2021, the Group announced that the FDA informed the Group that the review of its NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this report, the FDA's review of the Group's NDA for FT218 remains ongoing.

The Group conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of FT218 or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on 27 April 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test

("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 orphan drug designation for the treatment of narcolepsy, which makes FT218 potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, the Group announced that the first patient was dosed in its open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS or cataplexy in patients with narcolepsy. The OLE/switch study is examining the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning 17 April 2021. The first poster described FT218 improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning 10 June 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 or Type 2. Additionally, a post-hoc analysis showed that FT218 was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

New data was presented at the American College of Chest Physicians annual meeting, beginning 17 October 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

New data was presented at World Sleep 2022 congress, which was held 11-16 March, 2022 in Rome, Italy. A total of eight posters were presented, including five new post-hoc analyses from the REST-ON trial. Most notably, the post-hoc analyses showed that FT218 demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5 g starting dose, with even greater improvement at week 2 soon after starting the 6 g dose compared to placebo. Additional post-hoc analyses, stratified by narcolepsy type, as well as concomitant stimulant use, or without stimulants, demonstrated positive results that are generally consistent with previously reported positive endpoints from REST-ON and add to the existing body of evidence for FT218.

In addition, the results of a discrete choice experiment ("DCE") were presented, which confirmed that once-nightly dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-nightly) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE OLE/switch study, which showed

that FT218 has generally been well-tolerated, with some patients receiving therapy for more than 18 months, and no new safety signals have been observed.

The Group believes that FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS or cataplexy in patients with narcolepsy, which are twice-nightly sodium oxybate formulations.

Micropump Drug-Delivery Technology

The Group's Micropump drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, the Group believes there could be other product development opportunities for our Micropump drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Previously Approved FDA Products

On 30 June 2020 (the "Closing Date"), the Group announced the sale of its portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC ("Exela Buyer").

Basis of Presentation. The directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Companies Act 2014. The consolidated financial statements include the accounts of the parent company and all subsidiaries. All inter-group accounts and transactions have been eliminated. The format of the consolidated profit and loss account has been adopted where necessary to better reflect the nature of the business.

Reclassifications. Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation.

Out of Period Adjustments. In 2021, the Group determined that 0.50% of additional interest expense (the "Additional Interest"), as defined in the indenture dated as of 16 February 2018 among Avadel Finance Cayman Ltd, Avadel Pharmaceuticals PLC, and The Bank of New York Mellon as trustee (the "Indenture"), was owed on its long term 4.50% exchangeable unsecured senior notes due 2023 (the "2023 Notes") from a period of 17 February 2019 through 31 December 2021, totaling $817, $773, and $635 for the years ended 31 December 2021, 2020 and 2019, respectively. At 31 December 2020, the Group's accrued interest was understated by $1,408. The Additional Interest resulted from not removing a restrictive legend from the 2023 Notes 365 days following their original issuance on 16 February 2018. The restrictive legend was removed in March 2022 and the Additional Interest is no longer applicable following the date of removal of the restrictive legend. The Group identified and recorded an out of period adjustment for cumulative amount of the Additional Interest in 2021 of $1,408. The directors assessed the materiality of the impact of the out of period adjustment on its financial statements, both quantitatively and qualitatively, and determined that it was not material for any quarterly or annual period.

The 2023 Notes were issued on 16 February 2018 (the "Original Issuance") with a restrictive legend which remained in place until 14 March 2022. Per the terms of the Indenture, if the restrictive legend on the 2023 Notes was not removed on the 365th day following the original issuance of the 2023 Notes, the Group owed Additional Interest, payable on each of the semi-annual interest payment dates of 1 February and 1 August beginning 1 August 2019 and each of the semi-annual payment dates thereafter until the restrictive legend was removed. The non-payment of the Additional Interest expense on the semi-annual payment dates, which was first due beginning 1 August 2019, is defined as an "Event of Default" in the Indenture, causing the Group to be in technical default of its 2023 Notes until the default was cured. The Additional Interest was paid to the trustee on 10 March 2022, which under the terms of the indenture, the directors believe cured the Event of Default for all periods. Additionally, on 14 March 2022, the restrictive legend on the 2023 Notes was removed and the Group is not subject to the Additional Interest after that date. Had the Group identified and been unable to cure the technical default prior to the issuance of its financial statements for fiscal years 2020 and 2019, it could have resulted in the reclassification of the long-term principal

balance of 2023 Notes reported in those periods. As a result of curing the technical default, the Group classified the 2023 Notes as long-term at 31 December 2021 and 2020.

NOTE 2: Accounting Estimates and Related Accounting Policies

Accounting Estimates and the related Accounting Policies

Turnover Recognition. Prior to 30 June 2020, the Group recognized turnover for sales of pharmaceutical products. See *Note 4: Disposal of the Hospital Products* for more information on the disposal of the Hospital Products.

Product Sales

The Group sold products primarily through wholesalers and considered these wholesalers to be the Group's customers. Revenue from product sales is recognized when the customer obtains control of the Group's product, which occurs typically upon receipt by the customer. The Group's gross product sales were subject to a variety of price adjustments in arriving at reported net product sales. These adjustments included estimates of product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis.

For a complete discussion of the accounting for net product revenue, see *Note 5: Revenue Recognition*.

Research and Development ("R&D"). R&D expenses consist primarily of costs related to outside services, personnel expenses, clinical studies and other R&D expenses. Outside services and clinical studies costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third-party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Other R&D expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred. Raw materials used in the production of pre-clinical and clinical products are expensed as R&D costs.

The Group recognizes refundable R&D tax credits received for spending on innovative R&D as an offset of R&D expenses. The amount offset to expense was $529 and $77 for the financial years ended 31 December 2021 and 2020, respectively.

Share-based Compensation. The Group accounts for share-based compensation based on the estimated grant-date fair value. The fair value of stock options is estimated using Black-Scholes option-pricing valuation models ("Black-Scholes model"). As required by the Black-Scholes model, estimates are made of the underlying volatility of Avadel stock, a risk-free rate and an expected term of the option or warrant. The Group estimates the expected term using a simplified method, as it does not have enough historical exercise data for a majority of such options upon which to estimate an expected term. The Group recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes. The Group accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Group determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Group recognizes deferred tax assets to the extent that the Group believes that these assets are more likely than not to be realized. In making such a determination, the Group considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Group determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Group would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Group records uncertain tax positions on the basis of a two-step process in which (1) the Group determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Group recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Group recognizes interest and penalties related to unrecognized tax benefits in the taxation credit line in the consolidated profit and loss account. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

Goodwill. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Group has determined that it operates in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The Group tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Group determined that no impairment of goodwill existed at 31 December 2021 and 2020.

True and fair override. Irish company law requires goodwill to be amortized. However, the directors do not believe this gives a true and fair view because not all goodwill decline in value. In addition, since goodwill that does decline in value rarely do so on a straight-line basis, straight-line amortization of goodwill over an arbitrary period does not reflect the economic reality. Therefore, in order to present a true and fair view of the economic reality, and consistent with US GAAP, goodwill is not amortized but are tested for impairment at each reporting date. If goodwill amortized, the impact on the financial statements would be an additional expense in the Consolidated Profit and Loss Account and Statement of Comprehensive Profit (Loss) and a corresponding decrease to the carrying value of the asset.

Long-Lived Assets. Long-lived assets include tangible assets and intangible assets. Prior to the disposal of the Group's portfolio of sterile injectable drugs used in the hospital setting ("Hospital Products") on 30 June 2020, intangible assets consisted primarily of purchased licenses and intangible assets recognized as part of the Éclat Pharmaceuticals acquisition. Acquired in-process research and development ("IPR&D") had an indefinite life and was not amortized until completion and development of the project, at which time the IPR&D became an amortizable asset, for which amortization of such intangible assets was computed using the straight-line method over the estimated useful life of the assets.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset or other market-based value approaches. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. On 30 June 2020, the Group transferred its remaining intangible asset to the Exela Buyer as part of the disposal of the Hospital Products.

Summary of Other Accounting Policies

Cash at Bank and In Hand. The Group classifies cash on hand and deposited in banks including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Group of three months or less, as cash at bank and in hand.

Marketable Securities. The Group's marketable securities are considered to be available for sale and are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of profit and loss account in shareholders' equity, with the exception of unrealized gains and losses on equity instruments and allowances for expected credit losses, if any, which are reported in earnings in the current period. The cost of securities sold is based upon the specific identification method. See *Note 19: Fair Value Measurements* for a discussed on how fair value is determined.

Tangible Assets. Tangible assets are stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Office and computer equipment	3 years
Leasehold improvements, furniture, fixtures and fittings	5-10 years

Advertising Expenses. The Group expenses the costs of advertising as incurred. Branded advertising expenses were $0 and $312 for the years ended 31 December 2021 and 2020 respectively.

Use of Estimates. The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Group to make estimates and assumptions that affect the reported amounts of assets and liabilities, including marketable securities and contingent liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. These estimates and assumptions are based on the best information available to the Group at the balance sheet dates and depending on the nature of the estimate can require significant judgments. Changes to these estimates and judgments can have and have had a material impact on our consolidated profit and loss account and balance sheet. Actual results could differ from those estimates under different assumptions or conditions.

Lease Obligations. The Group determines if a contract is a lease at the inception of the arrangement. Right-of-use assets and operating lease liabilities are recognized at commencement date based on the present value of remaining lease payments over the lease term. For this purpose, the Group considers only payments that are fixed and determinable at the time of commencement. The Group reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. Short term leases with an initial term of 12 months or less are not recorded on the balance sheet and the associated lease payments are recognized in the consolidated profit and loss account on a straight-line basis over the lease term. The Group's lease contracts do not provide a readily determinable implicit rate. The Group's estimated incremental borrowing rate is based on information available at the inception of the lease. The Group's lease agreements may contain variable costs such as common area maintenance, insurance, real estate taxes or other costs. Variable lease costs are expensed as incurred on the consolidated profit and loss account.

Allowance for Credit Losses. Amounts owed to the Group are presented net of an allowance that includes as assessment of expected credit losses. An allowance for credit losses is established based on expected losses. Expected losses are estimated by reviewing individual accounts, considering aging, financial condition of the debtor, payment history, current and forecast economic conditions and other relevant factors. To the extent that the Group identifies that any individual customer's credit quality has deteriorated, the Group establishes allowances based on the individual risk characteristics of that customer. The Group makes concerted efforts to collect all outstanding balances due from customers; however, amounts are written off against the allowance when the related balances are no longer deemed collectible.

NOTE 3: Effect of New Accounting Standards

Recently Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. The FASB's amendments primarily impact ASC 740, Income Taxes, and may impact both interim and annual reporting periods. ASU 2019-12 is effective for fiscal years beginning after 15 December 2020, and interim periods within those fiscal years and early adoption is permitted. The Group adopted the provisions of ASU 2019-12 on 1 January 2021. Adoption of ASU 2019-12 did not have any impact on the Group's consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging- Contracts in Entity's Own Equity (Subtopic 815-40)*, to reduce the complexity associated with applying U.S. GAAP principles for certain financial instruments with characteristics of liabilities and equity. The amendments in this ASU reduce the number of accounting models for convertible instruments and expand the existing disclosure requirements over earnings per share as it relates to convertible instruments. Convertible debt will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The update also requires the if-converted method to be used for convertible instruments and the effect of potential share settlement be included in the diluted earnings per share calculation when an instrument may be settled in cash or shares. This ASU will be effective for the Group's fiscal year beginning 1 January 2022 and interim periods therein. Early adoption is permitted, but no earlier than fiscal years beginning after 15 December 2020. The amendments may be adopted through either a modified retrospective method, or a fully retrospective method.

The Group elected to early adopt ASU 2020-06 as of 1 January 2021 using a modified retrospective method. The Group's 4.50% exchangeable senior notes due 2023 (the "2023 Notes") are a convertible instrument with a cash-conversion feature that is accounted for within the scope of Subtopic 470-20. The Group calculated the cumulative-effect adjustment as of 1 January 2021 by comparing (i) the historical amortization schedule for the 2023 Notes through 31 December 2020 and (ii) an updated amortization schedule wherein the conversion feature within the 2023 Notes would not be separated as an equity component

and subsequently recognized as non-cash interest expense under ASC 835-30. The adoption resulted in a $12,939 decrease in the profit and loss account and a $12,939 increase in long-term debt.

NOTE 4: Disposal of the Hospital Products

On 30 June 2020 (the "Closing date"), the Group announced the sale of the Hospital Products, which included its three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to the Exela Buyer pursuant to an Asset Purchase Agreement (the "Transaction").

Pursuant to the Transaction, the Exela Buyer agreed to pay a total aggregate consideration amount of $42,000, of which $14,500 was paid on the Closing Date and an additional $27,500 was paid in ten equal monthly installments following the Closing Date. During the year ended 31 December 2020, the Group collected four installment payments, totaling $11,000. The Group collected the remaining six installment payments, totaling $16,500 during 2021. In connection with the sale of the Hospital Products, the parties also agreed to cause the dismissal of the pending civil litigation related to Nouress in the District Court for the District of Delaware.

The Group was party to a Membership Interest Purchase Agreement, dated 13 March 2012, by and among the Group, Avadel Legacy, Breaking Stick Holdings, LLC, Deerfield Private Design International II, L.P. ("Deerfield International"), Deerfield Private Design Fund II, L.P. ("Deerfield Fund") and Horizon Santé FLML, Sarl ("Horizon") (the "Deerfield MIPA") and a Royalty Agreement, dated 4 February 2013, by and among the Group, Avadel Legacy, the Deerfield Fund and Horizon (the "Deerfield Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Deerfield Royalty Agreement for obligations that arise after the Closing Date.

The Group was also party to a Royalty Agreement, dated 3 December 2013, by and between the Company, Avadel Legacy and Broadfin Healthcare Master Fund, Ltd. (the "Broadfin Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Broadfin Royalty Agreement for obligations that arise after the Closing Date.

The Group recorded a net gain on the disposal of the Hospital Products of $45,760 during the year ended 31 December 2020 which has been recorded on the consolidated profit and loss account. The $45,760 gain represents the aggregate consideration of $42,000, less transaction fees of $2,928, plus the assets and liabilities either transferred to the Exela Buyer or eliminated by the Group due to the disposal of the Hospital Products, which are listed below.

	30 June 2020
Debtors	$ (1,229)
Stocks	(4,922)
Intangible assets	(2,061)
Provision for Liabilities	14,900
Net liabilities disposed of	6,688
Aggregate consideration	42,000
Less transaction fees	(2,928)
Net gain on the disposal of the Hospital Products	$ 45,760

Subsequent to the disposal of the Hospital Products, the Group entered into a separate and distinct agreement with the Exela Buyer, whereby the Exela Buyer assumed all future returns of the Hospital Products in exchange for cash consideration paid by the Group. The Group recorded a $518 gain from this transaction, which is recorded in "Distribution and administrative expenses" for the year ended 31 December 2020.

The Group evaluated various qualitative and quantitative factors related to the disposal of the Hospital Products and determined that it did not meet the criteria for presentation as a discontinued operation.

NOTE 5: Revenue Recognition

Prior to 30 June 2020, the Group generated revenue primarily from the sale of pharmaceutical products to customers. On 30 June 2020, the Group sold the Hospital Products. See *Note 4: Disposal of the Hospital Products*.

Product Sales and Services

Prior to 30 June 2020, the Group sold products primarily through wholesalers and considered these wholesalers to be our customers. Revenue from product sales was recognized when the customer obtained control of our product and our performance obligations were met, which occurred typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our gross product sales were subject to a variety of price adjustments in arriving at reported net product sales. These adjustments included estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

Reserves to reduce Gross Revenues to Net Revenues

Revenues from product sales were recorded at the net selling price, which included estimated reserves to reduce gross product sales to net product sales resulting from product returns, chargebacks, payment discounts, rebates, and other sales allowances that are offered within contracts between the Group and its customers and end users. These reserves were based on the amounts earned or to be claimed on the related sales and were classified as reductions of accounts receivable if the amount was payable to the customer, except in the case of the estimated reserve for future expired product returns, which were classified as a liability. The reserves were classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves took into consideration relevant factors such as the Group's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflected the Group's best estimates to reduce gross selling price to net selling price to which it expected to be entitled based on the terms of its contracts. The actual selling price ultimately received may differ from the Group's estimates.

Product Returns

Consistent with industry practice, the Group maintained a returns policy that generally offered customers a right of return for product that has been purchased from the Group. The Group estimated the amount of product returns and records this estimate as a reduction of revenue in the period the related product revenue was recognized. The Group estimated product return liabilities based on analysis of historical data for the product or comparable products, as well as future expectations for such products and other judgments and analysis.

Chargebacks, Discounts and Rebates

Chargebacks, discounts and rebates represent the estimated obligations resulting from contractual commitments to sell products to its customers or end users at prices lower than the list prices charged to our wholesale customers. Customers charged the Group for the difference between the gross selling price they pay for the product and the ultimate contractual price agreed to between the Group and these end users. These reserves were established in the same period that the related revenue was recognized, resulting in a reduction of product revenue and accounts receivable. Chargebacks, discounts and rebates were estimated at the time of sale to the customer.

Disaggregation of revenue

The Group's primary source of revenue is from the sale of pharmaceutical products, which are equally affected by the same economic factors as it relates to the nature, amount, timing, and uncertainty of revenue and cash flows. For further detail about the Group's revenues by product, see *Note 20: Group Operations by Product, Customer and Geographic Area*.

Contract Balances

The Group does not recognize revenue in advance of invoicing its customers and therefore has no related contract assets.

A receivable is recognized in the period the Group sells its products and when the Group's right to consideration is unconditional.

There were no material deferred contract costs at 31 December 2021 and 2020.

Transaction Price Allocated to the Remaining Performance Obligation

For product sales, the Group generally satisfies its performance obligations within the same period the product is delivered. Product sales recognized in 2020 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial. No product sales were recognized in 2021.

The Group has elected certain of the practical expedients from the disclosure requirement for remaining performance obligations for specific situations in which an entity need not estimate variable consideration to recognize revenue. Accordingly, the Group applies the practical expedient in ASC 606 to its stand-alone contracts and does not disclose information about variable consideration from remaining performance obligations for which the Group recognizes revenue.

NOTE 6: Taxation Credit

The components of loss before taxation for the years ended 31 December are as follows:

Loss on Ordinary Activities Before Taxation	2021	2020
Ireland	$ (36,631)	$ (27,205)
U.S.	(56,687)	22,335
France	173	(212)
Loss on ordinary activities before taxation	$ (93,145)	$ (5,082)

The taxation credit for the years ended 31 December are as follows:

Taxation Credit	2021	2020
Current:		
U.S. - Federal	$ —	$ (12,810)
U.S. - State	60	20
Total current	60	(12,790)
Deferred:		
U.S. - Federal	(15,876)	680
Total deferred	(15,876)	680
Taxation credit	$ (15,816)	$ (12,110)

The items accounting for the difference between the taxation charge computed at the jurisdiction of incorporation statutory rate and the Group's effective tax rate are as follows for the years ended 31 December:

Reconciliation to Effective Income Tax Rate:	2021	2020
Taxation credit - at statutory tax rate	$ (11,642)	$ (636)
Differences in international tax rates	(8,950)	1,755
Non-deductible changes in fair value of contingent consideration	—	988
Change in valuation allowances	4,296	4,231
Nondeductible share-based compensation	645	1,060
Hospital Products sale	—	(9,328)
Unrecognized tax benefit	239	(274)
State and local taxes (net of federal)	60	20
Change in U.S. tax law	—	(9,124)
Nondeductible interest expense	2,173	1,728
Orphan drug and R&D tax credit	(1,524)	(2,793)
Other	(1,113)	263
Taxation credit - at effective income tax rate	$ (15,816)	$ (12,110)

In 2021, the income tax benefit increased by $3,706 when compared to the same period in 2020. The increase in the income tax benefit in 2021 was primarily driven by the additional tax benefit from an increase in the net operating losses in the U.S. in 2021, when compared to the same period in 2020. This was partially offset by the nonrecurring nature of tax benefits recognized in 2020 from the sale of the Group's Hospital Products and passage of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") in the U.S.

Unrecognized Tax Benefits

The Group or one of its subsidiaries files income tax returns in Ireland, France, U.S. and various states. The Group is no longer subject to Irish, French, U.S. Federal, and state and local examinations for years before 2017. During 2020, the Group completed the 2015 through 2017 U.S. Federal Tax Audit. Completion of the audit resulted in an assessment of $1,937 for the 2015 through 2017 U.S. Federal Tax Returns compared to the IRS Claims of $50,695 made on 2 July 2019 and the updated IRS Claims of $9,302 on 2 October 2019 made as part of the Specialty Pharma bankruptcy proceedings, which at this time does not include interest and penalties.

The following table summarizes the activity related to the Group's unrecognized tax benefits for the twelve months ended 31 December:

Unrecognized Tax Benefit Activity	2021	2020
Balance at January 1:	$ 3,143	$ 6,465
Settlements	—	(3,322)
Balance at December 31:	$ 3,143	$ 3,143

The Group expects that within the next twelve months the unrecognized tax benefits could decrease by an immaterial amount and the interest could increase by an immaterial amount.

At 31 December 2021 and 2020, there are $2,483 and $2,483 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

The Group recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended 31 December 2021 and 2020, the Group recognized approximately $239 and $203 in interest and penalties. The Group had approximately $1,777 and $1,475 for the payment of interest and penalties accrued at 31 December 2021 and 2020 respectively.

Deferred Tax Assets (Liabilities)

Deferred income tax provisions reflect the effect of temporary differences between consolidated financial statement and tax reporting of income and expense items. The net deferred tax assets (liabilities) at 31 December 2021 and 2020 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 35,990	$ 31,302
Orphan drug and R&D tax credit	4,964	2,793
Share-based compensation	4,108	2,626
Amortization	3,429	3,701
Other	662	423
Gross deferred tax assets	49,153	40,845
Deferred tax liabilities:		
Other	(925)	(890)
Prepaid expenses	(75)	(75)
Total deferred tax liabilities	(1,000)	(965)
Less: valuation allowance	(24,025)	(21,624)
Net deferred tax assets	$ 24,128	$ 18,256

At 31 December 2021, the Group had $124,720 of net operating losses in Ireland that do not have an expiration date and $74,406 of net operating loss in the U.S. Of the $74,406 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC") and $64,041 are due to the losses at US Holdings. The portion due to the acquisition of FSC will expire in 2034 through 2035. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended 31 December 2021, the Group recorded $4,045 of valuation allowances related to Irish net operating losses. The U.S. net operating losses are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and will not be fully utilized before they expire.

The Group recorded a valuation allowance against all of our net operating losses in Ireland and France as of 31 December 2021 and 2020. The Group intends to continue maintaining a full valuation allowance on the Irish net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances.

While the Group believes it is more likely than not that it will be able to realize the deferred tax assets in the U.S., we continue to monitor any unfavorable changes that could ultimately impact our assessment of the realizability of our U.S. deferred tax assets. If we experience an ownership change under Internal Revenue Code Section 382, the U.S. net operating losses could also be limited in their utilization.

At 31 December 2021, the Group has unremitted earnings of $3,916 outside of Ireland as measured on a U.S. GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may be different for tax purposes, these earnings, which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the Group were to sell our stock in the subsidiaries, net of any prior income taxes paid. It is not practicable to estimate the amount of deferred tax liability on such earnings, if any.

R&D Tax Credits Receivable

The French and Irish governments provide tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in years after being incurred or, if not so utilized, are recoverable in cash after a specified period of time, which may differ depending on the tax credit regime. As of 31 December 2021, the Group's net research tax credit receivable amounts to $3,668 and represents a French gross research tax credit of $3,139 and an Irish gross research tax credit of $529. As of 31 December 2020, the Group's net Research tax credit receivable amounts to $6,771 and represents a French gross research tax credit of $6,396 and an Irish gross research tax credit of $375.

2020 CARES Act

The CARES Act, enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses. Under the temporary provisions of the CARES Act, net operating loss carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, net operating losses arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. During the twelve months ended December 31, 2020, the income tax benefit includes a discrete tax benefit of $9,124 as a result of the Company's ability under the CARES Act to carry back net operating losses incurred to periods when the statutory U.S. Federal tax rate was 35% versus the Company's current U.S. Federal tax rate of 21%. During the twelve months ended December 31, 2020, the Company received $3,351 in cash tax refunds from carryback claims related to the CARES Act from the carryback of 2018 tax losses. The Company filed refund claims for $18,753 associated with the carryback of 2019 tax losses and a $10,273 refund claim associated with the carryback of 2020 tax losses.

NOTE 7: (Loss) Profit Per Ordinary Share

Basic net (loss) profit per share is calculated by dividing net (loss) profit by the weighted average number of shares outstanding during each period. Diluted net (loss) profit per share is calculated by dividing net (loss) profit - diluted by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net (loss) profit, diluted net (loss) profit per share would be calculated assuming the impact of the conversion of the 2023 Notes, the conversion of the Group's preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under the Group's Employee Share Purchase Plan ("ESPP").

The Group has a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. The Group utilizes the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result is anti-dilutive. This method assumes the conversion of the 2023 Notes into shares of our ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

The dilutive effect of the stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under our ESPP has been calculated using the treasury stock method. The dilutive effect of the Performance Share Units ("PSUs") will be calculated using the treasury stock method, if and when the contingent vesting condition is achieved.

A reconciliation of basic and diluted net (loss) profit per share, together with the related shares outstanding in thousands for the years ended 31 December 2021 and 2020, is as follows:

Basic and Diluted (Loss) Profit Per Share:	2021	2020
(Loss) profit per share numerator:		
(Loss) profit from ordinary operations attributable to common shareholders before allocation of earnings to participating securities	$ (77,329)	$ 7,028
Less: earnings allocated to participating securities	—	—
(Loss) profit attributable to common shareholders, after allocation of earnings to participating securities	$ (77,329)	$ 7,028
(Loss) profit per share denominator:		
Weighted-average shares outstanding - basic	58,535	52,996
Impact of dilutive securities	—	1,945
Weighted-average shares outstanding - dilute	58,535	54,941
Basic (loss) profit per share attributable to common shareholders:	$ (1.32)	$ 0.13
Diluted (loss) profit per share attributable to common shareholders:	$ (1.32)	$ 0.13

Potential common shares of 15,327 and 14,915 were excluded from the calculation of weighted average shares for the years ended 31 December 2021, and 2020, respectively, because either their effect was considered to be anti-dilutive or they were related to shares from PSUs for which the contingent vesting condition had not been achieved. For the years ended 31 December 2021, the effects of dilutive securities were entirely excluded from the calculation of loss per share as a net loss was reported in this period.

NOTE 8: Debtors

At the end of fiscal 2021 and 2020, debtors were comprised of:

	2021	2020
Debtors (amounts receivable within one year):		
Income tax receivable	29,097	18,615
Prepaid and other expenses	3,179	1,018
Research and development tax credit receivable	2,443	3,326
Guarantee from Armistice (see *Note 18: Contingent Liabilities and Commitments*)	279	318
Other	160	457
Value-added tax recoverable	111	341
Receivable from Exela	—	16,500
Short-term deposit	—	1,477
Total	$ 35,269	$ 42,052
Debtors (amounts receivable after one year):		
Deferred tax assets	$ 24,128	$ 18,256
Right of use assets at contract manufacturing organizations	8,549	5,201
Research and development tax credit receivable	1,225	3,445
Guarantee from Armistice (see *Note 18: Contingent Liabilities and Commitments*)	771	1,050
Other	329	432
Total	$ 35,002	$ 28,384
Total	$ 70,271	$ 70,436

NOTE 9: Investments

The Group has investments in available-for-sale debt securities that are recorded at fair market value. The change in the fair value of available-for-sale debt investments is recorded in the Profit and Loss Account in shareholders' equity, net of income tax effects. As of 31 December 2021, the Group considered any decreases in fair value on our marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the Group's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of 31 December 2021 and 2020, respectively:

	2021			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Money market and mutual funds	$ 78,331	$ 813	$ (1,046)	$ 78,098
Corporate bonds	16,478	94	(93)	16,479
Government securities - U.S.	9,530	39	(98)	9,471
Other fixed-income securities	2,473	2	(10)	2,465
Total	$ 106,812	$ 948	$ (1,247)	$ 106,513

	2020			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Money market and mutual funds	$ 103,404	$ 1,288	$ (20)	$ 104,672
Corporate bonds	21,811	350	(6)	22,155
Government securities - U.S.	18,849	155	(5)	18,999
Other fixed-income securities	3,839	22	(7)	3,854
Total	$ 147,903	$ 1,815	$ (38)	$ 149,680

The Group determines realized gains or losses on the sale of marketable securities on a specific identification method. The Group reflects these gains and losses as a component of interest income in the accompanying consolidated profit and loss account.

We recognized gross realized gains of $174 and $474 for the twelve months ended 31 December 2021 and 2020 respectively. These realized gains were offset by realized losses of $275 and $912 for the twelve-months ended 31 December 2021 and 2020 respectively.

The following table summarizes the estimated fair value of the Group's investments in marketable debt securities, accounted for as available-for-sale securities and classified by the contractual maturity date of the securities as of 31 December 2021:

	Maturities				
Marketable Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 5,288	$ 10,873	$ 318	$ —	$ 16,479
Government securities - U.S.	1,531	5,938	807	1,195	9,471
Other fixed-income securities	—	1,860	605	—	2,465
Total	$ 6,819	$ 18,671	$ 1,730	$ 1,195	$ 28,415

The Group has classified its investment in available-for-sale marketable securities as current assets in the consolidated balance sheets at 31 December 2021 and 2020, respectively, as the securities need to be available for use, if required, to fund current operations. There are no restrictions on the sale of any securities in the Group's investment portfolio.

Total gross unrealized losses of our available-for-sale debt securities at 31 December 2021 were immaterial and have been in an unrealized loss position for less than one year. The unrealized losses are driven by factors other than credit risk. The Group does not intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases.

NOTE 10: Tangible Assets

Tangible asset activity for fiscal year 2021 and 2020 was as follows:

	Office and Computer Equipment	Furniture, Fixtures, and Fittings	Operating lease right-of-use assets	Total Tangible Assets
Cost:				
At 31 December 2019	$ 1,258	$ 300	$ 4,489	$ 6,047
Additions	98	—	—	98
Disposals	—	—	(363)	(363)
Currency translation and other	87	—	(9)	78
At 31 December 2020	$ 1,443	$ 300	$ 4,117	$ 5,860
Additions	24	2	763	789
Disposals	(980)	—	—	(980)
Currency translation and other	(39)	—	—	(39)
At 31 December 2021	$ 448	$ 302	$ 4,880	$ 5,630
Depreciation:				
At 31 December 2019	$ (887)	$ (127)	$ (877)	$ (1,891)
Depreciation expense	(241)	(46)	(999)	(1,286)
Disposal of tangible assets	—	—	363	363
Currency translation and other	(83)	—	—	(83)
At 31 December 2020	$ (1,211)	$ (173)	$ (1,513)	$ (2,897)
Depreciation expense	(65)	(32)	(715)	(812)
Disposal of tangible assets	980	—	—	980
Currency translation and other	36	—	—	36
At 31 December 2021	$ (260)	$ (205)	$ (2,228)	$ (2,693)
Net Book Value				
At 31 December 2020	$ 232	$ 127	$ 2,604	$ 2,963
At 31 December 2021	$ 188	$ 97	$ 2,652	$ 2,937

Gain or loss on disposal of tangible assets was immaterial in both fiscal 2021 and 2020.

NOTE 11: Goodwill and Intangible Assets

Intangible asset activity for fiscal 2021 and 2020 was as follows:

	Goodwill	Acquired Developed Technology	Total Intangible Assets
Cost:			
At 31 December 2019	$ 18,491	$ 47,309	$ 65,800
Disposal of the Hospital Products [(a)]	(1,655)	(47,309)	(48,964)
At 31 December 2020	$ 16,836	$ —	$ 16,836
At 31 December 2021	$ 16,836	$ —	$ 16,836
Amortization:			
At 31 December 2019	$ —	$ (46,496)	$ (46,496)
Amortization expense	—	(406)	(406)
Disposal of the Hospital Products [(a)]	—	46,902	46,902
At 31 December 2020	$ —	$ —	$ —
At 31 December 2021	$ —	$ —	$ —
Net Book Value			
At 31 December 2020	$ 16,836	$ —	$ 16,836
At 31 December 2021	$ 16,836	$ —	$ 16,836

(a) In connection with the disposal of the Hospital Products (see *Note 4: Disposal of the Hospital Products*), the Group allocated goodwill of $1,655 on a relative fair value basis to the Hospital Products and included this amount in the net gain on

the disposal of the Hospital Products on the consolidated profit and loss account during the year ended 31 December 2020. The acquired developed technology intangible was assumed by the Exela Buyer as part of the disposal of the Hospital Products on 30 June 2020.

The Group recorded amortization expense related to amortizable intangible assets of $0 and $406 for the years ended 31 December 2021 and 2020, respectively.

No impairment loss related to goodwill or intangible assets was recognized during the years ended 31 December 2021 and 2020.

NOTE 12: Creditors (amounts falling due within one year)

At the end of fiscal 2021 and 2020, creditors (amounts falling due within one year) were comprised of:

Creditors (amounts falling due within one year):	2021	2020
Trade creditors	7,679	2,934
Other	7,668	7,662
Accrued compensation	3,167	1,697
Accrued outsourced contract costs	1,048	473
Current portion of operating lease liability	900	474
Customer allowances	217	1,030
Accrued employee severance	41	520
Total	$ 20,720	$ 14,790

NOTE 13: Creditors (amounts falling due after more than a year)

At the end of fiscal 2021 and 2020, creditors (amounts falling due after more than a year) were comprised of:

Creditors (amounts falling after more than a year):	2021	2020
Debt (*Note 15: Long-Term Debt*)	$ 142,397	$ 128,210
Long-term operating lease liability	1,707	1,840
Other	—	16
Total	$ 144,104	$ 130,066

NOTE 14: Provisions for Liabilities

	Related Party Payable (Note 16)	Unrecognized Tax Benefits (Note 6)	Guarantee to Deerfield (Note 18)	Provision for Liabilities
At 31 December 2019	$ 17,326	$ 6,465	$ 1,827	$ 25,618
Additions during the year	—	—	—	—
Amounts charged against the provision	(6,188)	(3,322)	(455)	(9,965)
Changes in the fair value	3,762	—	—	3,762
Disposal of the Hospital Products	(14,900)	—	—	(14,900)
At 31 December 2020	$ —	$ 3,143	$ 1,372	$ 4,515
Additions during the year	—	—	—	—
Amounts charged against the provision	—	—	(318)	(318)
Changes in the fair value	—	—	—	—
At 31 December 2021	$ —	$ 3,143	$ 1,054	$ 4,197

NOTE 15: Long-Term Debt

Long-term debt is summarized as follows:

	31 December	
	2021	2020
Principal amount of 4.50% exchangeable senior notes due 2023	$ 143,750	$ 143,750
Less: unamortized debt discount and issuance costs, net	(1,353)	(15,540)
Net carrying amount of liability component	142,397	128,210
Less: current maturities	—	—
Long-term debt	$ 142,397	$ 128,210
Equity component:		
Equity component of exchangeable notes, net of issuance costs	$ —	$ (26,699)

For the years ended 31 December 2021 and 2020, the total interest expense was $9,942, and $12,994, respectively, with coupon interest expense of $6,469 for each period and the amortization of debt issuance costs and debt discount of $1,248 and $6,525, respectively. Current period interest expense also included $2,225 of additional interest expense owed as a result of not removing a restrictive legend from the 2023 Notes 365 days following original issuance of the 2023 Notes on 16 February 2018. See *Note 1: Background and Basis of Presentation* for further details.

As described in *Note 3: Effect of New Accounting Standards*, the Group elected to early adopt ASU 2020-06 as of 1 January 2021 using a modified retrospective method. The adoption resulted in a $12,939 decrease in the profit and loss account and a $12,939 increase in long-term debt.

2023 Notes

On 16 February 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company (the "Issuer") and an indirect wholly-owned subsidiary of the Company, issued $125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the "2023 Notes") in a private placement (the "Offering") to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the Offering, the Issuer granted the initial purchasers of the 2023 Notes a 30-day option to purchase up to an additional $18,750 aggregate principal amount of the 2023 Notes, which was fully exercised on 16 February 2018. Net proceeds received by the Group, after issuance costs and discounts, were approximately $137,560. The 2023 Notes are the Group's senior unsecured obligations and rank equally in right of payment with all of the Group's existing and future senior unsecured indebtedness and effectively junior to any of the Group's existing and future secured indebtedness, to the extent of the value of the assets securing such indebtedness.

The 2023 Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per $1 principal amount of 2023 Notes, which is equivalent to an initial exchange price of approximately $10.79 per ADS. Such initial exchange price represents a premium of approximately 20% to the $8.99 per ADS closing price on The Nasdaq Global Market on 13 February 2018. Upon the exchange of any 2023 Notes, the Issuer will pay or cause to be delivered, as the case may be, cash, ADSs or a combination of cash and ADSs, at the Issuer's election. Holders of the 2023 Notes may convert their 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding 1 August 2022, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after 1 August 2022 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding 1 August 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per $1 principal amount of 2023 Notes, as determined following a request by a holder of the 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.

- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding 1 August 2022, regardless of whether a holder of the 2023 Notes has the right to require the Group to repurchase the 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding 1 August 2022, all or any portion

of a the holder's 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Group gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.

- Prior to the close of business on the business day immediately preceding 1 August 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on 30 June 2018 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

- If the Group calls the 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding August 1, 2022, then a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time prior to the close of business on the second business day prior to the redemption date, even if the 2023 Notes are not otherwise exchangeable at such time. After that time, the right to exchange shall expire, unless the Group defaults in the payment of the redemption price, in which case a holder of the 2023 Notes may exchange its 2023 Notes until the redemption price has been paid or duly provided for.

The Group considered the guidance in ASC 815-15, *Embedded Derivatives*, to determine if this instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. The Group determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. The Group has therefore applied the guidance provided by ASC 470-20, *Debt with Conversion and Other Options,* as amended by ASU 2020-06.

NOTE 16: Contingent Consideration Payable

Prior to the sale of the Hospital Products on 30 June 2020, the Group computed the fair value of the contingent consideration using several significant assumptions and when those assumptions changed, due to underlying market conditions, the fair value of these liabilities changed as well. Prior to the sale of the Hospital Products, these changes had a material impact on the Group's consolidated profit and loss account and balance sheet. As part of the sale of the Hospital Products on 30 June 2020, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy and the Group under the Deerfield Royalty Agreement and the Broadfin Royalty Agreement. As of 31 December 2021 and 2020, the balance of the contingent consideration payable is $0.

Contingent consideration payable and related activity are reported at fair value and consist of the following at 31 December 2020:

		Activity during the Twelve Months Ended 31 December 2020				
			Changes in Fair Value of Contingent Consideration Payable			
	Balance, 31 December 2019	Payments	Operating Loss	Other Expense	Disposal of the Hospital Products	Balance, 31 December 2020
Acquisition-related:						
Earn-out payments - Éclat Pharmaceuticals [(a) (d)]	$ 15,472	$ (5,323)	$ 3,327	$ —	$ (13,476)	$ —
Financing-related:						
Royalty agreement - Deerfield [(b) (d)]	1,251	(587)	—	272	(936)	—
Royalty agreement - Broadfin [(c) (d)]	604	(279)	—	163	(488)	—
Total contingent consideration payable	$ 17,327	$ (6,189)	$ 3,327	$ 435	$ (14,900)	$ —
Less: current portion	(5,554)					—
Total long-term contingent consideration payable	$ 11,773					$ —

(a) In March 2012, the Group acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. ("Breaking Stick", formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with

a minority interest owned by the Group's former CEO, and certain other current and former employees. As part of the consideration, the Group committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity. In connection with the disposal of the Hospital Products on 30 June 2020 as discussed in *Note 4: Disposal of the Hospital Products*, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy and the Company under the Deerfield Royalty Agreement.

(b) As part of a February 2013 debt financing transaction conducted with Deerfield, the Group received cash of $2,600 in exchange for entering into a royalty agreement whereby the Group shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until 31 December 2024. In connection with such debt financing transaction, the Group granted Deerfield a security interest in the product registration rights of the Éclat Pharmaceuticals products. In connection with the disposal of the Hospital Products on 30 June 2020 as discussed in *Note 4: Disposal of the Hospital Products*, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy and the Group under the Deerfield Royalty Agreement.

(c) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a former related party and shareholder, the Group received cash of $2,200 in exchange for entering into a royalty agreement whereby the Group shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until 31 December 2024. In connection with the disposal of the Hospital Products on 30 June 2020 as discussed in *Note 4: Disposal of the Hospital Products*, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of the Group under the Broadfin Royalty Agreement.

(d) Deerfield and Broadfin Healthcare Master Trust disposed of their 2023 Notes and ordinary shares in the Group during the year ended 31 December 2020 and are no longer considered related parties.

Prior to the disposal of the Hospital Products on 30 June 2020, the fair value of each contingent consideration payable listed in (a), (b) and (c) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat products using an appropriate risk-adjusted discount rate of 14%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related contingent consideration payables, resulting primarily from management's revision of key assumptions, will be recorded in the consolidated profit and loss account in the line items entitled "Changes in fair value of contingent consideration" for items noted in (b) above and in "Other (expense) income - changes in fair value of contingent consideration payable" for items (b) and (c) above. See *Note 2: Accounting Estimates and Related Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements for more information on key assumptions used to determine the fair value of these liabilities.

Prior to 30 June 2020 the Group chose to make a fair value election pursuant to ASC 825, "Financial Instruments" for its royalty agreements detailed in items (b) and (c) above. These financing-related liabilities were recorded at fair market value on the consolidated balance sheet and the periodic change in fair market value is recorded as a component of "Other expense – change in fair value of contingent consideration payable" on the consolidated profit and loss account.

The following table summarizes changes to the contingent consideration payables, a recurring Level 3 measurement, for the twelve-month periods ended 31 December 2020:

Contingent Consideration Payable:	**Balance**
Balance at 31 December 2019	$ 17,327
Payments of contingent consideration payable	(6,189)
Fair value adjustments [(1)]	3,762
Disposal of the Hospital Products	(14,900)
Balance at 31 December 2020	$ —

[(1)] Fair value adjustments are reported as changes in fair value of contingent consideration and other expense -changes in fair value of contingent consideration payable in the consolidated profit and loss account.

NOTE 17: Called-up Share Capital and Reserves

Called-up Share Capital

Upon exercise of stock options or warrants, or upon the issuance of free share awards, the Group issues new shares.

(In thousands, except per share data)	2021	2020
Authorised:		
25 deferred ordinary shares of €1.00 each at 31 December 2021 and 2020	$ 26	$ 26
500,000 ordinary shares of $0.01 each at 31 December 2021 and 2020	5,000	5,000
50,000 preferred shares of $0.01 each at 31 December 2021 and 2020	500	500
Allotted, Called Up and Fully Paid:		
25 deferred ordinary shares of €1.00 each at 31 December 2021 and 2020	$ 26	$ 26
58,620 and 58,396 ordinary shares of $0.01 each at 31 December 2021 and 2020, respectively	586	583
488 preferred shares of $0.01 at 31 December 2021 and 2020	5	5
Called up share capital presented as equity	$ 617	$ 614

The Board of Directors is authorized to issue preferred stock in series, and with respect to each series, to fix its designation, relative rights (including voting, dividend, conversion, sinking fund, and redemption rights), preferences (including dividends and liquidation) and limitations. We have 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 488 are currently issued and outstanding as of 31 December 2021.

Cancellation of Treasury Shares

In August 2020, the Group cancelled all of our 5,407 treasury shares. As a result, we transferred $54 of ordinary shares to capital redemption reserves within other reserves during the twelve months ended 31 December 2020.

February 2020 Private Placement

On 21 February 2020, the Group announced that we entered into a definitive agreement for the sale of its ADSs and Series A Non-Voting Convertible Preferred Shares ("Series A Preferred") in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately $65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of $60,570.

Pursuant to the terms of the private placement, the Group issued 8,680 ADSs and 488 shares of Series A Preferred at a price of $7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on 25 February 2020. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including an open-label extension study for REST-ON, a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, as well as for general corporate purposes.

Issuance costs of $4,430 have been recorded as a reduction of Other Reserves.

May 2020 Public Offering

In connection with the shelf registration statement described above, on 28 April 2020, the Group announced the pricing of an underwritten public offering of 11,630 Ordinary Shares, in the form of ADSs at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs were offered by us and the gross proceeds to us from the offering were approximately $125,000, before deducting underwriting discounts and commissions and offering expenses, which resulted in net proceeds of $116,924. The offering closed on 1 May 2020. Proceeds from the public offering will be used to fund continued clinical and program development of FT218, including an open-label extension ("OLE") study for REST-ON, a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, as well as for general corporate purposes.

Issuance costs of $8,098 have been recorded as a reduction of Other Reserves.

Called-up Share Capital - Ordinary

In fiscal 2021, the change in ordinary shares of $3 is a result of the vesting of restricted shares of $2 and the exercise of stock options of $1.

Share Premium Account

In fiscal 2021, the share premium account increased due to the exercise of stock options of $168 and employee share purchase plan issuance of $94.

Other Reserves

In fiscal 2021, other reserves increased, driven by the issuance of $8,872 of share-based compensation, partially offset by the vesting of restricted shares of $2.

Profit and Loss Account

In fiscal 2021, the profit and loss account activity was driven by the 2021 net loss of $77,329, the impact of the adoption of new accounting standards of $12,939, and the change in other comprehensive loss of $2,889.

NOTE 17.1: Equity Instruments and Stock Based Compensation

Compensation expense included in the consolidated profit and loss account for all share-based compensation arrangements was as follows for the periods ended 31 December:

Share-based Compensation Expense:	2021	2020
Research and development	$ 758	$ 139
Distribution and administrative	8,114	3,281
Restructuring costs	—	(421)
Total share-based compensation expense	$ 8,872	$ 2,999

As of 31 December 2021, the Group expects $18,429 of unrecognized expense related to granted, but non-vested share-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 3.2 years.

The excess tax benefit related to share-based compensation recorded by the Group was immaterial for the years ended 31 December 2021 and 2020.

Upon exercise of stock options or warrants, or upon the issuance of restricted share awards, the Group issues new shares.

At 31 December 2021, there were 1,336 shares authorized for stock option grants, warrant grants and restricted share award grants in subsequent periods.

Inducement Plan

In November 2021, the Board of Directors approved the Avadel Pharmaceuticals plc 2021 Inducement Plan (the "Inducement Plan"), which allows the Group to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Group to accept employment and provide them with a proprietary interest in the Group. The maximum number of shares reserved and available for issuance under the Plan is 1,500 shares. As of 31 December 2021, the Group had not issued any shares under this Inducement Plan.

Determining the Fair Value of Stock Options and Warrants

The Group measures the total fair value of stock options on the grant date using the Black-Scholes option-pricing model and recognizes each grant's fair value as compensation expense over the period that the option vests. Options are granted to employees of the Group and become exercisable ratably over four years following the grant date and expire ten years after the

grant date. Prior to 2021, the Group issued stock options to our Board of Directors as compensation for services rendered that are exercisable ratably over three years following the grant date, and expire ten years after the grant date. In 2021, the Group issued stock options to our Board of Directors as compensation for services rendered and are exercisable one year following the grant date and expire ten years after the grant date.

The weighted-average assumptions under the Black-Scholes option-pricing model for stock option grants as of 31 December 2021 and 2020, are as follows:

Stock Option Assumptions:	2021	2020
Stock option grants:		
Expected term (years)	6.20	6.08
Expected volatility	73.91 %	75.76 %
Risk-free interest rate	1.10 %	0.72 %
Expected dividend yield	—	—

Expected term: The expected term of the options represents the period of time between the grant date and the time the options are either exercised or forfeited, including an estimate of future forfeitures for outstanding options. Given the limited historical data, the simplified method has been used to calculate the expected life.

Expected volatility: The expected volatility is calculated based on an average of the historical volatility of the Group's stock price for a period approximating the expected term.

Risk-free interest rate: The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant and a maturity that approximates the expected term.

Expected dividend yield: The Group has not distributed any dividends since our inception, and has no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Group's stock option plans for the year ended 31 December 2021 is as follows:

Stock Option Activity and Other Data:	Number of Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Stock options outstanding, 1 January 2021	5,898	$ 7.02		$ —
Granted	2,857	8.20		
Exercised	(48)	3.54		
Forfeited	(234)	7.13		
Expired	(70)	12.62		
Stock options outstanding, 31 December 2021	8,403	$ 7.39	7.83 years	$ 12,204
Stock options exercisable, 31 December 2021	3,256	$ 7.88	5.88 years	$ 6,291

A summary of the combined stock option activity and other data for the Group's stock option plans for the year ended 31 December 2020 is as follows:

Stock Option Activity and Other Data:	Number of Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Stock options outstanding, 1 January 2020	5,121	$ 7.51		$ —
Granted	2,551	6.90		
Exercised	(403)	5.08		
Forfeited	(566)	3.24		
Expired	(805)	13.37		
Stock options outstanding, 31 December 2020	5,898	$ 7.02	7.96 years	$ 7,115
Stock options exercisable, 31 December 2020	2,172	$ 9.48	5.58 years	$ 1,841

The aggregate intrinsic value of options exercised during the years ended 31 December 2021 and 2020 was $6,291 and $1,841, respectively.

The weighted average grant date fair value of options granted during the years ended 31 December 2021 and 2020 was $5.36 and $4.63, per share, respectively.

Warrants

A summary of the combined warrant activity and other data for the year ended 31 December 2020 is as follows:

Warrant Activity and Other Data:	Number of Warrants	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Warrants outstanding, 1 January 2020	291	$ 13.59		
Exercised	—	—		
Expired	(291)	13.59		
Warrants outstanding, 31 December 2020	—	$ —	0 years	$ —
Warrants exercisable, 31 December 2020	—	$ —	0 years	$ —

All outstanding warrants expired in August 2020. Each of the above warrants was convertible into one ordinary share. There was no aggregate intrinsic value of warrants exercised during the year ended 31 December 2020.

Restricted Share Awards

Restricted share awards represent Group shares issued free of charge to employees of the Group as compensation for services rendered. The Group measures the total fair value of restricted share awards on the grant date using the Group's stock price at the time of the grant. Restricted share awards granted from 2017-2020 vest over a three-year period; two-thirds (2/3) vesting on the second anniversary of the grant date and the remaining one-third (1/3) vesting on the third anniversary of the grant date. In 2021, restricted share awards granted to employees vest over a four-year period; one-fourth (1/4) on each anniversary of the grant date. In 2018, the Group issued restricted share awards to our Board of Directors vesting over a three-year period; one-third (1/3) vesting on each of the three anniversaries of the grant date. Compensation expense for such awards granted during and after 2017 is recognized over the applicable vesting period.

A summary of the Group's restricted share awards as of 31 December 2021, and changes during the year then ended, is reflected in the table below.

Restricted Share Activity and Other Data:	Number of Restricted Share Awards	Weighted Average Grant Date Fair Value
Non-vested restricted share awards outstanding, 1 January 2021	347	$ 5.87
Granted	99	8.22
Vested	(160)	5.05
Forfeited	(12)	7.08
Non-vested restricted shares awards outstanding, 31 December 2021	274	$ 7.14

A summary of the Group's restricted share awards as of 31 December 2020, and changes during the year then ended, is reflected in the table below.

Restricted Share Activity and Other Data:	Number of Restricted Share Awards	Weighted Average Grant Date Fair Value
Non-vested restricted share awards outstanding, 1 January 2020	347	$ 4.73
Granted	186	7.69
Vested	(115)	6.01
Forfeited	(71)	4.83
Non-vested restricted shares awards outstanding, 31 December 2020	347	$ 5.87

The weighted average grant date fair value of restricted share awards granted during the years ended 31 December 2021 and 2020 was $8.22 and $7.69, respectively.

Performance Share Units Awards

PSUs represent Group shares issued free of charge to employees of the Group as compensation for achieving various results. The Group measures the total fair value of performance share unit awards on the grant date using the Group's stock price at the time of the grant. In 2020, the Group granted performance share awards, of which 50% vest upon the achievement of certain regulatory milestones related to FT218 and the other 50% vest one year following achievement of those milestones ("2020 PSU awards"). The Group has not yet recognized any share-based compensation expense related to the 2020 PSU awards as the regulatory milestones have not yet been met; however, in the event the performance conditions are met before a certain date, approximately 100% of the outstanding shares, or $1,786 of compensation expense will be recognized by the Group for the 2020 PSU awards outstanding as of December 31, 2021.

In 2021, the Group granted performance share awards of which 50% vest upon achievement of certain corporate objectives and the second 50% vests one year following achievement of those objectives ("2021 PSU awards"). The Group has not yet recognized any share-based compensation expense related to the 2021 PSU awards as the objectives have not yet been met; however, in the event the performance conditions are met and exceeded, approximately 150% of the outstanding shares, or $3,509 of compensation expense will be recognized by the Group for the 2021 PSU awards outstanding as of December 31, 2021.

A summary of the Group's performance share units awards as of 31 December 2021, and changes during the year then ended, is reflected in the table below.

Performance Unit Share Activity and Other Data:	Number of Performance Unit Share Awards	Weighted Average Grant Date Fair Value
Non-vested performance share awards outstanding, 1 January 2021	257	$ 7.09
Granted	285	8.20
Vested	—	—
Forfeited	(7)	5.36
Non-vested performance shares awards outstanding, 31 December 2021	535	$ 7.71

A summary of the Group's performance share units awards as of 31 December 2020, and changes during the year then ended, is reflected in the table below.

Performance Unit Share Activity and Other Data:	Number of Performance Unit Share Awards	Weighted Average Grant Date Fair Value
Non-vested performance share awards outstanding, 1 January 2020	—	$ —
Granted	257	7.09
Vested	—	—
Forfeited	—	—
Non-vested performance shares awards outstanding, 31 December 2020	257	$ 7.09

The weighted average grant date fair value of performance share awards granted during the years ended 31 December 2021 and 2020 was $8.20 and $7.09 per share, respectively.

Employee Share Purchase Plan

In 2017, the Board of Directors approved the Avadel Pharmaceuticals plc 2017 Avadel Employee Share Purchase Plan ("ESPP"). The total number of Company ordinary shares, nominal value $0.01 per share, or ADSs representing such ordinary shares (collectively, "Shares") which may be issued under the ESPP is 1,000. The purchase price at which a share will be issued or sold for a given offering period will be established by the Compensation Committee of the Board ("Committee") (and may differ among participants, as determined by the Committee in its sole discretion) but will in no event be less than 85% of the lesser of: (a) the fair market value of a Share on the offering date; or (b) the fair market value of a Share on the purchase date. During the years ended 31 December 2021 and 2020, the Group issued 17 and 49 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended 31 December 2021 and 2020 was immaterial.

NOTE 18: Contingent Liabilities and Commitments

Litigation

The Group is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Group accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At 31 December 2021 and 31 December 2020, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Group's consolidated financial position, results of operations, cash flows or liquidity.

First Complaint

On 12 May 2021, Jazz Pharmaceuticals, Inc. ("Jazz") filed a formal complaint (the "First Complaint") initiating a lawsuit in the United States District Court for the District of Delaware (the "Court") against Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Management Corporation, Avadel Legacy Pharmaceuticals, LLC, Avadel Specialty Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals, LLC (collectively, the "Avadel Parties"). In the First Complaint, Jazz alleges the sodium oxybate product ("Proposed Product") described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The First Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 3 June 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Avadel Answer") with the Court in response to the First Complaint. The Avadel Answer generally denies the allegations set forth in the First Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patents-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of each patent-in-suit, and ii) a declaratory judgment of invalidity of each patent-in-suit.

On 18 June 2021, Jazz filed its Answer ("Jazz Answer") with the Court in response to the Avadel Answer. The Jazz Answer generally denies the allegations set forth in the Avadel Answer and sets forth a single affirmative defense asserting that Avadel has failed to state a claim for which relief can be granted.

On 21 June 2021, the Court issued an oral order requiring the parties to i) confer regarding proposed dates to be included in the Court's scheduling order for the case, and ii) submit a proposed order, including a proposal for the length and timing of trial, to the Court by no later than 21 July 2021.

On 30 July 2021, the Court issued a scheduling order establishing timing for litigation events including i) a claim construction hearing date of 2 August 2022, and ii) a trial date of 30 October 2023.

On 18 October 2021, consistent with the scheduling order, Jazz filed a status update with the Court indicating that Jazz did not intend to file a preliminary injunction with the Court at this time. Jazz further indicated that it would provide the Court with an update regarding whether preliminary injunction proceedings may be necessary after receiving further information regarding the FDA's action on Avadel's NDA.

On 4 January 2022, the Court entered an agreed order dismissing this case with respect to Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation. A corresponding order was entered in the two below cases on the same day.

On January 4, 2022, the Court entered an agreed order dismissing this case with respect to Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation. A corresponding order was entered in the two below cases on the same day.

On February 25, 2022, Jazz filed an amended Answer to Avadel's Counterclaims ("the Jazz First Amended Answer"). The Jazz First Amended Answer is substantially similar to the Jazz Answer except insofar as it adds an affirmative defense for judicial estoppel and unclean hands. Corresponding amended Answers were filed in the two below cases on the same day.

Second Complaint

On 4 August 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11077079. The Second Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 9 September 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Second Avadel Answer") with the Court in response to the Second Complaint. The Second Avadel Answer generally denies the allegations set forth in the Second Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity of the patent-in-suit.

On 22 October 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on 12 May 2021.

Third Complaint

On 10 November 2021, Jazz filed another formal complaint (the "Third Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Third Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11147782. The Third Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses. This case will proceed on the same schedule as the cases associated with the First and Second Complaints above.

On 7 January 2022, Avadel CNS Pharmaceuticals LLC timely filed its Answer and Counterclaims (the "Third Avadel Answer") with the Court in response to the Third Complaint. The Third Avadel Answer generally denies the allegations set forth in the Third Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity/unenforceability of the patent-in-suit.

On 21 December 2021, the Court entered a revised schedule for the First, Second and Third Complaints, setting a new claim construction date of 31 August 2022.

Material Commitments

At 31 December 2021, the Group has one commitment with our primary contract manufacturer related to facility upgrades and the purchase and validation of equipment to be used in the manufacture of FT218. The total cost of this commitment is estimated to be approximately $5,500 and is expected to be started and completed during the year ending 31 December 2022. The Group has incurred approximately $3,348 of this commitment during the year ended 31 December 2021.

The Group also has a commitment with another contract manufacturer that commences in the first quarter of 2022 and will continue until FDA approval of the contract manufacturer. The commitment will be approximately $3,000 per year.

Guarantees

Deerfield Guarantee

The fair values of our guarantee to Deerfield and the guarantee received by us from Armistice largely offset and when combined are not material.

In connection with the Group's February 2018 divestiture of our pediatric assets, including four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™ ("FSC products"), to Cerecor, Inc. ("Cerecor") the Group guaranteed to Deerfield a quarterly royalty payment of 15% on net sales of the FSC products through 6 February 2026 ("FSC Product Royalties"), in an aggregate amount of up to approximately $10,300. Given the Group's explicit guarantee to Deerfield, the Group recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was $1,054 and $1,372 at 31 December 2021 and 2020, respectively. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Armistice Guarantee

In connection with the Group's February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to the Group the FSC Product Royalties. The Group recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was $1,050 and $1,368 at 31 December 2021 and 2020, respectively. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

NOTE 19: Fair Value Measurements

The Group is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value extensively when accounting for and reporting certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business combination. Fair value is estimated by applying the hierarchy described below, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

ASC 820, *Fair Value Measurements and Disclosures* defines fair value as a market-based measurement that should be determined based on the assumptions that marketplace participants would use in pricing an asset or liability. When estimating fair value, depending on the nature and complexity of the asset or liability, we may generally use one or each of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.
- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

As a basis for considering the assumptions used in these techniques, the standard establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Quoted prices for identical assets or liabilities in active markets.
- Level 2 - Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means.
- Level 3 - Unobservable inputs that reflect estimates and assumptions.

The following table summarizes the financial instruments measured at fair value on a recurring basis classified in the fair value hierarchy (Level 1, 2 or 3) based on the inputs used for valuation in the accompanying consolidated balance sheet:

	As of 31 December 2021			As of 31 December 2020		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Investments (see *Note 9: Investments*)						
Money market and mutual funds	$ 78,098	$ —	$ —	$ 104,672	$ —	$ —
Corporate bonds	—	16,479	—	—	22,155	—
Government securities - U.S.	—	9,471	—	—	18,999	—
Other fixed-income securities	—	2,465	—	—	3,854	—
Total assets	$ 78,098	$ 28,415	$ —	$ 104,672	$ 45,008	$ —

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain investments or liabilities. During the fiscal year ended 31 December 2021, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended 31 December 2021, and 2020, we did not recognize any allowances for credit losses.

The following table summarizes changes to the Group's investments, a recurring Level 1 and Level 2 measurement, for the twelve-month period ended 31 December 2021:

Investments	**Balance**
Balance at 31 December 2020	$ 149,680
Purchases	61,769
Issues	(102,224)
Total gains or losses:	
Profit and Loss Account	(635)
Other Comprehensive Income	(2,077)
Balance at 31 December 2021	$ 106,513

Some of the Group's financial instruments, such as cash and cash equivalents, trade debtors and creditors, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

Debt

The Group estimates the fair value of its $143,750 aggregate principal amount of the 2023 Notes, based on interest rates that would be currently available to the Group for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers (a Level 2 input). The estimated fair value of the 2023 Notes at 31 December 2022 is $153,273.

See *Note 15: Long-Term Debt* for additional information regarding our debt obligations.

NOTE 20: Group Operations by Product, Customer and Geographic Area

The Group has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology. The Group's Chief Operating Decision Maker is the CEO. The CEO reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products are included in one segment because the Group's products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

On June 30, 2020, the Group sold the Hospital Products. See *Note 4: Disposition of the Hospital Products*. The Group had no revenue during the twelve months ended 31 December 2021.

The following table presents a summary of total turnover by product for the year ended 31 December 2020:

Turnover by Product:	2020
Bloxiverz	$ 2,201
Vazculep	10,429
Akovaz	9,545
Other	159
Product sales	22,334

The following table presents a summary of total turnover by significant customer for the twelve months ended 31 December 2020:

Turnover by Significant Customer:	2020
McKesson Corporation	$ 5,758
Cardinal Health	5,155
AmerisourceBergen	3,155
QuVa Pharma	3,117
Others	5,149
Product Sales	$ 22,334

All turnover earned during the year ended 31 December 2020 was generated in the U.S.

Concentration of credit risk with respect to accounts receivable was limited due to the high credit quality comprising a significant portion of the Group's customers. Management periodically monitors the creditworthiness of our customers and believes that it has adequately provided for any exposure to potential credit loss.

Currently, the Group is working with contract manufacturing organizations for the manufacture of FT218. Additionally, the Company purchases raw materials used in FT218 from a limited number of suppliers, including a single supplier for certain key ingredients.

Non-monetary long-lived assets primarily consist of tangible assets, goodwill and intangible assets. The following table summarizes non-monetary long-lived assets by geographic region as of 31 December 2021 and 2020:

Long-lived Assets by Geographic Region:	2021	2020
United States	$ 19,605	$ 20,424
France	—	11
Ireland	9,817	6,047
Total	$ 29,422	$ 26,482

NOTE 21: Loss Attributable to Avadel Pharmaceuticals plc

In accordance with Section 304(2) of the Companies Act 2014, the Group is availing itself of the exemption from presenting and filing its parent company profit and loss account. Avadel Pharmaceuticals plc loss for the year ended 31 December 2021 as determined in accordance with Irish GAAP (FRS 102) was $15,700 (2020: loss $10,247).

NOTE 22: Key Management Compensation

Key Management Compensation	2021	2020
Aggregate emoluments	$ 2,338	$ 2,875
Aggregate amount of gains on the exercise of share options during the financial year	—	474
Aggregate amount of the money or value of other assets under long term incentive schemes	6,374	4,737
Compensation for loss of office	—	400
Total	$ 8,712	$ 8,486

Total key managements' share-based compensation charged to profit and loss in accordance with ASC 718 was $4,137 and $1,272 for the year ended 31 December 2021 and 2020 respectively.

See *Note* 5: *Directors' Remuneration* to the Company Financial Statements for directors' remuneration.

NOTE 23: Auditor's Remuneration

Auditor's remuneration was as follows:

	2021	2020
Audit of group financial statements	$ 166	$ 186
Other assurance services	36	46
Total	$ 202	$ 232

No amounts were incurred for other non-audit services. The Group incurred additional fees of $763 and $1,121 during fiscal 2021 and 2020, respectively, payable to affiliates of Deloitte Ireland LLP. These additional amounts reflect fees for all professional services rendered, including audit fees payable to Deloitte & Touche LLP in the United States for the audit of the 10-K.

NOTE 24: Employees

The average number of persons, including executive directors, employed by the Group during the year was as follows:

Average Number of Employees	2021	2020
Research and development	3	3
General, administrative and sales	47	29
Total	50	32

Employee costs consisted of the following:

Employee Costs	2021	2020
Wages and salaries	$ 13,389	$ 7,964
Social security costs and other tax	662	616
Defined contribution (credit)/cost	360	216
Stock based compensation	8,871	3,419
Total	$ 23,282	$ 12,215

During fiscal 2021 and 2020, the Group received credits of $956 and $155, respectively, related to the Employee Retention Credit under the CARES Act. These amounts are not included in the table above.

There was an immaterial amount of employee costs capitalized during the years ended 31 December 2021 and 2020.

NOTE 25: Post Balance Sheet Events

Exchange Transaction Closing

On 5 April 2022, Avadel completed the exchange of $117,375 of its February 2023 Notes for a new series of its Exchangeable Senior Notes due 2 October 2023. The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and will maintain a maturity date of 1 February 2023. The Group paid $4,800 in fees paid to note holders of the October 2023 Notes and $5,400 in fees paid to third parties as part of the completed Exchange Transaction. See *Note 15: Long-Term Debt* for additional information regarding the Company's debt obligations.

Jazz Litigation

On 14 April 2022, Avadel CNS Pharmaceuticals LLC and Avadel Pharmaceuticals plc (collectively the "Avadel Plaintiffs") filed a formal complaint (the "Avadel Complaint") initiating a lawsuit in the United States District Court for the District of Delaware (the "Court") against Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Ltd. (collectively, the "Jazz Parties"). In the Avadel Complaint, the Avadel Plaintiffs allege that the Jazz Parties breached certain confidential disclosure agreements and misappropriated certain of Avadel's trade secrets. The Avadel Complaint further includes typical relief requests such as injunctive relief, monetary damages and attorneys' fees, costs and expenses, as well as seeking correction of inventorship of certain Jazz patents to include former Avadel scientists.

NOTE 26: Related Party Disclosures

As noted in *Note 4: Disposal of the Hospital Products,* prior to 30 June 2020*,* the Group was party to a Membership Interest Purchase Agreement by and among the Group, Avadel Legacy, Breaking Stick Holdings, LLC, Deerfield Private Design International II, L.P. ("Deerfield International"), Deerfield Private Design Fund II, L.P. ("Deerfield Fund") and Horizon Santé FLML, Sarl ("Horizon") (the "Deerfield MIPA") and a Royalty Agreement by and among the Group, Avadel Legacy, the Deerfield Fund and Horizon (the "Deerfield Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Deerfield Royalty Agreement for obligations that arise after the Closing date.

Prior to 30 June 2020, the Group was also party to a Royalty Agreement by and between itself, Avadel Legacy and Broadfin Healthcare Master Fund, Ltd. (the "Broadfin Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Broadfin Royalty Agreement for obligations that arise after the Closing Date.

Refer to *Note 16: Contingent Consideration Payable* for a summary of payments made for and changes to the fair value of the related party payable for the year ended 31 December 2019. Deerfield and Broadfin disposed of their 2023 Notes and ordinary shares in the Group during the year ended 31 December 2020 and are no longer considered related parties for the years ended 31 December 2021 and 2020.

NOTE 27: Subsidiary Undertakings

As of 31 December 2021, the Group had 100% interest in the equity of the following subsidiaries:

Name	Jurisdiction	Registered Office
Avadel Pharmaceuticals plc (the Registrant):	Ireland	10 Earlsfort Terrace Dublin 2
1) Avadel US Holdings, Inc. *(f/k/a Flamel US Holdings, Inc.)*	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
A. Avadel Legacy Pharmaceuticals, LLC *(f/k/a Éclat Pharmaceuticals LLC)*	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
B. Avadel Management Corporation	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
C. Avadel CNS Pharmaceuticals, LLC	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
2) Flamel Ireland Limited *(t/a Avadel Ireland Ltd.)*	Ireland	10 Earlsfort Terrace Dublin 2
3) Avadel Investment Company, Ltd.	Cayman Islands	PO Box 309, Ugland House Grand Cayman Cayman Islands, KY 1-1104
4) Avadel France Holding SAS	France	2 Bis Rue tête d'or 69006 Lyon
A. Avadel Research SAS	France	2 Bis Rue tête d'or 69006 Lyon
5) Avadel Finance Ireland Designated Activity Company	Ireland	10 Earlsfort Terrace Dublin 2
A. Avadel Finance Cayman Ltd.	Cayman Islands	PO Box 309, Ugland House Grand Cayman Cayman Islands, KY 1-1104

The Group does not have any interest in any other subsidiaries, other than the ones mentioned above.

NOTE 28: Subsidiary Bankruptcy and Deconsolidation

On 6 February 2019, the Group deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy and recorded a non-cash charge of approximately $2,678 for the year ended 31 December 2019. The Group recognized a non-cash gain of $217 and $3,364 from the release of certain liabilities that had been retained following the deconsolidation of Specialty Pharma. These gains are included in "Gain from release of certain liabilities" within non-operating (loss) income for the years ended 31 December 2021 and 2020.

On 26 October 2021, the U.S. Bankruptcy Court for the District of Delaware issued the Final Decree and Order, dismissing the bankruptcy case and dissolving Specialty Pharma.

Note 29: Restructuring Costs

2019 French Restructuring

During the second quarter of 2019, the Group initiated a plan to discontinue all French R&D activities, which resulted in the redundancy of its entire workforce at its Vénissieux, France site (“2019 French Restructuring”). This reduction was part of an effort to align the Group’s cost structure with its ongoing and future planned projects. The reduction in workforce was completed during the year ended 31 December 2020. Restructuring charges associated with this plan recognized during the years ended 31 December 2021 and 2020 were immaterial. At 31 December 2021, there are no future expected retirement indemnity benefits to be paid. The Group does not expect to incur any additional expenses related to the 2019 French Restructuring. The following table sets forth activities for the Group’s cost reduction plan obligations for the years ended 31 December 2021 and 2020:

2019 French Restructuring Obligation:	2021	2020
Balance of restructuring accrual at 1 January	$ 248	$ 1,922
Charges for employee severance, benefits and other costs	(122)	172
Payments	(77)	(1,813)
Foreign currency impact	(8)	(33)
Balance of restructuring accrual at 31 December	$ 41	$ 248

The 2019 French Restructuring liability of $41 is included in the consolidated balance sheet in creditors at 31 December 2021.

2019 Corporate Restructuring

During the first quarter of 2019, the Group announced a plan to reduce its Corporate workforce by more than 50% (the "2019 Corporate Restructuring"). The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019 (see *Note 28: Subsidiary Bankruptcy and Deconsolidation*), as well as an effort to better align the Group's remaining cost structure at our U.S. and Ireland locations with its ongoing and future planned projects. The reduction in workforce was completed during the year ended 31 December 2020. Restructuring income associated with this plan for the years ended 31 December 2021 and 2020 were immaterial. The Group does not expect to incur any additional expenses related to the 2019 Corporate Restructuring.

During the years ended 31 December 2021 and 2020, the Group paid $272 and $1,014 respectively, and has no remaining obligation for the 2019 Corporate Restructuring plan as of 31 December 2021.

NOTE 30: Leases

The Group leases office space and a production suite. All leased facilities are classified as operating leases with remaining lease terms between two and four years. The Group determines if a contract is a lease at the inception of the arrangement. The Group reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. The Group's lease agreements do not contain any material residual value guarantees or material variable lease payments.

The components of lease costs, which are included in selling, general and administrative expenses in the consolidated profit and loss account of years ended 31 December 2021 and 2020 were as follows:

Lease cost:	2021	2020
Operating lease costs [(1)]	$ 821	$ 1,133
Sublease income [(2)]	(110)	(336)
Total lease cost	$ 711	$ 797

[(1)] Variable lease costs were immaterial for the years ended 31 December 2021 and 2020.
[(2)] Represents sublease income received for office leases.

During the years ended 31 December 2021 and 2020, the Group reduced its operating lease liabilities by $578 and $769 for cash paid. During the year ended 31 December 2021, the Group remeasured its production suite lease liability. During the year ended 31 December 2021, the Group did not enter into any new operating or finance leases.

As of 31 December 2021, the Group's operating leases have a weighted-average remaining lease term of 2.9 years and a weighted-average discount rate of 4.9%. The Group's lease contracts do not provide a readily determinable implicit rate. The Group's estimated incremental borrowing rate is based on information available at the inception of the lease.

Maturities of the Group's operating lease liabilities were as follows:

Maturities:	Operating Leases
2022	$ 974
2023	1,013
2024	614
2025	206
2026	—
Thereafter	—
Total lease payments	2,807
Less: interest	200
Present value of lease liabilities	$ 2,607

AVADEL PHARMACEUTICALS PLC
Company Financial Statements
For the year ended 31 December 2021

Independent auditor's report to the members of Avadel Pharmaceuticals plc

Report on the audit of the financial statements

Opinion on the financial statements of Avadel Pharmaceuticals plc (the 'company')

In our opinion the parent company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the parent company as at 31 December 2021; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The parent company financial statements we have audited comprise:

- the Company Balance Sheet;
- the Company Statement of Changes in Equity; and
- the related notes 1 to 15, including a summary of significant accounting policies as set out in note 1.

The relevant financial reporting framework that has been applied in the preparation of the financial statements is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" ("the relevant financial reporting framework").

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report.

We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Our evaluation of the directors' assessment of the parent company's ability to continue to adopt the going concern basis of accounting included:

- As part of our risk assessment procedures, obtaining an understanding of the relevant controls in place regarding going concern;
- Reviewing documentation supporting the key inputs to budgets and forecasts including obtaining evidence supporting the following; exchange of February 2023 loan notes for October 2023 loan notes, fees incurred for the debt extension and the group's capital commitments;
- challenging the reasonableness of the key assumptions applied by the directors in their going concern assessment, which covers a period of at least 12 months from the date of signing the financial statements;
- obtaining an understanding of the Group's controls over the development and approval of the projections and assumptions used in the cash flow forecasts to support the going concern assumption and assessing the design and determining the implementation of these controls;
- testing the clerical accuracy of the forecasts; and
- assessing the adequacy of the disclosures in the financial statements.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Summary of our audit approach

Key audit matter	The key audit matter that we identified in the current year was: • Carrying value of financial assets
Materiality	The materiality that we used in the current year was $1.6 million which was determined on the basis of net assets.
Scoping	We have determined the scope of our audit by obtaining an understanding of the Company and its environment, including assessing the risks of material misstatement at the Company level.
Significant changes in our approach	No significant changes to note.

Key Audit Matter

Key audit matter is a matter that, in our professional judgment, is of most significance in our audit of the financial statements of the current financial period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. The matter was addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on this matter.

Carrying Value of Financial Assets

Key audit matter description	There is a risk that an impairment in the company's investments in subsidiary is not appropriately recorded in the financial statements. At 31 December 2021 the market capitalisation of the Group was lower than the net assets of the parent company. This was considered an indicator of impairment. Refer also to Note 1 (accounting policy for Investments in Subsidiary) and Note 6 (Financial Fixed Assets).
How the scope of our audit responded to the key audit matter	We considered the appropriateness of the directors' approach to impairment review which considers the valuation of the parent company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Group adjusted for control premium. We assessed the methodology applied by management in determining share prices and control premium, and we reviewed key inputs to supporting evidence. There was no impairment recorded to the carrying value of financial assets during the year. We assessed the adequacy of the related disclosures.
Key observations	We have no observations that impact on our audit in respect of the carrying value of financial assets.

Our audit procedures relating to the key audit matter were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on this individual matter.

Our application of materiality

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

We determined planning materiality for the company to be $1.6 million which was determined based on net assets of the company. We have considered net assets to be the critical component for determining materiality because we determined net

assets to be of most importance to the principal external users of these financial statements as this is the key balance in this legal entity and holding this investment is the purpose of the entity.

We agreed with the Audit Committee that we would report to the Audit Committee any audit differences in excess of $0.08 million or 5.0% of materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

An overview of the scope of our audit

Our audit is a risk-based approach taking into account the structure of the company, our knowledge of the Group and industry in which the company operates and the accounting processes and controls in place.

Other information

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements for the financial year ended 31 December 2021, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the parent company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.

- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland), and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Opinion on other matters prescribed by the Companies Act 2014

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The Company Balance Sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report as specified in our review is consistent with the financial statements and has been prepared in accordance with the Companies Act 2014.

Matters on which we are required to report by exception

Based on the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in those parts of the directors' report that have been specified for our review.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Other Matters

We have reported separately on the consolidated financial statements of Avadel Pharmaceuticals plc for the financial year ended 31 December 2021.

Use of our report

This report is made solely to the Company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume

responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

/s/ Cathal Treacy
Cathal Treacy
For and on behalf of Deloitte Ireland LLP
Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House
Earlsfort Terrace
Dublin 2
Date: 9 May 2022

AVADEL PHARMACEUTICALS PLC
COMPANY BALANCE SHEET
AT 31 DECEMBER 2021
(*Amounts in $ thousands*)

	Note	2021	2020
FIXED ASSETS			
Intangible assets	*6*	$ 55	$ 59
Financial assets	*7*	430,474	422,836
		430,529	422,895
CURRENT ASSETS			
Debtors			
-Due within one year	*8*	43,475	39,785
-Due after one year	*8*	328	424
Cash at bank and in hand		37,339	54,669
		81,142	94,878
CURRENT LIABILITIES			
Creditors (amounts falling due within one year)	*9*	(948)	(485)
NET CURRENT ASSETS		80,194	94,393
Total assets less current liabilities		510,723	517,288
NET ASSETS		$ 510,723	$ 517,288
CAPITAL AND RESERVES			
Called up share capital presented as equity	*10*	$ 617	$ 614
Share premium	*11*	277,127	276,865
Other reserves	*11*	15,830	6,958
Profit and loss account		217,149	232,851
SHAREHOLDERS' FUNDS		$ 510,723	$ 517,288

In accordance with Section 304(2) of the Irish Companies Act 2014, Avadel Pharmaceuticals plc is availing itself of the exemption from presenting and filing its individual profit and loss account. Avadel Pharmaceuticals plc's net loss as determined in accordance with FRS 102 was $15,700 (2020: loss $10,247).

The financial statements were approved by the board on 9 May 2022 and signed on its behalf by:

/s/ Peter J. Thornton
Peter J. Thornton
Director

/s/ Gregory J. Divis
Gregory J. Divis
Director

AVADEL PHARMACEUTICALS PLC
STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 31 DECEMBER 2021
(*Amounts in $ Thousands*)

	Share Capital - Ordinary	Share Capital - Preferred	Share Premium	Other Reserves	Profit and Loss Account	Total Equity
At 31 December 2019	$ 455	$ —	$ 84,866	$ 16,433	$ 243,099	$ 344,853
Result for the Period	$ —	$ —	$ —	$ —	$ (10,247)	$ (10,247)
Vesting of restricted shares	1	—	—	—	(1)	—
Share-based compensation expense	—	—	—	2,999	—	2,999
Employee share purchase plan issuance	—	—	144	—	—	144
Exercise of stock options	4	—	2,041	—	—	2,045
February 2020 private placement	87	5	64,908	(4,430)	—	60,570
May 2020 public offering	116	—	124,906	(8,098)	—	116,924
Cancellation of treasury shares	(54)	—	—	54	—	—
At 31 December 2020	$ 609	$ 5	$ 276,865	$ 6,958	$ 232,851	$ 517,288
Result for the Period	$ —	$ —	$ —	$ —	$ (15,700)	$ (15,700)
Vesting of restricted shares	2	—	—	—	(2)	—
Share-based compensation expense	—	—	—	8,872	—	8,872
Employee share purchase plan issuance	—	—	94	—	—	94
Exercise of stock options	1	—	168	—	—	169
At 31 December 2021	$ 612	$ 5	$ 277,127	$ 15,830	$ 217,149	$ 510,723

Share premium

In 2020, the share premium account increased due to the employee purchase plan issuance of $144 and the exercise of stock options of $2,041. In 2021, the share premium account increased due to the employee purchase plan issuance of $94 and the exercise of stock options of $168.

In February 2020, the Company entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares ("Series A Preferred") in a private placement to a group of institutional accredited investors, which resulted in an increase of $64,908 to share premium. In May 2020, the Company closed a public offering of 11,630 Ordinary Shares, which resulted in an increase of $124,906 to share premium. See *Note 19: Called-up Share Capital and Reserves* in the Group's Notes to Consolidated Financial Statements.

Other reserves

The increase in the balance as of 31 December 2020 was due to $2,999 of accumulated share-based compensation and $54 of capital redemption reserve arising on the cancellation of treasury shares, offset by issuance costs of $4,430 and $8,098 related to the February 2020 private placement and May 2020 public offering, respectively.

The increase in the balance as of 31 December 2021 was due to $8,872 of accumulated share-based compensation.

AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2021

NOTE 1: Accounting Policies

Basis of preparation and statement of compliance

The company financial statements have been prepared on a going concern basis and comply with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and have been prepared in accordance with the Companies Act 2014. The financial statements are prepared for the year ended 31 December 2021 with comparatives presented for the year ended 31 December 2020.

The principal accounting policies are summarised below. They have all been applied consistently throughout the financial year.

In accordance with section 304 of the Companies Act 2014, the company is availing of the exemption from presenting the individual statement of comprehensive income.

General information and basis of accounting

Avadel Pharmaceuticals plc was incorporated on 1 December 2015 as an Irish private limited company under the Companies Act 2014, and re-registered as an Irish public limited company, or plc, on 21 November 2016. Its registered office is located at 10 Earlsfort Terrace, Dublin 2, Ireland. Its headquarters are in St. Louis, MO, USA. Its website is www.Avadel.com. The Company registration number is 572535.

The Company is the successor to Flamel Technologies S.A., a French société anonyme ("Flamel"), as the result of the merger of Flamel with and into the company which was completed at 11:59:59 p.m., Central Europe Time, on 31 December 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of 29 June 2016. Immediately prior to the merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the merger agreement, Flamel ceased to exist as a separate entity and the company continued as the surviving entity and assumed all of the assets and liabilities of Flamel. These assets and liabilities were valued using the book value of the assets and liabilities at the time of the merger.

On 1 January 2017, Avadel Pharmaceuticals plc contributed all the assets and liabilities associated with the research and development services business performed in France to Avadel Research SAS, which is a wholly owned subsidiary of Avadel France Holding SAS, in exchange for stock in Avadel Research SAS.

The functional currency of the Company is considered to be US dollar because that is the currency of the primary economic environment in which the company operates.

Going concern

The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis of accounting in preparing the financial statements. See *Note 1: Background and Basis of Presentation* of the Group's Notes to Consolidated Financial Statements for further information.

Intangible assets

Intangible assets are stated at cost or valuation, net of amortisation and any provisions for impairment. Amortisation is provided on amortisable intangible assets at rates calculated to write off the cost or valuation, less estimated residual value, of each asset on a straight-line basis over its expected useful life, as follows:

Asset:	Useful life:
Software	3-10 years

Residual value represents the estimated amount which would currently be obtained from disposal of an asset, after deducting estimated costs of disposal, if the asset were already of the age and in the condition expected at the end of its useful life.

Financial instruments

Financial Assets and Liabilities (including Investment in Subsidiary Undertakings)

For financial instruments, the company has adopted the recognition and measurement criteria of sections 11 and 12 of FRS 102. All financial assets and liabilities are initially measured at transaction price (including transaction costs), except for those financial assets classified as at fair value through profit or loss, which are initially measured at fair value (which is normally the transaction price excluding transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a finance transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Non-current debt instruments which meet the following conditions are subsequently measured at amortised cost using the effective interest method:

a. Returns to the holder are (i) a fixed amount; or (ii) a fixed rate of return over the life of the instrument; or (iii) a variable return that, throughout the life of the instrument, is equal to a single referenced quoted or observable interest rate; or (iv) some combination of such fixed rate and variable rates, providing that both rates are positive.

b. There is no contractual provision that could, by its terms, result in the holder losing the principal amount or any interest attributable to the current period or prior periods.

c. Contractual provisions that permit the issuer to prepay a debt instrument or permit the holder to put it back to the issuer before maturity are not contingent on future events, other than to protect the holder against the credit deterioration of the issuer or a change in control of the issuer, or to protect the holder or issuer against changes in relevant taxation or law.

d. There are no conditional returns or repayment provisions except for the variable rate return described in (a) and prepayment provisions described in (c).

Debt instruments that are classified as payable or receivable within one year and which meet the above conditions are measured at the undiscounted amount of the cash or other consideration expected to be paid or received, net of impairment.

Other debt instruments not meeting these conditions are measured at fair value through profit or loss.

Financial assets are derecognised when and only when:

a. The contractual rights to the cash flows from the financial asset expire or are settled,

b. The Company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or

c. The Company, despite having retained some significant risks and rewards of ownership, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer.

Impairment of Assets

Assets, other than those measured at fair value, are assessed for indicators of impairment at each balance sheet date. If there is objective evidence of impairment, an impairment loss is recognised in profit or loss as described below.

Financial Fixed Assets (including investments in subsidiaries)

For financial assets carried at amortised cost, the amount of an impairment is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the financial asset's original effective interest rate.

For financial assets carried at cost less impairment, the impairment loss is the difference between the asset's carrying amount and the best estimate of the amount that would be received for the asset if it were to be sold at the reporting date.

The Company's investment in subsidiaries are initially recorded at fair value of consideration given plus any directly attributable costs (at cost). The investments are carried at cost less accumulated impairment if circumstances or indicators suggest that impairment may exist. Where there are indicators of impairment of financial assets, the Company performs impairment tests based on the valuation of the Company's subsidiaries and net assets against other indicators of value, such as

the overall group market capitalisation adjusted for control premium and carrying value of net assets in the consolidated financial statements.

Where indicators exist for a decrease in impairment loss, and the decrease can be related objectively to an event occurring after the impairment was recognised, the prior impairment loss is tested to determine reversal. An impairment loss is reversed on an individual impaired financial asset to the extent that the revised recoverable value does not lead to a revised carrying amount higher than the carrying value had no impairment been recognised.

Taxation

Current tax, including Irish corporation tax and foreign tax, is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date.

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date where transactions or events that result in an obligation to pay more tax in the future or a right to pay less tax in the future have occurred at the balance sheet date. Timing differences are differences between the company's taxable profits and its results as stated in the financial statements that arise from the inclusion of gains and losses in tax assessments in periods different from those in which they are recognised in the financial statements.

Unrelieved tax losses and other deferred tax assets are recognised only to the extent that, on the basis of all available evidence, it can be regarded as more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

When the amount that can be deducted for tax for an asset (other than goodwill) that is recognised in a business combination is less (more) than the value at which it is recognised, a deferred tax liability (asset) is recognised for the additional tax that will be paid (avoided) in respect of that difference. Similarly, a deferred tax asset (liability) is recognised for the additional tax that will be avoided (paid) because of a difference between the value at which a liability is recognised and the amount that will be assessed for tax. The amount attributed to goodwill is adjusted by the amount of deferred tax recognised.

Deferred tax liabilities are recognised for timing differences arising from investments in subsidiaries and associates, except where the company is able to control the reversal of the timing difference and it is probable that it will not reverse in the foreseeable future.

Deferred tax is measured using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date that are expected to apply to the reversal of the timing difference. Deferred tax relating to tangible assets measured using the revaluation model and investment property is measured using the tax rates and allowances that apply to sale of the asset.

The tax expense or income is presented in the same component of comprehensive income or equity as the transaction or other event that resulted in the tax expense or income.

Current tax assets and liabilities are offset only when there is a legally enforceable right to set off the amounts and the company intends either to settle on a net basis or to realise the asset and settle the liability simultaneously.

Deferred tax assets and liabilities are offset only if: a) the company has a legally enforceable right to set off current tax assets against current tax liabilities; and b) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Financial Guarantees

At the time the Company issues a guarantee, the Company recognizes an initial liability for the fair value of the obligation which the Company assumes under that guarantee.

Foreign currency

Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are reported at the rates of exchange prevailing at that date.

Exchange differences arising on translation of the opening net assets are reported in other comprehensive income and accumulated in equity. Other exchange differences are recognised in profit or loss in the period in which they arise except for exchange differences arising on gains or losses on non-monetary items which are recognized in other comprehensive income.

Cash and cash equivalents

Cash and cash equivalents on the Balance Sheet comprise cash at banks and in hand and short term deposits readily convertible to known amounts of cash with an original maturity date of three months or less.

Share-based payment

The Company issues equity-settled share options and equity-settled share appreciation rights to certain employees within the Group. Equity-settled share based payment transactions are measured at fair value of the equity instruments (excluding the effect of non market-based vesting conditions) at the date of grant. The fair value determined at the grant date of the equity-settled share based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of non market-based vesting conditions.

Fair value of the equity-settled share options is measured by use of the Black Scholes pricing model which is considered by management to be the most appropriate method of valuation. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations. Fair value of the equity-settled share appreciation rights is measured on the grant date using the Group's stock price at the time of the grant.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of the investment in subsidiary undertakings by the value associated with the share-based payment. In the event that there is a net forfeiture this would result in a decrease in the value of the investment in subsidiary undertakings.

Statement of cash flow exemption and other disclosure exemptions under FRS 102

The Company meets the definition of a qualifying entity under FRS 102 and has therefore taken advantage of the disclosure exemptions available to it in respect of its separate financial statements, which are presented alongside the consolidated financial statements. Exemptions have been taken in relation to presentation of a cash flow statement, share-based payments, financial instruments and remuneration of key management personnel. Please refer to the Consolidated Statement of Cash Flows, *Note 17.1: Equity Instruments and Stock Based Compensation*, *Note 19: Fair Value Measurements* and *Note 22: Key Management Compensation* in the Group's Notes to Consolidated Financial Statements.

NOTE 2: Critical Accounting Judgements and Key Sources of Estimation Uncertainty

In the application of the Company's accounting policies, which are described in *Note 1: Accounting Policies*, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following are the critical judgements, apart from those involving estimations (which are dealt with separately below), that the directors have made in the process of applying the company's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

Impairment of Financial Fixed Assets

Where there are indicators of impairment of financial assets, the Company performs impairment tests based on the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Avadel Pharmaceutical Group and carrying value of net assets in the consolidated financial statements. The overall market capitalisation calculation used an average stock price of Avadel Pharmaceutical plc at the year end, increased by a control premium based on available data from similar, observable market transactions. Additional, publicly-available analysis from unrelated parties is also used to verify market capitalisation assumptions for the analysis

NOTE 3: Turnover

The Company did not have any turnover for the year ended 31 December 2021 (2020: $nil).

NOTE 4: Auditor's Remuneration (Amounts in $ thousands)

The analysis of the auditor's remuneration is as follows:

Auditor's remuneration for work carried out for the Company in respect of the financial period is as follows:	2021	2020
Audit of Company accounts	$ 17	$ 19
Other assurance services	149	167

No amounts were incurred for tax advisory services or other non-audit services. *Note 23: Auditor's Remuneration* to the Group's Notes to Consolidated Financial Statements provides additional details of fees paid by the Group.

NOTE 5: Directors' Remuneration (Amounts in $ thousands)

Directors' Remuneration	2021	2020
Aggregate emoluments in respect to qualifying services	$ 1,245	$ 1,238
Aggregate amount of the money or value of other assets under long term incentive schemes in respect qualifying services	2,730	3,584
Total	$ 3,975	$ 4,822

The Company had no other employees apart from the directors during the financial year and the prior financial year. Total directors' share-based compensation charged to profit and loss was $2,441 and $1,124 for the years ended 31 December 2021 and 2020 respectively. All required disclosure items in section 305 - 306 of CA 14 are $0 for the years ended 31 December 2021 and 2020, other than those included in the table above.

See *Note 22: Key Management Compensation* to the Group's Notes to Consolidated Financial Statements for key management compensation.

NOTE 6: Intangible Assets (Amounts in $ thousands)

	Software	Total
Cost:		
At 31 December 2020	$ 59	$ 59
Additions	—	$ —
At 31 December 2021	$ 59	$ 59
Depreciation		
At 31 December 2020	$ —	$ —
Charge for the year	4	$ 4
At 31 December 2021	$ 4	$ 4
Net Book Value:		
At 31 December 2020	$ 59	$ 59
At 31 December 2021	$ 55	$ 55

For the year ended 31 December 2020, the Company recorded $59 of intangible assets related to software. The software was placed into service during the year ended 31 December 2021.

NOTE 7: Financial Fixed Assets (Amounts in $ thousands)

Principal Company Investments - Subsidiary Undertakings

	Financial Fixed Assets
At 31 December 2019	**$ 317,070**
Deemed contributions of stock based compensation	2,266
Contribution of cash to US Holdings	103,500
At 31 December 2020	**$ 422,836**
Deemed contributions of stock based compensation	7,638
At 31 December 2021	**$ 430,474**

Avadel Pharmaceuticals plc has investments in the following subsidiary undertakings. All ownership related to subsidiaries is common equity. An impairment review was performed at the 31 December 2021, which considered the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall group market capitalisation adjusted for control premium. No impairment charge was recorded during the year

Direct Subsidiary Undertakings:	Country	Principal Activity	%
Avadel US Holdings Inc	USA	Marketing Services	100
Avadel France Holding SAS	France	Holding Company	100
Flamel Ireland Ltd	Ireland	Research & Development	100
Avadel Investment Company Limited	Cayman Islands	Investment Services	100
Avadel Finance Designated Activity Company	Ireland	Finance Services	100

Refer to *Note 27: Subsidiary Undertakings* of the Group's Notes to Consolidated Financial Statements for the full list of subsidiary undertakings for the Group and respective registered offices.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of their investment in subsidiary undertakings by the value associated with the share-based payment. In 2021 and 2020, the value associated with share-based payments provided to employees in subsidiary undertakings was $7,638 and $2,266, respectively.

In 2020, Avadel Pharmaceuticals plc contributed $103,500 of cash to Avadel US Holdings as a capital contribution. There were no capital contributions in 2021.

NOTE 8: Debtors (Amounts in $ thousands)

	2021	2020
Amounts Falling Due Within One Year:		
Prepayments and accrued income	$ 552	$ 625
VAT receivable	116	237
Intercompany accounts receivable	42,807	38,923
Total	$ 43,475	$ 39,785
Amounts Falling Due After One Year:		
Prepayments	$ 328	$ 424
Total	$ 328	$ 424

At 31 December 2021, the outstanding intercompany receivable balances were comprised of a $11,297 (2020: $14,037) receivable from Avadel US Holdings and a $31,510 (2020: $24,886) receivable from Flamel Ireland Ltd.

NOTE 9: Creditors (Amounts in $ thousands)

	2021	2020
Amounts Falling Due Within One Year:		
Trade creditors	$ 225	$ 205
Accruals and other creditors	723	280
	$ 948	485

Trade creditors are repayable within 30 to 60 days of the amount owing.

NOTE 10: Called Up Share Capital (Amounts in $ thousands, except per share data)

	2021	2020
Authorised:		
25 deferred ordinary shares of €1.00 each at 31 December 2021 and 2020	$ 26	$ 26
500,000 ordinary shares of $0.01 each at 31 December 2021 and 2020	5,000	5,000
50,000 preferred shares of $0.01 each at 31 December 2021 and 2020	500	500
Allotted, Called Up and Fully Paid:		
25 deferred ordinary shares of €1.00 each at 31 December 2021 and 2020	$ 26	$ 26
58,620 and 58,396 ordinary shares of $0.01 each at 31 December 2021 and 2020, respectively	586	583
488 preferred shares of $0.01 at 31 December 2021 and 2020	5	5
Called up share capital presented as equity	$ 617	$ 614

The Board of Directors is authorized to issue preferred stock in series, and with respect to each series, to fix its designation, relative rights (including voting, dividend, conversion, sinking fund, and redemption rights), preferences (including dividends and liquidation) and limitations. We have 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 488 are currently issued and outstanding as of 31 December 2021.

In 2021, 17 shares were issued as part of the employee share purchase plan for $94. In 2020, 49 shares were issued as part of employee share purchase for $144.

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depository Receipts in the open market with an indefinite duration. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. Additionally, on 12 February 2018, the Board of Directors approved an authorization to repurchase up to $18,000 of Avadel ordinary shares represented by American Depository Shares in connection with our Convertible Notes Offering completed on 16 February 2018. See *Note 15: Long-Term Debt* Group's Notes to Consolidated Financial Statements. In March 2018, the Board of Directors approved an authorization to repurchase up to $7,000 of Avadel ordinary shares represented by American Depository Shares, bring the total authorization to $50,000. As of 31 December 2018, the Group had repurchased 5,407 ordinary shares for $49,998. There were no additional repurchases of shares during 2019. In August 2020, the Company cancelled all of its 5,407 treasury shares. As a result, we reduced share capital by $54 during the twelve months ended 31 December 2020. See *Note 17: Called-up Share Capital and Reserves* in the Group's Notes to Consolidated Financial Statements.

On 21 February 2020, we announced that we entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares ("Series A Preferred") in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately $65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of $60,570. The closing of the private placement occurred on 25 February 2020. See *Note 17: Called-up Share Capital and Reserves* in the Group's Notes to Consolidated Financial Statements.

On 28 April 2020, we announced the pricing of an underwritten public offering of 11,630 Ordinary Shares, in the form of ADSs at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs were offered by us and the gross proceeds to us from the offering were approximately $125,000, before deducting underwriting

discounts and commissions and offering expenses, which resulted in net proceeds of $116,924. The offering closed on 1 May 2020. See *Note 17: Called-up Share Capital and Reserves* in the Group's Notes to Consolidated Financial Statements.

Called-up Share Capital - Ordinary

In fiscal 2021, the change in ordinary shares of $3 is a result of the vesting of restricted shares of $2 and the exercise of stock options of $1.

NOTE 11: Other Reserves (Amounts in $ thousands)

Share premium

This reserve records the excess of the fair value of the consideration receivable for issued shares above the nominal value of shares issued. On 6 March 2017, following approval from the High Court, $317,254 of the Company's share premium can be treated as distributable reserves. This amount was transferred to the Profit and Loss Account.

In 2020, the share premium account increased due to the employee purchase plan issuance of $144 and the exercise of stock options of $2,041. In 2021, the share premium account increased due to the employee purchase plan issuance of $94 and the exercise of stock options of $168.

In February 2020, the Company entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares ("Series A Preferred") in a private placement to a group of institutional accredited investors, which resulted in an increase of $64,908 to share premium. In May 2020, the Company closed a public offering of 11,630 Ordinary Shares, which resulted in an increase of $124,906 to share premium. See *Note 19: Called-up Share Capital and Reserves* in the Group's Notes to Consolidated Financial Statements.

Other reserves

The increase in the balance as of 31 December 2020 was due to $2,999 of accumulated share-based compensation and $54 of capital redemption reserve arising on the cancellation of treasury shares, offset by issuance costs of $4,430 and $8,098 related to the February 2020 private placement and May 2020 public offering, respectively.

The increase in the balance as of 31 December 2021 was due to $8,872 of accumulated share-based compensation.

NOTE 12: Guarantees (Amounts in $ thousands)

At 31 December 2021, Avadel Pharmaceuticals plc has provided guarantees to several financing and leasing agreements of certain of its subsidiaries. Material guarantees are as follows:

As set out in *Note 15: Long-Term Debt* to the Group's Notes to Consolidated Financial Statements, Avadel Pharmaceuticals plc is a guarantor to $143,750 of convertible loan notes issued by its subsidiary, Avadel Cayman Limited. At the balance sheet date the company assessed the likelihood being called upon to honor the guarantee as unlikely and accordingly no provision was made.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in the United States where Avadel Ireland Ltd leases office space in Chesterfield, Missouri.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in the United States where Avadel Ireland Ltd leases a production suite in Winchester, Kentucky.

NOTE 13: Post Balance Sheet Events

Note 25: Post Balance Sheet Events to the Group's Notes to Consolidated Financial Statements provides details of post balance sheet events. Avadel Pharmaceuticals plc was a party (along with other entities in the Group) to the listed post balance sheet event.

NOTE 14: Related Party Disclosures

The company has availed of the exemption provided in FRS 102 Section 33 “Related Party Disclosures” for wholly owned subsidiary undertakings whose voting rights are controlled within the group, from the requirements to give details of transactions with entities that are part of the group or investees of the group qualifying as related parties.

NOTE 15: Approval of the Financial Statements

The financial statements were approved and authorised for issue on 9 May 2022.