UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

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

For the transition period from to

Commission File Number: 001-38503

Iterum Therapeutics plc

(Exact name of registrant as specified in its charter)

Ireland	**98-1283148**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

25 North Wall Quay,
Dublin 1,
Ireland
(Address of principal executive offices)
Not applicable
(Zip Code)

(+353) 1 903-8354

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary Shares, $0.01 par value per share	ITRM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

As of November 13, 2025, the registrant had 52,787,679 ordinary shares, $0.01 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our use of cash reserves;
- our ability to continue as a going concern;
- our ability to manufacture, sell, market and distribute ORLYNVAH™ with EVERSANA Life Science Services, LLC, or EVERSANA, and/or other third-parties, including our ability to build and maintain a sales force for ORLYNVAH™;
- our ability to regain and maintain compliance with listing requirements of the Nasdaq Capital Market;
- our ability to raise additional capital from the Nasdaq Capital Market given our limited ordinary shares currently available and authorized for issuance;
- the design, initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- our manufacturing plans;
- our sales, marketing and distribution capabilities and strategy;
- the market opportunity for and the potential market acceptance of ORLYNVAH™ for uncomplicated urinary tract infections caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options;
- market acceptance of any product we successfully commercialize;
- the pricing, coverage and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to defend and enforce any such intellectual property rights;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- our expectations regarding how far into the future our cash on hand will fund our ongoing operations;
- our financial performance;
- developments relating to our competitors and our industry;
- the impact of general economic conditions, including inflation and tariffs; and
- the potential sale, license, or other disposition of our rights to ORLYNVAH™ and results of discussions regarding strategic alternatives.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and

assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Quarterly Report and the documents that we have filed with the Securities and Exchange Commission, as exhibits to this Quarterly Report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Quarterly Report also contains industry, market and competitive position data from our own internal estimates and research as well as industry and general publications and research surveys and studies conducted by third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the markets in which we operate and our management's understanding of industry conditions. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source. The industry in which we operate is subject to a high degree of uncertainty and risks due to various factors, including those described in the section titled "Risk Factors".

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

SUMMARY OF RISK FACTORS

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

- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. As of September 30, 2025, we had $11.0 million of cash and cash equivalents. Based on our available cash resources, we do not believe that our existing cash and cash equivalents will enable us to fund our operating expenses for the next 12 months from the date of filing of this Quarterly Report on Form 10-Q.
- We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses unless we successfully commercialize our sulopenem program.
- We will require additional capital to fund our operations including to support the ongoing commercialization of ORLYNVAH™ in the United States and the ongoing clinical development related to our sulopenem program. If we fail to obtain financing when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Changes in and uncertainty surrounding trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.
- In the event that we are unable to raise sufficient capital to fund our operations and continue to fund the marketing, sale and distribution of ORLYNVAH™ in the United States, our board of directors may determine that a liquidation and dissolution of our business approved by shareholders is the best method to seek to maximize shareholder value. In such an event, the amount of cash available for distribution to our shareholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We are heavily dependent on the success of our sulopenem program including the ongoing commercialization of ORLYNVAH™ in the United States, and our ability to develop, obtain additional marketing approvals for and successfully commercialize oral sulopenem and IV sulopenem in jurisdictions outside the United States and/or for other indications. If we are unable to achieve and sustain profitability, the market value of our ordinary shares will likely decline.
- While we continue to engage in business development discussions with other companies to sell, license, or otherwise dispose of our rights to sulopenem, on August 20, 2025, we commercially launched ORLYNVAH™ in the United States with our commercialization partner, EVERSANA Life Science Services, LLC (EVERSANA), to serve patients with limited or no treatment options. We are heavily dependent on the success of such commercial launch of ORLYNVAH™ in the United States. Any failure to successfully commercialize ORLYNVAH™, inability to enter a business development transaction satisfactory to our board of directors to sell, license, or otherwise dispose of our rights to sulopenem, or inability to obtain marketing approval for any other product candidates, or significant delays in doing so, will materially harm our business.
- Serious adverse events or undesirable side effects or other unexpected properties of ORLYNVAH™, sulopenem or any other product candidate may be identified during development or after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.
- Even though ORLYNVAH™ has obtained regulatory approval in the United States and we may obtain regulatory approval for other product candidates, they may never achieve the market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community that is necessary for commercial success, and the market opportunity may be smaller than we estimate.
- We currently have a limited commercial organization. If we are unable to expand and maintain sales, marketing and distribution capabilities with our commercialization partner, EVERSANA, enter into sales, marketing and distribution agreements with third parties, or enter into a strategic alternative with a partner that has established commercial capabilities in the United States, the ongoing commercialization of ORLYNVAH™ in the United States may not be successful.
- We contract with third parties, including ACS Dobfar S.p.A., for the manufacture of preclinical and clinical supplies of ORLYNVAH™ and expect to continue to do so in connection with any future clinical trials and commercialization of our products and product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities

of our products and/or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

•We rely heavily on the exclusive license agreement with Pfizer Inc. (Pfizer), for the patent rights and know-how required for the development of sulopenem and to commercialize ORLYNVAH™ and the know-how required to develop the IV formulation of sulopenem. If we fail to comply with our obligations in our agreement with Pfizer, we could lose such rights that are important to our business.

•If we are unable to obtain and maintain patent protection or other intellectual property rights for ORLYNVAH™ or our other technology and product candidates, or if the scope of the patent protection or intellectual property rights we obtain is not sufficiently broad, we may not be able to continue to commercialize ORLYNVAH™ or develop and commercialize any other product candidates or technology or otherwise compete effectively in our markets.

•The price of our ordinary shares has been volatile and could be subject to volatility related or unrelated to our operations and our shareholders' investment in us could suffer a decline in value.

•The volatility of our shares and shareholder base may hinder or prevent us from engaging in beneficial corporate initiatives. Our shareholder base is comprised of a large number of retail (or non-institutional) investors, which creates more volatility since shares change hands frequently. As a result, there can be a significant turnover of shareholders between the record date and the meeting date which makes it harder to get shareholders to vote. While we make every effort to engage retail investors, such efforts can be expensive, and the frequent turnover creates logistical issues for obtaining shareholder approval. Further, retail investors tend to be less likely to vote in comparison to institutional investors. Failure to secure sufficient votes may impede our ability to move forward with initiatives that are intended to grow the business and create shareholder value or prevent us from engaging in such initiatives at all.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)
(Unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 11,002	$ 24,125
Accounts receivable	448	—
Inventory	1,149	—
Income taxes receivable	—	48
Prepaid expenses and other current assets	1,128	614
Total current assets	13,727	24,787
Intangible asset, net	18,710	19,746
Property and equipment, net	18	23
Restricted cash	29	34
Other assets	19	5
Total assets	$ 32,503	$ 44,595
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 577	$ 251
Accrued expenses	5,216	2,651
Exchangeable notes	—	14,463
Royalty-linked notes	281	—
Income taxes payable	24	—
Other current liabilities	332	240
Total current liabilities	$ 6,430	$ 17,605
Pfizer promissory note	21,215	20,300
Royalty-linked notes	12,239	10,771
Total liabilities	$ 39,884	$ 48,676
Commitments and contingencies (Note 17)		
Shareholders' deficit		
Undesignated preferred shares, $0.01 par value per share: 100,000,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued at September 30, 2025 and December 31, 2024	—	—
Ordinary shares, $0.01 par value per share: 80,000,000 shares authorized at September 30, 2025 and December 31, 2024, 48,991,860 shares issued at September 30, 2025; 31,534,233 shares issued at December 31, 2024	490	315
Additional paid-in capital	498,580	481,676
Accumulated deficit	(506,451)	(486,072)
Total shareholders' deficit	(7,381)	(4,081)
Total liabilities and shareholders' deficit	$ 32,503	$ 44,595

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

ITERUM THERAPEUTICS PLC
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Product Revenue, net	$ 390	$ —	$ 390	$ —
Costs and expenses:				
Cost of sales	(20)	—	(20)	—
Amortization of intangible asset	(349)	—	(1,036)	—
Research and development	(1,261)	(3,107)	(2,852)	(9,159)
Selling, general and administrative	(6,491)	(1,780)	(13,452)	(5,867)
Total operating expenses	(8,121)	(4,887)	(17,360)	(15,026)
Operating loss	(7,731)	(4,887)	(16,970)	(15,026)
Interest expense, net	(441)	(590)	(1,291)	(1,648)
Adjustments to fair value of derivatives	(673)	(433)	(1,807)	(1,226)
Other expense, net	(2)	(48)	(60)	(77)
Total other expense	(1,116)	(1,071)	(3,158)	(2,951)
Loss before income taxes	(8,847)	(5,958)	(20,128)	(17,977)
Income tax expense	(132)	(136)	(251)	(215)
Net loss	$ (8,979)	$ (6,094)	$ (20,379)	$ (18,192)
Net loss per share – basic and diluted	$ (0.20)	$ (0.30)	$ (0.51)	$ (1.05)
Weighted average ordinary shares outstanding – basic and diluted	45,801,927	20,044,270	39,975,269	17,352,918
Statements of Comprehensive Loss				
Net loss	$ (8,979)	$ (6,094)	$ (20,379)	$ (18,192)
Other comprehensive income:				
Unrealized loss on marketable securities	—	3	—	1
Comprehensive loss	$ (8,979)	$ (6,091)	$ (20,379)	$ (18,191)

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

ITERUM THERAPEUTICS PLC
Condensed Consolidated Statements of Cash Flows
(In thousands, except share and per share data)
(Unaudited)

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (20,379)	$ (18,192)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	19	23
Amortization of intangible asset	1,036	—
Share-based compensation expense	170	274
Interest on short-term investments	—	1
Amortization of debt discount and deferred financing costs	194	1,713
Interest on exchangeable notes - non-cash	88	542
Financing transaction costs included in financing activities	—	1,977
Interest on promissory note - non-cash	1,415	—
Adjustments to fair value of derivatives	1,807	1,226
Other	1,820	1,233
Changes in operating assets and liabilities:		
Accounts receivable	(448)	—
Prepaid expenses and other current assets	(2,196)	(2,575)
Inventory	(1,149)	—
Accounts payable	326	(4,161)
Accrued expenses	2,642	(4,270)
Income taxes	(35)	(4)
Other liabilities	(568)	(301)
Net cash used in operating activities	(15,258)	(22,514)
Cash flows from investing activities:		
Purchases of property and equipment	(14)	(2)
Purchases of short-term investments	—	(12,390)
Proceeds from sale of short-term investments	—	29,500
Net cash (used in) / provided by investing activities	(14)	17,108
Cash flows from financing activities:		
Repayment of exchangeable notes	(14,745)	—
Proceeds from issuance of ordinary shares, net of transaction costs	16,909	12,814
Net cash provided by financing activities	2,164	12,814
Effect of exchange rates on cash and cash equivalents	(20)	(73)
Net (decrease) / increase in cash, cash equivalents and restricted cash	(13,128)	7,335
Cash, cash equivalents and restricted cash, at beginning of period	24,159	6,105
Cash, cash equivalents and restricted cash, at end of period	$ 11,031	$ 13,440
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid - U.S.	$ 120	$ 220

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

ITERUM THERAPEUTICS PLC
Condensed Consolidated Statements of Stockholders' Deficit
(In thousands, except share and per share data)
(Unaudited)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive In come (Loss)	Total
	Shares	Amount				
Balance at June 30, 2025	42,131,328	$ 421	$ 493,164	$ (497,472)	$ —	(3,887)
Issuance of ordinary shares, net	6,860,532	69	5,363	—	—	5,432
Share-based compensation expense	—	—	53	—	—	53
Net loss	—	—	—	(8,979)	—	(8,979)
Balance at September 30, 2025	48,991,860	$ 490	$ 498,580	$ (506,451)	$ —	$ (7,381)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive In come (Loss)	Total
	Shares	Amount				
Balance at December 31, 2024	31,534,233	$ 315	$ 481,676	$ (486,072)	$ —	$ (4,081)
Issuance of ordinary shares, net	17,431,145	175	16,702	—	—	16,877
Exercise of warrants for ordinary shares	26,482	—	32	—	—	32
Share-based compensation expense	—	—	170	—	—	170
Net loss	—	—	—	(20,379)	—	(20,379)
Balance at September 30, 2025	48,991,860	$ 490	$ 498,580	$ (506,451)	$ —	$ (7,381)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Inco me (Loss)	Total
	Shares	Amount				
Balance at June 30, 2024	16,584,029	$ 166	$ 462,318	$ (473,396)	$ (1)	$ (10,913)
Issuance of ordinary shares, net	6,121,965	61	2,651	—	—	2,712
Issue of warrants for ordinary shares, net	—	—	2,718	—	—	2,718
Share-based compensation expense	—	—	67	—	—	67
Net loss	—	—	—	(6,094)	—	(6,094)
Unrealized gain on available-for-sale securities	—	—	—	—	3	3
Balance at September 30, 2024	22,705,994	$ 227	$ 467,754	$ (479,490)	$ 2	$ (11,507)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Inco me (Loss)	Total
	Shares	Amount				
Balance at December 31, 2023	13,499,003	$ 135	$ 454,759	$ (461,298)	$ 1	$ (6,403)
Issuance of ordinary shares, net	9,177,847	92	9,974	—	—	10,066
Issue of warrants for ordinary shares, net	—	—	2,718	—	—	2,718
Exercise of share options	29,144	—	29	—	—	29
Share-based compensation expense	—	—	274	—	—	274
Net loss	—	—	—	(18,192)	—	(18,192)
Unrealized gain on available-for-sale securities	—	—	—	—	1	1
Balance at September 30, 2024	22,705,994	$ 227	$ 467,754	$ (479,490)	$ 2	$ (11,507)

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

1. Basis of Presentation

Description of Business

Iterum Therapeutics plc (the Company) was incorporated under the laws of the Republic of Ireland in June 2015 as a limited company and re-registered as a public limited company on March 20, 2018. The Company maintains its registered office at 25 North Wall Quay, Dublin 1, D01 H104, Ireland. The Company commenced operations in November 2015. The Company licensed global rights to its novel anti-infective compound, sulopenem, from Pfizer Inc. (Pfizer). The Company is dedicated to maximizing the commercial potential of ORLYNVAH™ (sulopenem etzadroxil and probenecid), the first oral branded penem available in the United States and potentially the first and only oral and intravenous (IV) branded penem available globally and is focused on delivering differentiated anti-infectives aimed at combating the global crisis of multi-drug resistant pathogens to significantly improve the lives of people affected by serious and life-threatening diseases around the world. The Company is advancing the development of its first compound, sulopenem, a novel penem anti-infective compound, with an oral formulation and IV formulation. Sulopenem has demonstrated potent in vitro activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. In October 2024, the Company received approval from the United Sates Food and Drug Administration (FDA) of its New Drug Application for ORLYNVAH™ (oral sulopenem) for the treatment of uUTIs caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae,* or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options. The Company commercially launched ORLYNVAH™ into the community market in the United Sates in August 2025 and expects modest sales in 2025 during the early stages of its commercialization efforts.

The Company is continuing to build its commercial capabilities and infrastructure to continue to support the launch of ORLYNVAH™ in the United States. In June 2025, the Company's subsidiary, Iterum Therapeutics US Limited (ITUS), entered into a Product Commercialization Agreement (the EVERSANA Agreement) with EVERSANA Life Science Services, LLC (EVERSANA) for the commercialization of ORLYNVAH™. Pursuant to the EVERSANA Agreement, EVERSANA provides sales and commercial operations services to ITUS in the United States, as well as the provision of marketing, logistics, channel management, regulatory, medical affairs and other services related to the commercialization of ORLYNVAH™ in the United States.

Liquidity and Going Concern

Since inception, the Company has devoted substantially all of its efforts to research and development, recruiting management and technical staff, raising capital, and conducting pre-commercialization and commercialization activities. The Company began commercial operations in August 2025 and therefore has limited net product sales. The Company has financed its operations through the issuance of ordinary and convertible preferred shares, debt raised under a financing arrangement with Silicon Valley Bank (SVB) including the Paycheck Protection Program loan (PPP loan), a sub-award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program and the proceeds of a private placement (Private Placement) and subsequent rights offering (the 2020 Rights Offering) pursuant to which its wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda) issued and sold approximately $51,808 aggregate principal amount of 6.500% Exchangeable Senior Subordinated Notes (Exchangeable Notes) and $104 aggregate principal amount of Limited Recourse Royalty-Linked Subordinated Notes (the RLNs and, together with the Exchangeable Notes, the Securities), which Securities were sold in units consisting of an Exchangeable Note in the original principal amount of $1,000 and 50 RLNs (the Units). Beginning on January 21, 2021 through January 31, 2025, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes completed a non-cash exchange of their notes, including accrued and unpaid interest of $3,071, for an aggregate of 3,760,155 of the Company’s ordinary shares. On January 31, 2025, the Exchangeable Notes matured and Iterum Bermuda repaid in full to the holders thereof an aggregate principal amount of $11,117 together with accrued interest of $3,628.

The Company is subject to risks and uncertainties common to early-stage companies in the pharmaceutical industry, including, but not limited to, the ability to secure additional capital to fund operations, failure to successfully develop and commercialize its product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology and compliance with government regulations.

Even with receipt of FDA approval and the commercial launch of ORLYNVAH™, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and include the accounts of the Company and its subsidiaries.

The Company filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC), which was declared effective on October 17, 2022 (File No. 333-267795), and pursuant to which the Company registered for sale up to $100,000 of any combination of debt securities, ordinary shares, preferred shares, subscription rights, purchase contracts, units and/or warrants from time to time and at prices and on terms that the Company may determine. On October 7, 2022, the Company entered into a sales agreement with HC Wainwright (the Sales Agreement), as agent, pursuant to which it could offer and sell ordinary shares, nominal value $0.01 per ordinary share (the ordinary shares) for aggregate gross sales proceeds of up to $16,000 (subject to the availability of ordinary shares), from time to time through HC Wainwright by any method permitted that is deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the Securities Act). On

December 10, 2024, the Company filed a prospectus supplement with the SEC pursuant to which it may offer and sell ordinary shares having an aggregate offering price of up to an additional $25,000 through HC Wainwright pursuant to the Sales Agreement.

On August 9, 2024, the Company completed a rights offering (the 2024 Rights Offering) in which it sold an aggregate of 6,121,965 units (2024 Units) at a subscription price of $1.21 per whole 2024 Unit, consisting of (a) one ordinary share, (b) a warrant to purchase 0.50 ordinary shares, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration one year from the date of issuance (the 1-year warrants) and (c) a warrant to purchase one ordinary share, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration five years from the date of issuance (the 5-year warrants and, together with the 1-year warrants, the warrants). The Company's net proceeds from the 2024 Rights Offering, after deducting dealer-manager fees and other offering expenses payable by the Company, were $5,430. The warrants are exercisable upon issuance at a price of $1.21 per ordinary share. The 1-year warrants expired on August 9, 2025 and the 5-year warrants will expire on August 9, 2029.

The Company filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on February 19, 2025 (File No. 333-284774), and pursuant to which the Company registered for sale up to $150,000 of any combination of debt securities, ordinary shares, preferred shares, subscription rights, purchase contracts, units and/or warrants from time to time and at prices and on terms that the Company may determine.

On April 28, 2025, the Company entered into a securities purchase agreement with an institutional investor (the April 2025 Registered Direct Offering) pursuant to which it issued and sold an aggregate of (i) 3,040,000 ordinary shares, at a purchase price of $0.90 per ordinary share, and (ii) pre-funded warrants to purchase up to an aggregate of 2,515,556 ordinary shares at a purchase price of $0.89 per pre-funded warrant. The Company's net proceeds from the April 2025 Registered Direct Offering, after deducting placement agent fees and offering expenses payable by the Company were $4,177. Upon closing, the pre-funded warrants became exercisable immediately at an exercise price of $0.01 per ordinary share, subject to adjustment in certain circumstances, and expire when exercised in full, subject to certain conditions. As of September 30, 2025, all pre-funded warrants issued in connection with the April 28, 2025 Offering had been exercised.

In accordance with Accounting Standards Update (ASU) 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year of the date of issue of these quarterly condensed consolidated financial statements.

The Company has funded its operations to date primarily with proceeds from the sale of preferred shares and ordinary shares, warrants, debt raised under its financing arrangement with SVB including the PPP loan (both of which have been repaid), payments received under the CARB-X program, proceeds from the Private Placement and 2020 Rights Offering and product sales. The Company has incurred operating losses since inception, including net losses of $20,379 and $18,192 for the nine months ended September 30, 2025 and 2024, respectively, and a net loss of $24,774 for the year ended December 31, 2024. The Company had an accumulated deficit of $506,451 as of September 30, 2025 and expects to continue to incur net losses for the foreseeable future. The Company's future cash flows are dependent on key variables such as its ability to achieve its revenue growth from sales of ORLYNVAH™ in the United States and its ability to secure additional sources of funding in the form of public or private financing of debt or equity or collaboration agreements. Based on its available cash and cash equivalents, including amounts raised under the Sales Agreement with H.C. Wainwright & Co. LLC (HC Wainwright), as agent, subsequent to September 30, 2025 (see Note 19 – Subsequent Events), the Company does not have cash on hand to fund its current operations and capital expenditure requirements for the next 12 months from the date of this Quarterly Report on Form 10-Q. This condition raises substantial doubt about the Company's ability to continue as a going concern for one year from the date these condensed consolidated financial statements are issued.

The Company's ability to continue as a going concern is dependent on its ability to obtain additional funding to support its business objectives, including achieving its revenue growth rate from sales of ORLYNVAH™ in the United States. The Company has limited experience with and has not yet demonstrated an ability to successfully commercialize a product. Management expects that, in order to obtain additional funding for its operations and commercialization activities, it will need to raise funding through the possible sale of the Company's equity or debt through additional public or private financings. Although management plans to obtain additional funding to finance its operations, and has successfully raised capital in the past, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

If the Company is unable to obtain funding, it could be forced to significantly delay, scale back or discontinue the development and commercialization of its sulopenem program, or otherwise change its strategy, which could adversely affect its business prospects, or the Company may be unable to continue operations. Based on the Company's operating losses since inception, the expectation of continued operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations, management has concluded there is substantial doubt about the Company's ability to continue as a going concern within one year from the date these condensed consolidated financial statements are issued.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes

the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Interim Financial Information

The condensed consolidated balance sheet at December 31, 2024 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of September 30, 2025 and for the three and nine months ended September 30, 2025 and 2024 have been prepared by the Company pursuant to the rules and regulations of the SEC for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K filed with the SEC on February 7, 2025. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2025, and results of operations for the three and nine months ended September 30, 2025 and 2024, and cash flows for the nine months ended September 30, 2025 and 2024 have been made. The results of operations for the three and nine months ended September 30, 2025 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2025.

2. Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2024. In August 2025, ORLYNVAH™ was launched in the United States and the Company began recording net product revenue, cost of goods sold and related accounts receivable. New accounting policies have been described below.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, the reported amounts of expenses during the reporting period and the assessment of the Company's ability to continue as a going concern. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the valuation of the RLNs and the accounting for revenue allowances. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results could differ materially from those estimates.

Specifically, management has estimated variables used to calculate the discounted cash flow analysis (DCF) to value the RLN liability (see Note 4 – Fair Value of Financial Assets and Liabilities) and made estimates in the accounting for revenue allowances (see Note 3 – Revenue).

Cash and Cash Equivalents

The Company's cash and cash equivalents consist of cash balances and highly liquid investments with maturities of three months or less at the date of purchase. Accounts held at United States financial institutions are insured by the Federal Deposit Insurance Corporation up to $250, while accounts held at Irish financial institutions are insured under the Deposit Guarantee Scheme up to $117 (€100).

Cash accounts with any type of restriction are classified as restricted cash. If restrictions are expected to be lifted in the next twelve months, the restricted cash account is classified as current. Included within restricted cash on the Company's condensed consolidated balance sheet is $15 and $17 as of September 30, 2025 and December 31, 2024, respectively, relating to the warrants issued on June 5, 2020 pursuant to the securities purchase agreement (June 3, 2020 SPA) from the June 3, 2020 registered direct offering (June 3, 2020 Offering), $4 and $6 as of September 30, 2025 and December 31, 2024, respectively, relating to the warrants issued on July 2, 2020 pursuant to the securities purchase agreement (June 30, 2020 SPA) from the June 30, 2020 registered direct offering (June 30, 2020 Offering) and $10 and $11 as of September 30, 2025 and December 31, 2024, respectively, relating to warrants issued in the underwritten offering in October 2020 (October 2020 Offering). On the closing date of each of the registered direct offerings on June 3, 2020 (June 3, 2020 Offering) and June 30, 2020 (June 30, 2020 Offering) and the underwritten offering in the October 2020 Offering, each investor deposited $0.01 per warrant issued being the nominal value of the underlying ordinary share represented by each warrant. This amount will be held in trust by the Company pending a decision by the relevant investor to exercise the warrant by means of a "cashless exercise" pursuant to the terms of the warrant, in which case the $0.01 will be used to pay up the nominal value of the ordinary share issued pursuant to the warrant. Upon the exercise of the warrants other than by means of a

"cashless exercise", the amount held in trust will be returned to the relevant investor in accordance with the terms of the applicable purchase agreement or prospectus.

Accounts Receivable

Accounts receivable are recorded net of any estimated expected credit losses. The Company's measurement of expected credit losses is based on relevant information about past events, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. No allowance for credit losses was recorded as of September 30, 2025.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has most of its cash and cash equivalents at three accredited financial institutions in the United States and Ireland, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is also subject to credit risk related to its trade accounts receivable from product sales. ORLYNVAH™ is distributed primarily through a single retail pharmacy. The Company extends credit to its customer in the normal course of business after evaluating their overall financial condition, and subsequently through payment history and other factors.

Inventory

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-progress and finished goods (see Note 5 – Inventory for further details). The Company began capitalizing inventory costs following FDA approval of ORLYNVAH™ on October 25, 2024. Inventory is valued on a first-in, first-out basis. The Company periodically reviews inventory for expiry and obsolescence and writes it down accordingly, if necessary. Prior to FDA approval of ORLYNVAH™, the Company expensed all inventory-related costs, including costs incurred for clinical development, to research and development costs in the period in which such costs were incurred.

Revenue Recognition

The Company’s revenue consists of product sales of ORLYNVAH™. See Note 3 – Revenue for more detail on product revenue.

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of ORLYNVAH™ for commercial sale, including third-party manufacturing costs, raw material and component costs, packaging services, distribution fees and royalties to Pfizer on product sales. Prior to the FDA approval of ORLYNVAH™ in October 2024, costs incurred for the manufacture of ORLYNVAH™ were recorded as research and development expenses and therefore are not included in cost of goods sold. As a result, the cost of goods sold related to ORLYNVAH™ will initially reflect a lower average per unit cost of materials, as previously expensed inventory is utilized and sold to customers.

Net Loss Per Ordinary Share

Basic and diluted net loss per ordinary share is determined by dividing net loss attributable to ordinary shareholders by the weighted-average ordinary shares outstanding during the period in accordance with Accounting Standard Codification (ASC) 260, *Earnings per Share*. For the periods presented, the following ordinary shares underlying the options, warrants and the Exchangeable Notes have been excluded from the calculation because they would be anti-dilutive.

(In thousands, except share and per share data)

	Three and Nine Months Ended	
	September 30, 2025	September 30, 2024
Options to purchase ordinary shares	940,664	913,988
Warrants	5,906,416	9,663,125
Exchangeable Notes	—	2,541,786
Total	6,847,080	13,118,899

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

On October 9, 2023, the FASB issued ASU No. 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative (ASU 2023-06), which incorporates several disclosures and presentation requirements currently residing in SEC Regulations S-X and S-K. For entities subject to the existing SEC disclosure requirements, including those preparing for sale or issuance of securities, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later, with early adoption permitted. ASU 2023-06 is not expected to have a material impact on the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which enhances the annual income tax disclosures for the effective tax rate reconciliation and income taxes paid. The amendments are effective for public business entities, for annual periods beginning after December 15, 2024 and for annual periods beginning after December 15, 2025 for all other entities. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The ASU applies on a prospective basis to annual financial statements for periods beginning after the effective date. However, retrospective application in all prior periods presented is permitted. The Company is assessing what impact ASU 2023-09 will have on the consolidated financial statements.

On November 4, 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03), which requires new disclosures to disaggregate prescribed natural expenses underlying any income statement caption. ASU 2024-03 is effective for annual periods in fiscal years beginning after December 15, 2026, and interim periods thereafter. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. The Company is currently assessing the impact ASU 2024-03 will have on the consolidated financial statements and disclosures.

On November 26, 2024, the FASB issued ASU 2024-04, *Debt—Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments* (ASU 2024-04), which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU 2024-04 is effective for all entities for annual and interim periods in fiscal years beginning after December 15, 2025. Early adoption is permitted for all entities that have adopted the amendments in ASU 2020-06. ASU 2024-04 is not expected to have a material impact on the consolidated financial statements.

On January 6, 2025, the FASB issued ASU 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date* (ASU 2025-01), which amends the effective date of ASU 2024-03 to clarify that all public business entities are required to adopt the guidance in annual periods after December 15, 2026, and interim periods in fiscal years beginning after December 15, 2027.

On July 30, 2025, the FASB issued ASU 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* (ASU 2025-05), which provides certain entities with an additional practical expedient and an accounting policy election for estimating expected credit losses on current accounts receivable and current contract assets arising from revenue transactions under ASC 606. This ASU is effective for all entities for annual and interim periods in fiscal years beginning after December 15, 2025. Early adoption is permitted for all entities. ASU 2025-05 is not expected to have a material impact on the consolidated financial statements.

3. Revenue

The Company's revenue consists of product sales of ORLYNVAH™. ORLYNVAH™ was approved by the FDA in October 2024, and the Company began generating product revenue from sales of ORLYNVAH™ in August 2025. The Company uses a third

party logistics provider to fulfill orders of ORLYNVAH™ to the Company's customers. The third party logistics provider performs services for the Company that include warehousing, distribution, order and accounts receivable management, and data management.

Product revenue is recorded with each sale at the transaction price, net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts, chargebacks, rebates, co-payment assistance and product returns, as applicable, which are collectively referred to as "Gross-to-Net Adjustments". Estimates for Gross-to-Net Adjustments are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net income in the period of adjustment. Accounts receivable due to the Company from contracts with its customers are stated separately in the balance sheet, net of various allowances as described in the Accounts Receivable and Allowance policy in Note 2 – Summary of Significant Accounting Policies.

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain Gross-to-Net Adjustments. The specific considerations that the Company uses in estimating the amounts related to Gross-to-Net Adjustments are as follows:

Distribution Service Fees. The Company pays distribution service fees to its retail pharmacy. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchase amount. The Company considers these fees to be separate from the customer's purchase of the product and, therefore, they are recorded in other current liabilities on the condensed consolidated balance sheets.

Prompt Pay Discounts. The Company incentivizes on time invoice payments through prompt pay discounts. Prompt pay discounts are typically taken by customers, so an estimate of the discount is recorded at the time of sale based on the purchased amount. Prompt pay discount estimates are recorded as contra accounts receivable on the condensed consolidated balance sheets.

Chargebacks. Certain government entities and covered entities (e.g. Veterans Administration, 340B covered entities) can purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and WAC will be charged back to the Company. The Company estimates the amount of chargebacks based on the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the condensed consolidated balance sheets.

Rebates. The Company provides commercial rebates to pharmacy benefit managers and managed care organizations and is subject to mandatory discount obligations under the Medicare, Medicaid, and Tricare programs. The rebate amounts for these programs are determined by contractual arrangements or statutory requirements. Rebates are owed after the product has been dispensed to a patient and the Company has been invoiced. The Company estimates the amount in rebates based on the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

Co-payment Program. The Company offers co-payment assistance programs to commercially insured patients whose insurance requires a co-payment to be made when filling their prescription. The Company estimates the amount of co-payment assistance based on the expected volume and the average buy down rate associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Co-payment program estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

Product Returns. Customers have the right to return damaged product, product that is within six months or less of the labeled expiration date, or product that is past the expiration date by no more than twelve months. ORLYNVAH™ was commercially launched in August 2025 and due to the lack of historical sales and returns data, the Company used professional judgment and industry data to estimate returns. As time passes and historical data becomes available, the Company will use historical sales and returns data to estimate future product returns. No reserve for potential product returns was deemed necessary at September 30, 2025.

4. Fair Value of Financial Assets and Liabilities

The carrying amounts reported in the condensed consolidated balance sheets for accounts receivable, inventory, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair value based on the short-term maturity of these instruments.

(In thousands, except share and per share data)

The following table presents information about the Company's RLNs, promissory note to Pfizer (the Promissory Note) and Exchangeable Notes and indicates the fair value hierarchy of the valuation inputs utilized to determine the approximate fair value:

September 30, 2025 **Current Liabilities**	**Book Value**	**Approximate Fair Value**	**Level 1**	**Level 2**	**Level 3**
Royalty-linked notes					
Short-term royalty-linked notes	$ 281	$ 281	$ —	$ —	$ 281
Total current liabilities	$ 281	$ 281	$ —	$ —	$ 281
Long-term Liabilities					
Promissory Note					
Long-term promissory note	$ 21,215	$ 21,619	$ —	$ 21,619	$ —
Revenue Futures					
Royalty-linked notes	12,239	12,239	—	—	12,239
Total long-term liabilities	$ 33,454	$ 33,858	$	$ 21,619	$ 12,239

December 31, 2024 **Current Liabilities**	**Book Value**	**Approximate Fair Value**	**Level 1**	**Level 2**	**Level 3**
Exchangeable Notes					
Short-term exchangeable notes	$ 14,463	$ 14,444	$ —	$ 14,444	$ —
Total current liabilities	$ 14,463	$ 14,444	$ —	$ 14,444	$ —
Long-term Liabilities					
Promissory Note					
Long-term promissory note	$ 20,300	$ 20,412	$ —	$ 20,412	$ —
Revenue Futures					
Royalty-linked notes	10,771	10,771	—	—	10,771
Total long-term liabilities	$ 31,071	$ 31,183	$ —	$ 20,412	$ 10,771

The fair value of the Promissory Note was determined using DCF analysis using the effective interest rate calculated following the modification of the original license agreement with Pfizer for the worldwide exclusive rights to research, develop, manufacture and commercialize sulopenem (Pfizer License), which represents a Level 2 basis of fair value measurement (see Note 11 – Debt).

The fair value of Exchangeable Notes was determined using DCF analysis using the fixed interest rate outlined in the indenture governing the Exchangeable Notes (Exchangeable Notes Indenture), without consideration of transaction costs, which represents a Level 2 basis of fair value measurement.

The Level 3 liabilities held as of September 30, 2025 consist of a separate financial instrument that was issued as part of the Units, the RLNs (see Note 12 – Royalty-Linked Notes).

At any time on or after January 21, 2021 through January 31, 2025, subject to specified limitations, the Exchangeable Notes were exchangeable for the Company's ordinary shares, cash or a combination of ordinary shares and cash. Beginning on January 21, 2021 to January 31, 2025, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes completed a non-cash exchange of their notes for an aggregate of 3,760,155 of the Company's ordinary shares, which included accrued and unpaid interest relating to such notes. On January 31, 2025, the Exchangeable Notes matured and Iterum Bermuda repaid to the holders thereof an aggregate principal amount of $11,117 together with accrued interest of $3,628.

The RLN liability is carried at fair value on the condensed consolidated balance sheet (see Note 12 – Royalty-Linked Notes). The total fair value of $12,520 was determined using DCF analysis, without consideration of transaction costs, which represents a Level 3 basis of fair value measurement. The key inputs to valuing the RLNs were the terms of the indenture governing the RLNs (the RLN Indenture), the expected cash flows to be received by holders of the RLNs based on management's revenue forecasts of U.S. sulopenem sales and a risk-adjusted discount rate to derive the net present value of expected cash flows. The RLNs will be subject to a maximum return amount, including all principal and payments and certain default interest in respect of uncurable defaults, of $160.00 (or 4,000 times the principal amount of such note). The discount rate applied to the model was 22%. Fair value measurements are highly sensitive to changes in these inputs and significant changes in these inputs could result in a significantly higher or lower fair value.

There have been no transfers of assets or liabilities between the fair value measurement levels.

(In thousands, except share and per share data)

5. Inventory

	September 30, 2025	December 31, 2024
Raw materials	$ 95	$ —
Work-in-progress	106	—
Finished Goods	948	—
	$ 1,149	$ —

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-progress and finished goods. The Company began capitalizing inventory costs following FDA approval of ORLYNVAH™ in October 2024, and inventory production commenced in February 2025. The Company has not recorded any inventory write-downs for the nine months ended September 30, 2025. No allowance for excess, damaged, and obsolete inventory was recorded at September 30, 2025. The Company currently uses a limited number of third-party contract manufacturing organizations to produce its inventory.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2025	December 31, 2024
Other prepaid assets	$ 434	$ 138
Prepaid insurance	404	389
Prepaid research and development expenses	192	4
Research and development tax credit receivable	98	18
Right of use assets, net	—	65
Total	$ 1,128	$ 614

7. Intangible Asset, net

Intangible asset and related accumulated amortization are as follows:

	September 30, 2025	December 31, 2024
Gross intangible asset	$ 20,000	$ 20,000
Less: accumulated amortization	(1,290)	(254)
	$ 18,710	$ 19,746

On November 18, 2015, the Company and Iterum Therapeutics International Limited (ITIL), a wholly owned subsidiary of the Company, entered into the Pfizer License. Under the Pfizer License, ITIL agreed to make certain regulatory and sales payments, including a regulatory milestone payment of $20,000 to Pfizer upon approval of ORLYNVAH™ by the FDA for commercial sale in the United States. On October 25, 2024, the Company received FDA approval for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections in adult women who have limited or no alternative oral antibacterial treatment options, and the regulatory milestone payment was capitalized on that date. The milestone payment is being amortized over a period of 14.4 years based on the patent life of ORLYNVAH™. The Company deferred this payment for a two-year period, at an annual rate of eight percent on a daily compounded basis until paid in full, which was amended and restated on May 13, 2025 for an additional three-year deferral period, at an annual rate of ten percent for the extended deferral period, beginning on October 26, 2026, as permitted pursuant to the terms of the Pfizer License.

Amortization expense for the nine months ended September 30, 2025 was $1,036.

(In thousands, except share and per share data)

The estimated future amortization related to intangible assets included on the condensed consolidated balance sheet as of September 30, 2025 for the following five fiscal years and thereafter were as follows:

Due in 12 month period ending Sept 30,	
2026	$ 1,389
2027	1,389
2028	1,389
2029	1,389
2030	1,389
Thereafter	11,765
	$ 18,710

8. Property and Equipment, net

Property and equipment and related accumulated depreciation are as follows:

	September 30, 2025	December 31, 2024
Leasehold improvements	$ —	$ 148
Furniture and fixtures	—	120
Computer equipment	109	95
	109	363
Less: accumulated depreciation	(91)	(340)
	$ 18	$ 23

Depreciation expense was $19 and $23 for the nine months ended September 30, 2025 and 2024, respectively. In addition, accumulated depreciation decreased by $148 due to the removal of fully depreciated leasehold improvements and $120 due to the removal of fully depreciated furniture and fixtures during the nine months ended September 30, 2025 and $5 due to the removal of fully depreciated computer equipment during the nine months ended September 30, 2024.

9. Leases

The Company did not hold any operating leases at September 30, 2025 and previously held operating leases for office premises and a printer.

Operating lease expenses were recognized on a straight-line basis over the lease term. The Company recognized $0 and $65 of operating lease costs for right-of-use assets during the three and nine months ended September 30, 2025 respectively, and $101 and $299 of operating lease costs for right-of-use assets during the three and nine months ended September 30, 2024, respectively. The Company recognized $22 and $32 of rental expense on short-term leases during the three and nine months ended September 30, 2025, respectively. No rental expense was recognized on short-term leases during the three and nine months ended September 30, 2024.

Information related to the Company's right-of-use assets and related lease liabilities is as follows:

	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Cash paid for operating lease liabilities	$ —	$ 101	$ 68	$ 301

	September 30, 2025	December 31, 2024
Weighted-average remaining lease term	0.09 years	0.39 years
Weighted-average discount rate	10.0%	11.5%

There were no right-of-use assets and lease liabilities at September 30, 2025. Right-of-use assets and lease liabilities for the Company's operating leases were recorded in the condensed consolidated balance sheet as follows at December 31, 2024, representing

(In thousands, except share and per share data)

the Company's right to use the underlying asset for the lease term (Prepaid expenses and other current assets) and the Company's obligation to make lease payments (Other current liabilities):

	December 31, 2024
Prepaid expenses and other current assets	$ 65
Other current liabilities	$ 67

10. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2025	December 31, 2024
Accrued commercial expenses	$ 2,865	$ —
Accrued manufacturing expenses	1,228	1,148
Accrued payroll and bonus expenses	882	1,138
Accrued other expenses	241	365
Total	$ 5,216	$ 2,651

11. Debt

2025 Exchangeable Notes

On January 21, 2020, the Company completed a Private Placement pursuant to which its wholly owned subsidiary, Iterum Bermuda issued and sold $51,588 aggregate principal amount of Exchangeable Notes and $103 aggregate principal amount of RLNs to a group of accredited investors. On September 8, 2020, the Company completed a rights offering (the 2020 Rights Offering) pursuant to which Iterum Bermuda issued and sold $220 aggregate principal amount of Exchangeable Notes and $0.5 aggregate principal amount of RLNs, to existing shareholders. The Securities were sold in Units with each Unit consisting of an Exchangeable Note in the original principal amount of $1,000 and 50 RLNs. The Units were sold at a price of $1,000 per Unit.

At any time on or after January 21, 2021, subject to specified limitations, the Exchangeable Notes were exchangeable for the Company's ordinary shares, cash or a combination of ordinary shares and cash. Any accrued and unpaid interest being exchanged was calculated to include all interest accrued on the Exchangeable Notes being exchanged to, but excluding, the exchange settlement date. Beginning on January 21, 2021 through January 31, 2025, certain noteholders of $40,691 in aggregate principal amount of Exchangeable Notes completed a non-cash exchange of their notes, including accrued and unpaid interest of $3,071, for an aggregate of 3,760,155 of the Company's ordinary shares. On January 31, 2025, the Exchangeable Notes matured and Iterum Bermuda repaid in full to the holders thereof an aggregate principal amount of $11,117 together with accrued interest of $3,628.

The Company did not recognize any interest expense related to the Exchangeable Notes during the three months ended September 30, 2025 and recognized $88 of interest expense related to the Exchangeable Notes during the nine months ended September 30, 2025 and the Company recognized $181 and $542 of interest expense related to the Exchangeable Notes during the three and nine months ended September 30, 2024, respectively. The Company did not recognize any amortization of debt discounts and deferred financing costs during the three months ended September 30, 2025 and recognized $194 related to the amortization of the debt discounts and deferred financing costs during the nine months ended September 30, 2025, and $575 and $1,713 related to the amortization of the debt discounts and deferred financing costs during the three and nine months ended September 30, 2024, respectively. These amounts are recorded in interest expense, net in the condensed consolidated statements of operations and comprehensive loss.

Pfizer Promissory Note

On November 18, 2015, the Company and ITIL entered into the Pfizer License. Under the Pfizer License, ITIL agreed to make certain regulatory and sales milestone payments, including a regulatory milestone payment of $20,000 to Pfizer upon approval of oral sulopenem for commercial sale in the United States by the FDA. On October 25, 2024, the Company received FDA approval for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options.

(In thousands, except share and per share data)

On October 28, 2024, the Company notified Pfizer that it was electing to defer payment of the milestone payment for two years, or until October 25, 2026 (the Deferral Period), and delivered the Promissory Note issued by ITIL in the amount of the milestone payment to Pfizer, as permitted pursuant to the terms of the Pfizer License. The Promissory Note bears interest at an annual rate of eight percent (8.0%) on a daily compounded basis until paid in full and matures on October 25, 2026. ITIL has the right to prepay the unpaid principal balance of the Promissory Note together with accrued and unpaid interest at any time without premium or penalty. Pursuant to the terms of the Promissory Note, ITIL may (i) assign the Promissory Note to an affiliate of ITIL; (ii) designate one of its affiliates to perform its obligations thereunder; or (iii) assign the Promissory Note in the event of a change of control, provided that in the case of clauses (i) and (ii) ITIL is not relieved of any liability thereunder. Pursuant to the terms of the Pfizer License, if a change of control of ITIL or the Company occurs during the Deferral Period, Pfizer may, in its sole discretion and at its sole option, declare the milestone payment to be immediately due and payable together with all interest accrued under the Promissory Note. The Company has guaranteed all of the amounts payable by ITIL under the terms of the Pfizer License, including the amounts owed under the Promissory Note, pursuant to the guarantee entered into by and among ITIL, the Company and Pfizer on November 18, 2015 in connection with the Pfizer License.

On May 13, 2025, the Company and ITIL entered into an amended and restated promissory note (the A&R Note) and a letter agreement relating to the A&R Note and amending the Pfizer License Agreement in connection therewith (the Letter Agreement). The A&R Note extends the Deferral Period by an additional three years, or until October 25, 2029 (the Extended Deferral Period). In connection with the extension to the Deferral Period, ITIL agreed in the A&R Note to increase the annual rate of interest from eight percent (8%) to ten percent (10%) on a daily compounded basis during the Extended Deferral Period, beginning on October 26, 2026. The Company evaluated the A&R Note and the Letter Agreement under ASC 470 and determined that it should be accounted for as a debt modification as the cash flows under the amended terms do not differ by at least 10% from the cash flows under the original agreement. Accordingly, no gain or loss was recorded relating to the modification.

The Company recognized $562 and $1,415 of interest expense related to the Pfizer Promissory Note during the three and nine months ended September 30, 2025, respectively.

Principal Payments on Outstanding Debt

Scheduled principal payments on outstanding debt, including principal amounts owed to RLN holders (see Note 12 – Royalty-Linked Notes), as of September 30, 2025, for the following five fiscal years and thereafter were as follows:

Year Ending Sept 30,		
2026	$	—
2027		—
2028		—
2029		20,000
2030		—
Thereafter		45
Total	$	20,045

12. Royalty-Linked Notes

Liability Related to Sale of Future Royalties

On January 21, 2020, as part of the Private Placement, the Company issued 2,579,400 RLNs to a group of accredited investors. On September 8, 2020, as part of the 2020 Rights Offering, the Company issued 11,000 RLNs to existing shareholders. The RLNs will entitle the holders thereof to payments, at the applicable payment rate, based solely on a percentage of the Company's net revenues from U.S. sales of specified sulopenem products earned through December 31, 2045, but will not entitle the holders thereof to any payments unless the Company earns net revenues on such approved sulopenem product. If any portion of the principal amount of the outstanding RLNs, equal to $0.04 per RLN, has not been paid as of the end date on December 31, 2045, Iterum Bermuda must pay the unpaid portion of the principal amount. The RLNs will earn default interest if the Company breaches certain obligations under the RLN Indenture (but do not otherwise bear interest) and will be subject to a maximum return amount, including all principal and payments and certain default interest in respect of uncurable defaults, of $160.00 (or 4,000 times the principal amount of such note). The RLNs will be redeemable at the Company's option, subject to the terms of the RLN Indenture.

In accordance with exceptions allowed under ASC 815-10, *Derivatives and Hedging* (ASC 815), this transaction was initially accounted for as a debt liability under ASC 470, *Debt*. Subsequent to the listing of the RLNs on the Bermuda Stock Exchange in January 2021, the RLNs are accounted for as a derivative and are remeasured to fair value at each reporting date. In accordance with ASC 815, the fair value of the RLNs is determined using DCF analysis, without consideration of transaction costs, which represents a Level 3 basis of fair value measurement. Fair value measurements are highly sensitive to changes in inputs and significant changes to

(In thousands, except share and per share data)

inputs can result in a significantly higher or lower fair value. The Company periodically assesses the revenue forecasts of the specified sulopenem products and the related payments. The Company has no obligation to pay any amount to the noteholders until the net revenue of the specified products are earned.

The balance of the RLNs at each reporting date is as follows:

	September 30, 2025
Total liability related to the sale of future royalties, on inception	$ 10,990
Liability related to the sale of future royalties, arising from the 2020 Rights Offering	51
Amortization of discount and debt issuance costs	3,666
Adjustments to fair value	(2,129)
Repayments	(58)
Total liability related to the sale of future royalties at Sept 30, 2025	$ 12,520
Current Portion	281
Long-term Portion	$ 12,239

	December 31, 2024
Total liability related to the sale of future royalties, on inception	$ 10,990
Liability related to the sale of future royalties, arising from the 2020 Rights Offering	51
Amortization of discount and debt issuance costs	3,666
Adjustments to fair value	(3,936)
Total liability related to the sale of future royalties at December 31, 2024	$ 10,771
Current Portion	—
Long-term Portion	$ 10,771

13. Segment Reporting

In accordance with FASB ASC Topic 280, Segment Reporting, the Company has determined that it operates as a single business segment, which is the development and commercialization of innovative treatments for drug resistant bacterial infections. The financial results of the Company's operations are managed and reported to the Chief Executive Officer, Chief Financial Officer and Chief Commercial Officer, who together are considered the Company's chief operating decision maker (CODM), on a consolidated basis. The CODM assesses performance and allocates resources based on the Company's condensed consolidated statements of operations and key components and processes of the Company's operations are managed centrally. Segment asset information is not used by the CODM to allocate resources.

As a single reportable segment entity, the Company's segment performance measure is net income / (loss) attributable to shareholders. Significant segment expenses, as provided to the CODM, are presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Product Revenue, net	$ 390	$ —	$ 390	$ —
Segment cost of sales	(20)	—	(20)	—
Amortization of intangible asset (a)	—	—	—	—
Segment research and development (b) (c)	(1,244)	(3,077)	(2,795)	(8,998)
Segment selling, general and administration (b) (c)	(6,449)	(1,734)	(13,320)	(5,731)
Share-based compensation expense (see Note 15)	(53)	(68)	(170)	(274)
Depreciation and amortization	(355)	(8)	(1,055)	(23)
Operating loss	$ (7,731)	$ (4,887)	$ (16,970)	$ (15,026)

a)Amortization expense of $349 and $1,036 related to the Pfizer Intangible Asset has been excluded for the three and nine months ended September 30, 2025, respectively, and included within depreciation and amortization.

b)Share-based payment expense of $15 and $50 related to research and development and $38 and $120 related to general and administration have been excluded for the three and nine months ended September 30, 2025, respectively, and included within share-based compensation expense. Share-based payment expense of $25 and $147 related to research and

(In thousands, except share and per share data)

development and $43 and $127 related to general and administration have been excluded for the three and nine months ended September 30, 2024, respectively, and included within share-based compensation expense.

c)Depreciation expense of $2 and $7 related to research and development and $4 and $12 related to general and administration have been excluded for the three and nine months ended September 30, 2025, respectively, and included within depreciation and amortization. Depreciation expense of $5 and $14 related to research and development and $3 and $9 related to general and administration have been excluded for the three and nine months ended September 30, 2024, respectively, and included within depreciation and amortization.

Interest Expense, Net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Interest income	$ 121	$ 166	$ 406	$ 607
Interest expense	(562)	(756)	(1,697)	(2,255)
Interest expense, net	$ (441)	$ (590)	$ (1,291)	$ (1,648)

Long-Lived Assets

The distribution of long-lived assets by geographical area was as follows:

Long-lived assets	September 30, 2025	December 31, 2024
Ireland	$ 18,736	$ 19,759
U.S.	11	15
Total	$ 18,747	$ 19,774

14. Shareholders' Equity

The Company's capital structure consists of ordinary shares and undesignated preferred shares. Under Irish law, the Company is prohibited from allotting shares without consideration. Accordingly, at least the nominal value of the shares issued underlying any warrant, pre-funded warrant, restricted share award, restricted share unit, performance share award, bonus share or any other share-based grant must be paid pursuant to the Irish Companies Act 2014 (Irish Companies Act).

Ordinary Shares

On April 28, 2025, the Company entered into a securities purchase agreement with an institutional investor pursuant to which it issued and sold an aggregate of (i) 3,040,000 ordinary shares, at a purchase price of $0.90 per ordinary share, and (ii) pre-funded warrants to purchase up to an aggregate of 2,515,556 ordinary shares at a purchase price of $0.89 per pre-funded warrant. The Company's gross proceeds from the April 2025 Registered Direct Offering were $5,000 and net proceeds were $4,177 after deducting placement agent fees and offering expenses payable by the Company. Upon closing, the pre-funded warrants became exercisable immediately at an exercise price of $0.01 per ordinary share, subject to adjustment in certain circumstances, and will expire when exercised in full, subject to certain conditions. As of September 30, 2025, all pre-funded warrants issued in connection with the April 28, 2025 Offering had been exercised.

On August 9, 2024, the Company completed the 2024 Rights Offering in which it sold an aggregate of 6,121,965 2024 Units. Aggregate gross proceeds to the Company from the 2024 Rights Offering were $7,408 and net proceeds were $5,430 after deducting fees payable to the dealer-manager and other offering expenses payable by the Company.

At the Company's annual general meeting of shareholders on May 3, 2023, the Company's shareholders approved an increase of 60,000,000 ordinary shares of $0.01 par value each to the number of authorized ordinary shares and the Company's Articles of Association were amended accordingly. The Company has authorized ordinary shares of 80,000,000 ordinary shares of $0.01 par value each as of September 30, 2025. The holders of ordinary shares are entitled to one vote for each share held. There are no redemption or sinking fund provisions with respect to the authorized ordinary shares.

On October 7, 2022, the Company entered into the Sales Agreement with HC Wainwright, as agent, pursuant to which the Company could offer and sell ordinary shares for aggregate gross sales proceeds of up to $16,000 (subject to the availability of ordinary shares), from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. On December 10, 2024, the Company filed a prospectus

supplement with the SEC pursuant to which it may offer and sell ordinary shares having an aggregate offering price of up to an additional $25,000 through HC Wainwright pursuant to the Sales Agreement. During the three months ended September 30, 2025, the Company sold 6,860,532 ordinary shares pursuant to the Sales Agreement with HC Wainwright at an average net price of $0.79 per ordinary share for net proceeds of $5,417.

Beginning on January 21, 2021 through January 31, 2025, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes completed a non-cash exchange of their notes, including accrued and unpaid interest of $3,071 for an aggregate of 3,760,155 of the Company's ordinary shares. On January 31, 2025, the Exchangeable Notes matured and Iterum Bermuda repaid in full to the holders thereof an aggregate principal amount of $11,117 together with accrued interest of $3,628.

Warrants to purchase Ordinary Shares

On April 27, 2018, the Company's subsidiaries, Iterum Therapeutics International Limited, Iterum Therapeutics US Holding Limited and Iterum Therapeutics US Limited (the Borrowers), entered into a loan and security agreement (Loan and Security Agreement) with SVB pursuant to which SVB agreed to lend the Borrowers up to $30,000 in two term loans of which $15,000 was funded on closing. The Company did not satisfy the conditions for the second draw before the deadline of October 31, 2019. In connection with the initial drawdown under the Loan and Security Agreement, the Company issued SVB and Life Sciences Fund II LLC warrants to purchase an aggregate of 19,890 Series B convertible preferred shares (which converted into warrants to purchase 1,326 ordinary shares upon the Company's IPO) at an exercise price of $282.75 per ordinary share. These warrants will expire on April 27, 2028. No warrants had been exercised as of September 30, 2025.

In connection with the June 3, 2020 Offering completed on June 5, 2020, pursuant to the June 3, 2020 SPA, in a concurrent private placement, the Company issued and sold to institutional investors warrants to purchase up to 99,057 ordinary shares. Upon closing, the warrants became exercisable immediately at an exercise price of $24.30 per ordinary share, subject to adjustment in certain circumstances, and will expire on December 5, 2025. No warrants had been exercised as of September 30, 2025. Warrants to purchase 13,868 ordinary shares, amounting to 7% of the ordinary shares issued under the June 3, 2020 SPA, were issued to designees of the placement agent on the closing of the June 3, 2020 Offering. Upon closing, the warrants issued to such designees were exercisable immediately at an exercise price of $31.5465 per ordinary share. These warrants expired on June 3, 2025 and no warrants were exercised prior to expiration.

In connection with the June 30, 2020 Offering completed on July 2, 2020, pursuant to the June 30, 2020 SPA, in a concurrent private placement, the Company has also issued and sold to institutional investors warrants to purchase up to 112,422 ordinary shares. Upon closing, the warrants became exercisable immediately at an exercise price of $21.30 per ordinary share, subject to adjustment in certain circumstances, and will expire on January 2, 2026. As of September 30, 2025, warrants issued in connection with the June 30, 2020 Offering had been exercised for 84,317 ordinary shares, for net proceeds of $1,796. Warrants to purchase 15,739 ordinary shares, amounting to 7% of the ordinary shares issued under the June 30, 2020 SPA, were issued to designees of the placement agent on closing of the June 30, 2020 Offering. Upon closing, the warrants issued to such designees were exercisable immediately at an exercise price of $27.7965 per ordinary share. These warrants expired on June 30, 2025 and no warrants were exercised prior to expiration.

In connection with the October 2020 Offering, the Company issued and sold warrants to purchase up to 1,346,153 ordinary shares. Upon closing, the warrants became exercisable immediately at an exercise price of $9.75 per ordinary share, subject to adjustment in certain circumstances, and will expire on October 27, 2025. Warrants to purchase 125,641 ordinary shares, which represents a number of ordinary shares equal to 7.0% of the aggregate number of ordinary shares and pre-funded warrants sold in the October 2020 Offering, were issued to designees of the placement agent on closing of the October 2020 Offering. Upon closing, the warrants issued to such designees became exercisable immediately at an exercise price of $12.1875 per ordinary share and expire on October 22, 2025. As of September 30, 2025, warrants issued in connection with the October 2020 Offering had been exercised for 1,392,701 ordinary shares, for net proceeds of $13,885.

In connection with the underwritten offering in February 2021 (the February 2021 Underwritten Offering), the Company issued to the underwriter's designees warrants to purchase 162,318 ordinary shares, amounting to 7.0% of the aggregate number of ordinary shares sold in the February 2021 Underwritten Offering which closed on February 8, 2021. The warrants issued to such designees have an exercise price of $21.5625 per ordinary share, were exercisable upon issuance and will expire on February 3, 2026. As of September 30, 2025, warrants issued in connection with the February 2021 Underwritten Offering had been exercised for 25,333 ordinary shares, for net proceeds of $546.

In connection with the February 2021 Underwritten Offering, the Company granted the underwriter an option for a period of 30 days to purchase an additional 347,826 ordinary shares. Upon the underwriter's exercise of its option on February 10, 2021, the Company issued warrants to purchase an additional 24,347 ordinary shares to the underwriter's designees, amounting to 7.0% of the aggregate number of additional ordinary shares sold pursuant to the underwriter's option. The warrants issued to such designees have

(In thousands, except share and per share data)

an exercise price of $21.5625 per ordinary share, were exercisable upon issuance and will expire on February 3, 2026. No warrants had been exercised as of September 30, 2025.

In connection with the February 2021 Registered Direct Offering which closed on February 12, 2021, warrants to purchase 81,666 ordinary shares, amounting to 7.0% of the aggregate number of ordinary shares issued under the securities purchase agreement, were issued to designees of the placement agent upon closing. The warrants issued to such designees were exercisable upon issuance at an exercise price of $37.50 per ordinary share and will expire on February 9, 2026. No warrants had been exercised as of September 30, 2025.

In connection with the 2024 Rights Offering which closed on August 9, 2024, the Company issued and sold 1-year warrants to purchase up to 3,060,982 ordinary shares and 5-year warrants to purchase up to 6,121,965 ordinary shares. Upon closing, the warrants became exercisable immediately at an exercise price of $1.21 per ordinary share. The 1-year warrants expired on August 9, 2025 and the 5-year warrants will expire on August 9, 2029. As of September 30, 2025, 1-year warrants issued in connection with the 2024 Rights Offering had been exercised for 859,825 ordinary shares, for net proceeds of $1,040 and 5-year warrants issued in connection with the 2024 Rights Offering had been exercised for 664,802 ordinary shares for net proceeds of $804.

The Company has classified the warrants as equity in accordance with ASC 815. Accordingly, the proceeds were allocated between ordinary shares, the 1-year warrants and the 5-year warrants based on the relative fair value of the individual components. The fair value of the warrants was determined using a Black-Scholes option pricing model and the ordinary shares based on the closing date share price and were recorded in additional paid-in capital within shareholders' deficit on the condensed consolidated balance sheets. The following assumptions were used in the Black-Scholes option pricing model:

	August 9, 2024	
	1-year warrants	5-year warrants
Volatility	109%	109%
Expected term in years	1.00	5.00
Dividend rate	0%	0%
Risk-free interest rate	4.50%	3.80%
Share price	$ 1.18	$ 1.18
Strike price	$ 1.21	$ 1.21
Fair value of warrants issued	$ 0.50	$ 0.94

Undesignated Preferred Shares

The Company has authorized 100,000,000 undesignated preferred shares of $0.01 par value each as of September 30, 2025. The Company's board of directors is authorized by the Company's Articles of Association to determine the rights attaching to the undesignated preferred shares including rights of redemption, rights as to dividends, rights on winding up and conversion rights. There were no designated preferred shares issued as of September 30, 2025.

15. Share-Based Compensation

On November 18, 2015, the Company's board of directors adopted and approved the 2015 Equity Incentive Plan (the 2015 Plan), which authorized the Company to grant up to 14,895 ordinary shares in the form of incentive share options, nonstatutory share options, share appreciation rights, restricted share awards, restricted share units and other share awards. The types of share-based awards, including the rights, amount, terms, and exercisability provisions of grants are determined by the Company's Board of Directors. The purpose of the 2015 Plan was to provide the Company with the flexibility to issue share-based awards as part of an overall compensation package to attract and retain qualified personnel. On May 18, 2017, the Company amended the 2015 Plan to increase the number of ordinary shares available for issuance under the 2015 Plan by 14,640 shares to 29,535 shares.

On March 14, 2018, the Company's board of directors adopted and approved the 2018 Equity Incentive Plan (the 2018 Plan), which became effective upon the execution and delivery of the underwriting agreement related to the Company's IPO in May 2018. Since adopting the 2018 Plan, no further grants will be made under the 2015 Plan. The ordinary shares underlying any options that are forfeited, cancelled, repurchased or are otherwise terminated by the Company under the 2015 Plan will not be added back to the ordinary shares available for issuance.

The 2018 Plan originally authorized the Company to grant up to 67,897 ordinary shares in the form of incentive share options, nonstatutory share options, share appreciation rights, restricted share awards, restricted share units, performance share awards, performance cash awards and other share awards. The types of share-based awards, including the amount, terms, and exercisability provisions of grants are determined by the Company's Board of Directors. The ordinary shares underlying any options that are forfeited, cancelled, repurchased or are otherwise terminated by the Company under the 2018 Plan are added back to the ordinary shares available for issuance under the 2018 Plan.

(In thousands, except share and per share data)

On December 5, 2018, pursuant to powers delegated to it by the board of directors of the Company, the Compensation Committee approved an increase in the number of ordinary shares available to be granted pursuant to the 2018 Plan by 4% of the total number of shares of the Company's issued share capital on December 31, 2018, being 38,272 ordinary shares.

On February 14, 2020, pursuant to powers delegated to it by the board of directors of the Company, the Compensation Committee approved, by written resolution, an increase of 39,650 ordinary shares to the number of ordinary shares available to be granted pursuant to the 2018 Plan, being just under 4% of the total number of the Company's ordinary shares outstanding on December 31, 2019, in accordance with the terms of the 2018 Plan.

On June 10, 2020, at the Company's annual general meeting of shareholders, the shareholders approved and adopted an amended and restated 2018 Plan which, among other things, included an increase of 150,000 ordinary shares to the number of ordinary shares reserved for issuance under the 2018 Plan.

On June 23, 2021, at the Company's annual general meeting of shareholders, the shareholders approved an amendment to the amended and restated 2018 Plan to increase the number of ordinary shares reserved for issuance under the amended and restated 2018 Plan by 1,000,000 ordinary shares to 1,295,819 ordinary shares.

On November 24, 2021, the Company's board of directors adopted and approved the 2021 Inducement Equity Incentive Plan (the 2021 Inducement Plan) reserving 333,333 of its ordinary shares to be used exclusively for grants of awards to individuals that were not previously employees or directors of the Company (or following such individuals' bona fide period of non-employment with the company), as a material inducement to such individuals' entry into employment with the company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The terms and conditions of the 2021 Inducement Plan are substantially similar to the 2018 Plan.

Share Options

Unless specified otherwise in an individual option agreement, share options granted under the 2015 Plan, the 2018 Plan and the 2021 Inducement Plan generally have a ten year term and a four year vesting period for employees and a one year vesting period for directors. The vesting requirement is conditioned upon a grantee's continued service with the Company during the vesting period. Once vested, all awards are exercisable from the date of grant until they expire. The option grants are non-transferable. Vested options generally remain exercisable for 90 days subsequent to the termination of the option holder's service with the Company. In the event of an option holder's disability or death while employed by or providing service to the Company, the exercisable period extends to twelve months or eighteen months, respectively.

The fair value of options granted are estimated using the Black-Scholes option-pricing model. The inputs for the Black-Scholes model require significant management assumptions. The risk-free interest rate is based on a normalized estimate of the 7-year U.S. treasury yield. The Company has estimated the expected term utilizing the "simplified" method for awards that qualify as "plain vanilla". The expected volatility was determined with reference to the historical volatility of the Company's shares. Expected dividend yield is based on the fact that the Company has never paid cash dividends and the Company's future ability to pay cash dividends on its shares may be limited by the terms of any future debt or preferred securities and Irish law. The Company has elected to account for forfeitures as they occur.

The Company granted 200,000 share options to an employee during the nine months ended September 30, 2025. No share options were granted to employees and directors during the nine months ended September 30, 2024. There were 305,836 and 398,824 unvested employee and director share options outstanding as of September 30, 2025 and 2024, respectively. Total expense recognized related to employee share options was $53 and $170 for the three and nine months ended September 30, 2025, respectively, and $68 and $279 for the three and nine months ended September 30, 2024, respectively. Total unamortized compensation expense related to employee share options was $238 and $364 as of September 30, 2025 and 2024, respectively, which is expected to be recognized over a remaining weighted average vesting period of 2.63 years and 1.49 years as of September 30, 2025 and 2024, respectively.

The range of assumptions that the Company used to determine the grant date fair value of employee options granted were as follows:

	Nine Months Ended September 30, 2025
Volatility	107.6%
Expected term in years	6.25
Dividend rate	0%
Risk-free interest rate	4.03%
Share price	$ 0.98
Fair value of option on grant date	$ 0.82

The following table summarizes total share option activity for all Company plans:

	Equity Plans	Inducement Plan	Total
Options outstanding December 31, 2024	836,887	4,833	841,720
Granted	—	200,000	200,000
Exercised	—	—	—
Forfeited	(27,096)	(826)	(27,922)
Expired	(71,627)	(1,507)	(73,134)
Options outstanding September 30, 2025	738,164	202,500	940,664

The following table summarizes the number of options outstanding and the weighted-average exercise price as of September 30, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding December 31, 2024	841,720	$ 2.37	7.76	$ 549
Granted	200,000	$ 0.98	9.76	$ —
Exercised	—			
Forfeited	(27,922)	$ 1.06		
Expired	(73,134)	$ 6.01		
Options outstanding September 30, 2025	940,664	$ 2.16	7.13	$ —
Exercisable at September 30, 2025	634,828	$ 2.51	6.94	$ —

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares as of September 30, 2025 and December 31, 2024, respectively.

Restricted Share Units (RSUs)

The Company did not grant any RSUs to employees and directors during the nine months ended September 30, 2025 and 2024, respectively. There were no RSUs outstanding as of September 30, 2025 and 2024, respectively.

The fair value of the RSUs is determined on the date of grant based on the market price of the Company's ordinary shares on that date. The fair value of RSUs is expensed ratably over the vesting period, which is generally one year for directors and two years for employees under the 2018 Plan and four years for employees under the 2021 Inducement Plan. No amount was recognized relating to RSUs for the three and nine months ended September 30, 2025 or the three months ended September 30, 2024 and total benefit recognized related to the RSUs was $5 for the nine months ended September 30, 2024. There was no unamortized compensation expense related to the RSUs as of September 30, 2025 and 2024.

The Company's share-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development expense	$ 15	$ 25	$ 50	$ 147
Selling, general and administrative expense	38	43	120	127

There was a total of $238 and $364 unamortized share-based compensation expense for options as of September 30, 2025 and 2024, respectively, which is expected to be recognized over a remaining average vesting period of 2.63 years and 1.49 years as of September 30, 2025 and 2024, respectively.

16. Income Taxes

In accordance with ASC 270, *Interim Reporting,* and ASC 740, *Income Taxes,* at the end of each interim period, the Company is required to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. The Company recorded an income tax expense of $132 and $251 for the three and nine

months ended September 30, 2025, respectively and $136 and $215 for the three and nine months ended September 30, 2024, respectively.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, including the Company's history of losses and determined that it is more-likely-than-not that these net deferred tax assets will not be realized. As of September 30, 2025 and December 31, 2024, the Company has net operating loss carryforwards in Ireland which result in tax benefits of approximately $46,867 and $44,536, respectively, for which a full valuation allowance has been recognized. The net operating loss carryforwards do not expire, but are carried forward indefinitely. Realization of these deferred tax assets is dependent on the generation of sufficient taxable income. If the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets may change and the remaining valuation allowance may be released in part or in whole. While management expects to realize the deferred tax assets, net of valuation allowances, changes in estimates of future taxable income or in tax laws may alter this expectation.

17. Commitments and Contingencies

License Agreement

On November 18, 2015, the Company and ITIL entered into the Pfizer License under which the Company is obligated to make a potential one-time payment related to sublicensing income that exceeds a certain threshold. The Company is obligated to pay Pfizer potential future regulatory milestone payments, as well as sales milestones upon achievement of net sales ranging from $250,000 to $1,000 million for each product type. The Company is also obligated to pay Pfizer royalties ranging from a single-digit to mid-teens percentage based on marginal net sales of each licensed product.

Royalty-Linked Notes

On January 21, 2020, as part of the Private Placement, the Company issued 2,579,400 RLNs to a group of accredited investors. On September 8, 2020, as part of the 2020 Rights Offering, the Company issued 11,000 RLNs to existing shareholders. The RLNs will entitle the holders thereof to payments, at the applicable payment rate, based solely on a percentage of the Company's net revenues from U.S. sales of specified sulopenem products earned through December 31, 2045, but will not entitle the holders thereof to any payments unless the Company earns net revenues on such approved sulopenem product. If any portion of the principal amount of the outstanding RLNs, equal to $0.04 per RLN, has not been paid as of the end date on December 31, 2045, Iterum Bermuda must pay the unpaid portion of the principal amount. The RLNs will earn default interest if the Company breaches certain obligations under the RLN Indenture (but do not otherwise bear interest) and will be subject to a maximum return amount, including all principal and payments and certain default interest in respect of uncurable defaults, of $160.00 (or 4,000 times the principal amount of such note). The RLNs will be redeemable at the Company's option, subject to the terms of the RLN Indenture.

Other Contracts

In the course of normal business operations, the Company has agreements with contract service providers to assist in the performance of its research and development, manufacturing and commercial activities. Expenditures to CROs, CMOs and other service providers represent significant costs in research and development and commercial activities. Subject to required notice periods and the Company's obligations under binding purchase orders and any cancellation fees that it may be obligated to pay, the Company can elect to discontinue the work under these agreements at any time. The Company may enter into additional collaborative research and development, contract research, commercialization, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Other Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date the Company evaluates whether or not a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings. The Company has no contingent liabilities in respect of legal claims arising in the ordinary course of business.

Under the terms of their respective employment agreements, each of the named executive officers is eligible to receive severance payments and benefits upon a termination without "cause" (other than due to death or disability) or upon "resignation for good reason", contingent upon the named executive officer's continued performance for the Company. Under the terms of the Employee Severance Plan approved by the Compensation Committee in January 2022, an employee, who is not an executive officer of the Company, is entitled to severance pay and benefits on a "qualifying termination", that is termination at any time during the period beginning on the date that is 30 days prior to and ending on the date that is 12 months following a change of control without "cause" (other than due to death or disability) based on the employee's level/salary grade.

18. Condensed Consolidating Financial Statements

On January 21, 2020, the Company completed a Private Placement pursuant to which its wholly owned subsidiary, Iterum Bermuda, issued and sold $51,588 aggregate principal amount of Exchangeable Notes and $103 aggregate principal amount of RLNs to a group of accredited investors. On September 8, 2020, the Company completed a Rights Offering pursuant to which Iterum Bermuda issued and sold $220 aggregate principal amount of Exchangeable Notes and $0.44 aggregate principal amount of RLNs to existing shareholders. The Securities were sold in Units with each Unit consisting of an Exchangeable Note in the original principal amount of $1,000 and 50 RLNs. As of September 30, 2025, all RLNs remained outstanding. Payments owed for the period ended September 30, 2025 have been accrued and payment is due within 75 days of December 31, 2025, which is the next payment measuring period end.

The RLNs will entitle the holders thereof to payments, at the applicable payment rate, based solely on a percentage of the Company's net revenues from U.S. sales of specified sulopenem products earned through December 31, 2045.

The Units were issued by Iterum Bermuda, which was formed on November 6, 2019 and is a 100% owned "finance subsidiary" of the Company under Rule 3-10 of Regulation S-X with no independent function and no assets or operations other than those related to the issuance, administration and repayment of the RLNs, and previously the Exchangeable Notes. Iterum Therapeutics plc, as the parent company, has no independent assets or operations, and its operations are conducted solely through its subsidiaries. The assets, liabilities and results of operations of the Company, Iterum Bermuda and Iterum Therapeutics International Limited, Iterum Therapeutics US Holding Limited and Iterum Therapeutics US Limited (the Subsidiary Guarantors) are not materially different than the corresponding amounts presented in the condensed consolidated financial statements of this Quarterly Report on Form 10-Q. The Company and the Subsidiary Guarantors have provided a full and unconditional guarantee of Iterum Bermuda's obligations under the RLNs, and each of the guarantees constitutes the joint and several obligations of the applicable guarantor. The Subsidiary Guarantors are 100% directly or indirectly owned subsidiaries of the Company. There are no significant restrictions upon the Company's or the Subsidiary Guarantors' ability to obtain funds from their subsidiaries by dividend or loan. None of the assets of Iterum Bermuda or the Subsidiary Guarantors represent restricted net assets pursuant to Rule 4-08(e)(3) of Regulation S-X.

19. Subsequent Events

Equity

Subsequent to September 30, 2025, through November 13, 2025, the Company sold 3,795,819 ordinary shares under the Sales Agreement, with HC Wainwright as agent, at an average net price of $0.69 per ordinary share for net proceeds of $2,627.

On October 16, 2025, the Company filed a prospectus supplement with the SEC pursuant to which it may offer and sell ordinary shares having an aggregate offering price of up to $20,000 through HC Wainwright pursuant to the Sales Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a pharmaceutical company dedicated to maximizing the commercial potential of ORLYNVAH™ for the treatment of uncomplicated urinary tract infections (uUTIs) caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options. ORLYNVAH™, which we commercially launched in the United States in August 2025, is the first oral branded penem available in the United States and potentially the first and only oral and intravenous (IV) branded penem available globally. Penems, including thiopenems and carbapenems, belong to a class of antibiotics more broadly defined as ß-lactam antibiotics, the original example of which was penicillin, but which now also includes cephalosporins. Sulopenem is a potent, thiopenem antibiotic delivered intravenously which is active against bacteria that belong to the group of organisms known as gram-negatives and cause urinary tract and intra-abdominal infections. We have developed sulopenem in an oral tablet formulation, sulopenem etzadroxil-probenecid, which we refer to herein as oral sulopenem or ORLYNVAH™, as the context so requires. We refer to sulopenem delivered intravenously as sulopenem and sulopenem together with oral sulopenem/ORLYNVAH™, as our sulopenem program. We believe that sulopenem and ORLYNVAH™ have the potential to be important new treatment alternatives to address growing concerns related to antibacterial resistance without the known toxicities of some of the most widely used antibiotics, specifically fluoroquinolones.

On October 25, 2024, we received approval from the U.S. Food and Drug Administration (FDA) of our New Drug Application (NDA) for ORLYNVAH™ for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options.

ORLYNVAH™ was commercially launched in the United States in August 2025. Our launch strategy involves direct sales force outreach to high-volume prescribers of uUTI antibiotics in a limited geographic area. We expect modest sales of ORLYNVAH™ in 2025 during the early stages of our commercialization efforts.

We expect to continue to incur significant expenses and increased operating losses as we focus on maximizing the commercial potential of ORLYNVAH™ in the U.S., seek marketing approval for other product candidates, if clinical trials are successful, and engage and pursue the development of our sulopenem program in additional indications, including through preclinical and clinical development.

Commercialization Activities

We are continuing to build our commercial capabilities and infrastructure following the launch of ORLYNVAH™ in the United States in August 2025. In June 2025, our subsidiary Iterum Therapeutics US Limited (ITUS) entered into a Product Commercialization Agreement (the EVERSANA Agreement) with EVERSANA for the commercialization of our approved product, ORLYNVAH™. Pursuant to the EVERSANA Agreement, EVERSANA provides sales and commercial operations services to ITUS in the United States, as well as the provision of marketing, logistics, channel management, regulatory, medical affairs and other services related to the commercialization of ORLYNVAH™ in the United States (the Commercialization Services).

Under the terms of the EVERSANA Agreement, ITUS has legal, regulatory, and manufacturing responsibilities for ORLYNVAH™, and books sales for ORLYNVAH™. ITUS pays EVERSANA fees and reimburses EVERSANA for its expenses in performing the Commercialization Services as agreed in applicable statements of work issued pursuant to the EVERSANA Agreement. The term of the EVERSANA Agreement is five years following the date of commercial launch of ORLYNVAH™, subject to predefined termination provisions.

In addition, in July 2025, our subsidiary Iterum Therapeutics International Limited (ITIL), entered into a Commercial Manufacturing and Supply Agreement (the ACS Dobfar Agreement) with ACS Dobfar S.p.A, together with its affiliates (ACS Dobfar) for the manufacture and supply of materials for the Company's approved product, ORLYNVAH™.

We have hired a Chief Commercial Officer and, in the future, plan to hire additional personnel across core areas such as marketing, patient access and reimbursement, analytics and operations, and product distribution to support our planned commercialization efforts.

Going Concern

Since our inception, we have incurred significant operating losses. We began commercial operations in August 2025 and therefore have had limited net product sales to date, and have generated limited revenue from a funding arrangement with the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program and have otherwise funded our operations primarily through private and public offerings of equity or debt. We have incurred operating losses since inception, including net losses of $20.4 million and $18.2 million for the nine months ended September 30, 2025 and 2024, respectively, and a net loss of $24.8 million for the year ended December 31, 2024. As of September 30, 2025, we had an accumulated deficit of $506.5 million.

ORLYNVAH™ was launched in the United States in August 2025, with our commercialization partner, EVERSANA. We have incurred and expect to continue to incur significant expenses relating to the commercialization of ORLYNVAH™. We may also incur expenses in connection with the further clinical development of IV sulopenem and the clinical development of oral sulopenem in additional indications, the establishment of additional sources for the manufacture of oral sulopenem tablets and, if relevant, IV vials or the in-license or acquisition of additional product candidates. Additionally, we have incurred and expect to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses.

As a result, we will require additional capital to fund our operations, to continue to develop our sulopenem program and to execute our strategy. Until such time as we can generate significant revenue from product sales, if ever, or sell, license, or otherwise dispose of our rights to sulopenem, we expect to finance our operations through a combination of equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements, marketing and distribution arrangements or government funding. However, we may be unable to obtain such financing when needed or on acceptable terms.

Because of the numerous risks and uncertainties associated with commercialization of pharmaceuticals, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even with the commercialization of ORLYNVAH™, it is uncertain when, if ever, the Company will realize significant revenue from product sales and become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To continue as a going concern, we must secure additional funding to support our current operating plan or significantly delay, scale back or discontinue the commercialization of ORLYNVAH™ for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options and the development of our sulopenem program. As of September 30, 2025, we had cash and cash equivalents of $11.0 million. Based on our available cash resources we do not believe that our existing cash and cash equivalents, including amounts raised under our "at the market offering" agreement (the Sales Agreement) with H.C. Wainwright & Co. LLC (HC Wainwright), as agent, subsequent to September 30, 2025 (see Note 19 – Subsequent Events), will enable us to fund our operating expenses for the next 12 months from the date of filing this Quarterly Report on Form 10-Q. This condition raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to obtain additional funding to support our business objectives including achieving revenue growth from sales of ORLYNVAH™. We have limited experience with and have not yet demonstrated an ability to successfully commercialize a product. We expect that, in order to obtain additional funding, we will need to complete additional public or private financings of debt or equity. Although management intends to pursue plans to obtain additional funding to finance its operations, and we have successfully raised capital in the past, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We may also seek to procure additional funds through future arrangements with collaborators, licensees or other third parties, and these arrangements would generally require us to relinquish or encumber rights to some of our product candidates. We may not be able to complete financings or enter into third-party arrangements on acceptable terms, if at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may be forced to significantly delay, scale back or discontinue the development and commercialization of our sulopenem program, or otherwise change our strategy, which could adversely affect our business prospects, or we may be unable to continue operations.

We are continuously evaluating our corporate, strategic, financial and financing alternatives, with the goal of maximizing value for our stakeholders. These alternatives could potentially include the licensing, sale or divestiture of our assets or proprietary technologies, or another strategic transaction involving us. The evaluation of corporate, strategic, financial and financing alternatives may not result in any particular action or any transaction being pursued, entered into or consummated, and there is no assurance as to the timing, sequence or outcome of any action or transaction or series of actions or transactions.

Components of Our Results of Operations

Product Revenue

Revenues from product sales are recorded at the time of sale at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from distribution service fees, prompt pay discounts, chargebacks, rebates, co-payment assistance and product returns, as applicable. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no payments are required of us) or a current

liability (if a payment is required of us). Our estimates take into consideration current contractual and statutory requirements. Actual amounts of consideration ultimately received or paid may differ from our estimates.

Our revenue recognition is based on unit shipments from our third-party logistics warehouse to our customers. We have recognized limited net product sales in the United States since the commercial launch of ORLYNVAH™ in August 2025. As discussed in Note 3 – Revenue, gross revenues are adjusted for variable consideration, including our patient support programs. We expect product revenues to fluctuate in future periods as we continue with the commercial launch of ORLYNVAH™.

Costs and Expenses

Cost of Sales

Cost of sales consists primarily of direct and indirect costs related to the manufacture of ORLYNVAH™ for commercial sale, including salaries and related expenses for personnel, stock-based compensation, third-party manufacturing costs, raw material and component costs, excess or obsolete inventory adjustment charges, inventory write offs, packaging services, freight, storage costs, distribution fees, as applicable, and royalties to Pfizer on net product sales. Prior to the FDA approval of ORLYNVAH™ in October 2024, costs incurred for the manufacture of ORLYNVAH™ were recorded as research and development expenses. As a result, the cost of goods sold related to ORLYNVAH™ will initially reflect a lower average per unit cost of materials, as previously expensed inventory is utilized for commercial production and sold to customers. We expect the cost of goods sold for ORLYNVAH™ to increase in relation to product revenues as we deplete this inventory.

We periodically evaluates inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods as well as estimated sales trends. As of September 30, 2025, no inventory was determined to be obsolete.

Intangible Asset Amortization

*A*mortization relates to the finite-lived intangible asset recognized in relation to the regulatory milestone payment payable to Pfizer Inc. (Pfizer) upon approval of ORLYNVAH™ by the FDA.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our sulopenem program, which include:

•expenses incurred under agreements with contract research organizations (CROs), contract manufacturing organizations (CMOs), as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;

•manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches and reservation fees;

•employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;

•costs related to compliance with regulatory requirements, including the preparation and support of regulatory filings;

•facilities costs, depreciation, amortization and other expenses, which include rent under short-term and operating lease agreements and utilities; and

•payments made in cash, equity securities or other forms of consideration under third-party licensing agreements.

We expense research and development costs as incurred. Advance payments we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, related benefits and share-based compensation expense for personnel in executive, finance, commercial and administrative functions. Selling, general and administrative expenses also include pre-commercial launch activities prior to product launch, ongoing commercialization activities, director compensation, travel expenses, insurance, professional fees for legal, patent, consulting, accounting and audit services and market preparation expenses.

We expect our commercialization efforts for ORLYNVAH™ will result in a significant increase in payroll and other expenses to support commercial operations.

Interest Expense, Net

Interest expense, net consists of interest accrued and amortization of debt costs with respect to the 6.500% Exchangeable Senior Subordinated Notes, which were repaid in full on maturity on January 31, 2025 (Exchangeable Notes), interest accrued with respect to the promissory note issued by Iterum Therapeutics International Limited (ITIL) in the amount of the milestone payment to Pfizer in

connection with us electing to defer payment of the milestone payment due to Pfizer for five years until October 25, 2029 (the Pfizer Promissory Note), interest earned on our cash and cash equivalents, which are generally invested in money market accounts, interest earned on our investments in marketable securities and realized gains and losses on our short-term investments. Interest on the Exchangeable Notes was not payable until maturity of the instrument unless exchanged prior to maturity in accordance with the terms of the indenture governing the Exchangeable Notes (Exchangeable Notes Indenture) at which time any accrued and unpaid interest became due and payable. Interest on the Pfizer Promissory Note is compounded daily and is payable on maturity.

Adjustments to Fair Value of Derivatives

Derivative liabilities, which consist of the Limited Recourse Royalty-Linked Subordinated Notes (RLNs) issued in 2020, are revalued at each balance sheet date and the change in fair value during the reporting period is recorded in the condensed consolidated statements of operations as adjustments to fair value of derivatives.

Other Expense, Net

Other expense, net consists of realized and unrealized foreign currency gains and losses incurred in the normal course of business based on movement in the applicable exchange rates.

Provision for Income Taxes

We recognize income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of Irish, U.S. and other foreign pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying business.

Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax assets will not be realized. We account for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate our tax positions on a quarterly basis. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We believe that our critical accounting policies described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 7, 2025, involve the most judgment and complexity. Accordingly, we believe the policies set forth in such Annual Report on Form 10-K are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting estimates described in our Annual Report on Form 10-K filed with the SEC on February 7, 2025. In August 2025, ORLYNVAH™ was launched in the U.S. and we began recording net product revenue, cost of goods sold and related accounts receivable. New accounting policies have been included in Note 2 – Summary of Significant Accounting Policies.

Results of Operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our operating loss and loss before income taxes for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		
	2025	2024	Change
Product revenue, net	$ 390	$ —	$ 390
Costs and expenses:			
Cost of sales	(20)	—	(20)
Amortization of intangible asset	(349)	—	(349)
Research and development	(1,261)	(3,107)	1,846
Selling, general and administrative	(6,491)	(1,780)	(4,711)
Total operating expenses	(8,121)	(4,887)	(3,234)
Operating loss	(7,731)	(4,887)	(2,844)
Total other expense, net	(1,116)	(1,071)	(45)
Loss before income taxes	$ (8,847)	$ (5,958)	$ (2,889)

Revenue

Revenues were $0.4 million and $0.0 million for the three months ended September 30, 2025 and 2024, respectively. Revenues for the three months ended September 30, 2025 include $0.4 million in net product revenues for sales of ORLYNVAH™, which launched in August 2025.

Cost of Sales Expenses

Cost of goods sold was $0.0 million and $0.0 million for the three months ended September 30, 2025 and 2024, respectively. As costs incurred for the manufacture of ORLYNVAH™ were recorded as research and development expenses prior to October 2024, the cost of goods sold for the three months ended September 30, 2025 consisted primarily of royalties payable to Pfizer.

Amortization of intangible asset

Intangible asset amortization was $0.3 million and $0.0 million for the three months ended September 30, 2025 and 2024, respectively. The amortization relates to the regulatory milestone payable to Pfizer upon approval of ORLYNVAH™ which was capitalized on recognition.

Research and Development Expenses (in thousands)

	Three Months Ended September 30,		
	2025	2024	Change
CRO and other preclinical and clinical trial expenses	$ 604	$ 464	$ 140
Personnel related (including share-based compensation)	309	425	(116)
Chemistry, manufacturing and control (CMC) related expenses	52	1,516	(1,464)
Consulting fees	296	702	(406)
Total research and development expenses	$ 1,261	$ 3,107	$ (1,846)

The increase in CRO and other preclinical and clinical trial expenses of $0.1 million was primarily due to clinical costs incurred in 2025 relating to our Phase 1 pediatric study, which is a post marketing commitment. Personnel related costs decreased by $0.1 million primarily due to lower headcount and a decrease in accrued bonuses payable in 2025. Personnel related costs for the three months ended September 30, 2025 and 2024 included share-based compensation expense of $0.0 million and $0.0 million respectively. CMC related expenses decreased by $1.5 million primarily as a result of ORLYNVAH™ manufacturing costs being capitalized to inventory, following approval in October 2024. The decrease in consulting fees of $0.4 million in 2025 was due to the use of fewer consultants compared to 2024, during which consulting services were used in connection with the resubmission of our NDA for ORLYNVAH™.

Selling, General and Administrative Expenses (in thousands)

	Three Months Ended September 30,		
	2025	2024	Change
Personnel related (including share-based compensation)	$ 800	$ 814	$ (14)
Facility related and other	362	487	(125)
Professional and consulting fees	5,329	479	4,850
Total selling, general and administrative expenses	$ 6,491	$ 1,780	$ 4,711

Personnel related costs of $0.8 million were flat period on period. Personnel related costs for the three months ended September 30, 2025 and 2024 included share-based compensation expense of $0.0 million and $0.0 million, respectively. Facility related and other costs decreased by $0.1 million primarily as a result of a decrease in insurance costs and lower rent expenses. Professional and consulting fees increased by $4.9 million primarily as a result of an increase in consultants used for pre-commercialization and commercialization activities, including costs associated with our third party logistics provider to support the commercialization of ORLYNVAH™.

Total Other Expense, net

The following table summarizes our total other expense, net for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		
	2025	2024	Change
Interest expense, net	$ (441)	$ (590)	$ 149
Adjustments to fair value of derivatives	(673)	(433)	(240)
Other expense, net	(2)	(48)	46
Total other expense, net	$ (1,116)	$ (1,071)	$ (45)

Interest Expense, Net

Interest expense, net decreased by $0.1 million for the three months ended September 30, 2025 primarily as a result of a decrease in interest accrued and amortization of debt costs related to the Exchangeable Notes, which were repaid in January 2025, partially offset by an increase in interest accrued on the Pfizer Promissory Note and a decrease in interest income on money market funds.

Adjustments to Fair Value of Derivatives

Adjustments to the fair value of the derivative liability were $0.7 million and $0.4 million for the three months ended September 30, 2025 and 2024, respectively. This non-cash adjustment primarily related to an increase in the fair value of the RLNs due to the passage of time.

Other Expense, Net

Other expense, net consists of realized and unrealized foreign currency gains and losses incurred in the normal course of business based on movement in the applicable exchange rates.

Comparison of the nine months ended September 30, 2025 and 2024

The following table summarizes our operating loss and loss before income taxes for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,		
	2025	2024	Change
Product Revenue, net	$ 390	$ —	$ 390
Costs and expenses:			
Cost of sales	(20)	—	(20)
Amortization of intangible asset	(1,036)	—	(1,036)
Research and development	(2,852)	(9,159)	6,307
Selling, general and administrative	(13,452)	(5,867)	(7,585)
Total operating expenses	(17,360)	(15,026)	(2,334)
Operating loss	(16,970)	(15,026)	(1,944)
Total other expense, net	(3,158)	(2,951)	(207)
Loss before income taxes	$ (20,128)	$ (17,977)	$ (2,151)

Revenue

Revenues were $0.4 million and $0.0 million for the nine months ended September 30, 2025 and 2024, respectively. Revenues for the nine months ended September 30, 2025 include $0.4 million in net product revenues for sales of ORLYNVAH™, which launched in August 2025.

Cost of Sales Expenses

Cost of goods sold was $0.0 million and $0.0 million for the nine months ended September 30, 2025 and 2024, respectively. As costs incurred for the manufacture of ORLYNVAH™ were recorded as research and development expenses prior to October 2024, the cost of goods sold for the nine months ended September 30, 2025 consisted primarily of royalties payable to Pfizer.

Amortization of intangible asset

Intangible asset amortization was $1.0 million and $0.0 million for the nine months ended September 30, 2025 and 2024, respectively. The amortization relates to the regulatory milestone payable to Pfizer upon approval of ORLYNVAH™ which was capitalized on recognition.

Research and Development Expenses (in thousands)

	Nine Months Ended September 30,		
	2025	2024	Change
CRO and other preclinical and clinical trial expenses	$ 1,220	$ 3,124	$ (1,904)
Personnel related (including share-based compensation)	984	1,953	(969)
Chemistry, manufacturing and control (CMC) related expenses	(98)	2,535	(2,633)
Consulting fees	746	1,547	(801)
Total research and development expenses	$ 2,852	$ 9,159	$ (6,307)

The decrease in CRO and other preclinical and clinical trial expenses of $1.9 million was primarily due to higher costs incurred in 2024 to support the completion of our REASSURE trial. Personnel related costs decreased by $1.0 million primarily due to lower headcount and a decrease in accrued bonuses payable in 2025. Personnel related costs for the nine months ended September 30, 2025 and 2024 included share-based compensation expense of $0.1 million and $0.1 million, respectively. CMC related expenses decreased by $2.6 million primarily as a result of lower facilities rent and ORLYNVAH™ manufacturing costs being capitalized to inventory following approval in October 2024. The decrease in consulting fees of $0.8 million in 2025 was due to the use of fewer consultants compared to 2024, during which consulting services were used in connection with the resubmission of our NDA for ORLYNVAH™.

Selling, General and Administrative Expenses (in thousands)

	Nine Months Ended September 30,		
	2025	2024	Change
Personnel related (including share-based compensation)	$ 2,203	$ 2,474	$ (271)
Facility related and other	1,294	1,640	(346)
Professional and consulting fees	9,955	1,753	8,202
Total selling, general and administrative expenses	$ 13,452	$ 5,867	$ 7,585

Personnel related costs decreased by $0.3 million as a result of a decrease in accrued bonuses payable. Personnel related costs for the nine months ended September 30, 2025 and 2024 included share-based compensation expense of $0.1 million and $0.1 million, respectively. Facility related and other costs decreased by $0.3 million primarily as a result of a decrease in insurance costs and lower rent expenses. Professional and consulting fees increased by $8.2 million primarily as a result of an increase in consultants used for pre-commercialization and commercialization activities, including costs associated with our third party logistics provider to support the commercialization of ORLYNVAH™.

Total Other Expense, net

The following table summarizes our total other expense, net for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,		
	2025	2024	Change
Interest expense, net	$ (1,291)	$ (1,648)	$ 357
Adjustments to fair value of derivatives	(1,807)	(1,226)	(581)
Other expense, net	(60)	(77)	17
Total other expense, net	$ (3,158)	$ (2,951)	$ (207)

Interest Expense, Net

Interest expense, net decreased by $0.4 million primarily as a result of a decrease in interest accrued and amortization of debt costs related to the Exchangeable Notes, which were repaid in January 2025, partially offset by an increase in interest accrued on the Pfizer Promissory Note and a decrease in interest income on money market funds.

Adjustments to Fair Value of Derivatives

Adjustments to the fair value of the derivative liability were $1.8 million and $1.2 million for the nine months ended September 30, 2025 and 2024, respectively. This non-cash adjustment primarily related to an increase in the fair value of the RLNs due to the passage of time.

Other Expense, Net

Other expense, net consists of realized and unrealized foreign currency gains and losses incurred in the normal course of business based on movement in the applicable exchange rates.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We began commercial operations in August 2025 and have generated limited revenue to date from sales of ORLYNVAH™ and a funding arrangement with the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program and have funded our operations primarily through public offerings of ordinary shares and proceeds from private placements and registered direct offerings.

On October 7, 2022, we filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on October 17, 2022 (File No. 333-267795) (the 2022 Shelf Registration Statement), and pursuant to which we registered for sale up to $100.0 million of any combination of debt securities, ordinary shares, preferred shares, subscription rights, purchase contracts, units and/or warrants from time to time and at prices and on terms that we may determine. On October 7, 2022, we entered into the Sales Agreement, with HC Wainwright, as agent, pursuant to which we may offer and sell ordinary shares (subject to the availability of ordinary shares), from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. Also on October 7, 2022, we filed a prospectus with the SEC pursuant to which we could offer and sell ordinary shares having an aggregate offering price of up to $16.0 million pursuant to the Sales Agreement. On December 10, 2024, we filed a prospectus supplement (the 2024 Prospectus Supplement) with the SEC pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to an additional $25.0 million through HC Wainwright pursuant to the Sales Agreement.

On February 7, 2025, we filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on February 19, 2025 (File No. 333-284774) (the 2025 Shelf Registration Statement), and pursuant to which we registered for sale up to $150.0 million of any combination of debt securities, ordinary shares, preferred shares, subscription rights, purchase contracts, units and/or warrants from time to time and at prices and on terms that we may determine. On October 16, 2025. we filed a prospectus supplement (the 2025 Prospectus Supplement) with the SEC under the 2025 Shelf Registration Statement pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to $20.0 million through HC Wainwright pursuant to the Sales Agreement, which supersedes the 2024 Prospectus Supplement.

During the nine months ended September 30, 2025, we sold 11,875,589 ordinary shares under the Sales Agreement at an average net price of $1.07 per ordinary share for net proceeds of $12.7 million, after deducting commissions to HC Wainwright of $0.4 million. Subsequent to September 30, 2025, through November 13, 2025, we sold 3,795,819 ordinary shares under the Sales Agreement at an average net price of $0.69 per ordinary share for net proceeds of $2.7 million.

As of September 30, 2025, we had cash and cash equivalents of $11.0 million.

2025 Exchangeable Notes and Royalty-Linked Notes

On January 21, 2020, we completed the Private Placement pursuant to which our wholly owned subsidiary, Iterum Bermuda issued and sold $51.6 million aggregate principal amount of Exchangeable Notes and $0.1 million aggregate principal amount of RLNs to a group of accredited investors. On September 8, 2020, we completed the Rights Offering pursuant to which Iterum Bermuda issued and sold $0.2 million aggregate principal amount of Exchangeable Notes and $0.04 million aggregate principal amount of RLNs, to existing shareholders. The Exchangeable Notes and RLNs were sold in units (Units) with each Unit consisting of an Exchangeable Note in the original principal amount of $1,000 and 50 RLNs. The Units were sold at a price of $1,000 per Unit. At any time on or after January 21, 2021 through January 31, 2025, subject to specified limitations, the Exchangeable Notes were exchangeable for our ordinary shares, cash or a combination of ordinary shares and cash. The Exchangeable Notes matured on January 31, 2025. Beginning on January 21, 2021 through January 31, 2025, certain holders of $40.7 million aggregate principal amount of Exchangeable Notes completed a non-cash exchange of their notes, including accrued and unpaid interest of $3.1 million for an aggregate of 3,760,155 of our ordinary shares. On January 31, 2025, the Exchangeable Notes matured and Iterum Bermuda repaid in full to the holders thereof an aggregate principal amount of $11.1 million together with accrued interest of $3.6 million. The RLNs entitle holders to payments based on a percentage of our net revenues from potential U.S. sales of specified sulopenem products subject to the terms and conditions of the indenture governing the RLNs (the RLN Indenture). Pursuant to the RLN Indenture, the payments on the RLNs will be up to 15% of net revenues from U.S. sales of such products. The aggregate amount of payments on

each RLN is capped at $160.00 (or 4,000 times the principal amount of such RLN). Iterum Bermuda received net proceeds from the sale of the Units of $45.0 million, after deducting placement agent fees and offering expenses.

Pfizer Promissory Note

On November 18, 2015, the Company and ITIL entered into the Pfizer License. Under the Pfizer License, ITIL agreed to make certain regulatory and sales milestone payments, including a regulatory milestone payment of $20.0 million to Pfizer upon approval of oral sulopenem for commercial sale in the United States by the FDA. On October 25, 2024, the Company received FDA approval for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options.

On October 28, 2024, the Company notified Pfizer that it was electing to defer payment of the milestone payment for two years, or until October 25, 2026 (the Deferral Period), and delivered the Promissory Note issued by ITIL in the amount of the milestone payment to Pfizer, as permitted pursuant to the terms of the Pfizer License. The Promissory Note bears interest at an annual rate of eight percent (8.0%) on a daily compounded basis until the maturity date of October 25, 2026. ITIL has the right to prepay the unpaid principal balance of the Promissory Note together with accrued and unpaid interest at any time without premium or penalty. Pursuant to the terms of the Promissory Note, ITIL may (i) assign the Promissory Note to an affiliate of ITIL; (ii) designate one of its affiliates to perform its obligations thereunder; or (iii) assign the Promissory Note in the event of a change of control, provided that in the case of clauses (i) and (ii) ITIL is not relieved of any liability thereunder. Pursuant to the terms of the Pfizer License, if a change of control of ITIL or the Company occurs during the Deferral Period, Pfizer may, in its sole discretion and at its sole option, declare the milestone payment to be immediately due and payable together with all interest accrued under the Promissory Note. The Company has guaranteed all of the amounts payable by ITIL under the terms of the Pfizer License, including the amounts owed under the Promissory Note, pursuant to the guarantee entered into by and among ITIL, the Company and Pfizer on November 18, 2015 in connection with the Pfizer License.

On May 13, 2025, the Company and ITIL entered into an amended and restated promissory note with Pfizer (the A&R Note) and a letter agreement with Pfizer relating to the A&R Note and amending the Pfizer License Agreement in connection therewith (the Letter Agreement). The A&R Note extends the Deferral Period by an additional three years, or until October 25, 2029 (the Extended Deferral Period). In connection with the extension to the Deferral Period, ITIL agreed in the A&R Note to increase the annual rate of interest from eight percent (8%) to ten percent (10%) on a daily compounded basis during the Extended Deferral Period, beginning on October 26, 2026. The Company evaluated the A&R Note and the Letter Agreement under ASC 470 and determined that it should be accounted for as a debt modification as the cash flows under the amended terms do not differ by at least 10% from the cash flows under the original agreement. Accordingly, no gain or loss was recorded relating to the modification.

Registered Direct Offerings

June 3, 2020 Registered Direct Offering

On June 3, 2020, we entered into the securities purchase agreement (June 3, 2020 SPA) with certain institutional investors pursuant to which we issued and sold an aggregate of 198,118 ordinary shares, at a purchase price per ordinary share of $25.2375, for aggregate gross proceeds to us of $5.0 million and net proceeds of $4.3 million after deducting fees payable to the placement agent and other offering expenses payable by us (the June 3, 2020 Offering). We offered the ordinary shares in the June 3, 2020 Offering pursuant to our universal shelf registration statement on Form S-3, which was declared effective on July 16, 2019 (File No. 333-232569) (the 2019 Shelf Registration Statement). Pursuant to the June 3, 2020 SPA, in a concurrent private placement, we issued and sold to the certain purchasers warrants to purchase up to 99,057 ordinary shares. Upon closing, the warrants became exercisable immediately at an exercise price of $24.30 per ordinary share, subject to adjustment in certain circumstances, and will expire on December 5, 2025. The closing date of the June 3, 2020 Offering was June 5, 2020. Warrants to purchase 13,868 ordinary shares, amounting to 7% of the ordinary shares issued under the June 3, 2020 SPA, were issued to designees of the placement agent on the closing of the June 3, 2020 Offering. Upon closing, the warrants issued to such designees became exercisable immediately at an exercise price of $31.5465 per ordinary share, and expired on June 3, 2025.

June 30, 2020 Registered Direct Offering

On June 30, 2020, we entered into the securities purchase agreement (June 30, 2020 SPA) with certain institutional investors pursuant to which we issued and sold an aggregate of 224,845 ordinary shares, at a purchase price per ordinary share of $22.2375, for aggregate gross proceeds to us of $5.0 million and net proceeds of $4.2 million after deducting fees payable to the placement agent and other offering expenses payable by us (the June 30, 2020 Offering). We offered the ordinary shares in the June 30, 2020 Offering pursuant to the 2019 Shelf Registration Statement. Pursuant to the June 30, 2020 SPA, in a concurrent private placement, we issued and sold to certain purchasers warrants to purchase up to 112,422 ordinary shares. Upon closing, the warrants were exercisable immediately at an exercise price of $21.30 per ordinary share, subject to adjustment in certain circumstances, and will expire on January 2, 2026. The June 30, 2020 Offering closed on July 2, 2020. Warrants to purchase 15,739 ordinary shares, amounting to 7% of the ordinary shares issued under the June 30, 2020 SPA, were issued to designees of the placement agent on closing of the June 30, 2020 Offering. Upon closing, the warrants issued to such designees became exercisable immediately at an exercise price of $27.7965 per ordinary share, and expired on June 30, 2025.

February 2021 Registered Direct Offering

On February 9, 2021, we entered into the securities purchase agreement (February 2021 SPA) with certain institutional investors pursuant to which we issued and sold an aggregate of 1,166,666 ordinary shares, at a purchase price of $30.00 per ordinary share, for aggregate net proceeds to us of $32.2 million after deducting placement agent fees and other offering expenses payable by us (the February 2021 Registered Direct Offering). We offered the ordinary shares in the February 2021 Registered Direct Offering pursuant to the 2019 Shelf Registration Statement. The February 2021 Registered Direct Offering closed on February 12, 2021. Warrants to purchase 81,666 ordinary shares, amounting to 7.0% of the aggregate number of ordinary shares issued under the February 2021 SPA, were issued to designees of the placement agent on closing of the February 2021 Registered Direct Offering. Upon closing, warrants issued to such designees became exercisable immediately at an exercise price of $37.50 per ordinary share and will expire on February 9, 2026.

April 2025 Registered Direct Offering

On April 28, 2025, we entered into a securities purchase agreement (April 2025 SPA) with an institutional investor pursuant to which we issued and sold an aggregate of (i) 3,040,000 ordinary shares at a purchase price of $0.90 per ordinary share, and (ii) pre-funded warrants to purchase up to an aggregate of 2,515,556 ordinary shares at a price of $0.89 per pre-funded warrant, for aggregate net proceeds of approximately $4.2 million, after deducting placement agent fees and other offering expenses payable by us (the April 2025 Registered Direct Offering). We offered and sold the ordinary shares and pre-funded warrants in the April 2025 Registered Direct Offering pursuant to the 2022 Shelf Registration Statement. The April 2025 Registered Direct Offering closed on April 30, 2025. Upon closing, the pre-funded warrants issued under the April 2025 SPA became exercisable immediately at an exercise price of $0.01 per ordinary share, subject to adjustment in certain circumstances, and expire when exercised in full, subject to certain conditions. As of September 30, 2025, all pre-funded warrants had been exercised for net proceeds of $0.03 million.

October 2020 Offering

On October 27, 2020, we sold an aggregate of (i) 1,034,102 ordinary shares, $0.01 nominal value per ordinary share, (ii) pre-funded warrants exercisable for an aggregate of 760,769 ordinary shares and (iii) warrants exercisable for an aggregate of 1,346,153 ordinary shares (the October 2020 Offering). The pre-funded warrants were issued and sold to certain purchasers whose purchase of ordinary shares in the October 2020 Offering would have otherwise resulted in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding ordinary shares immediately following the consummation of the October 2020 Offering, if the purchaser so chose in lieu of ordinary shares that would have otherwise resulted in such excess ownership. The ordinary shares and pre-funded warrants were each offered together with the warrants, but the ordinary shares and pre-funded warrants were issued separately from the warrants. The combined offering price was $9.75 per ordinary share and warrant and $9.60 per pre-funded warrant and warrant. Our net proceeds from the October 2020 Offering, after deducting placement agent fees and other offering expenses payable by us, were approximately $15.5 million. The warrants are exercisable upon issuance at a price of $9.75 per ordinary share, subject to adjustment in certain circumstances, and expire on October 27, 2025. The pre-funded warrants are exercisable upon issuance at a price of $0.15 per ordinary share, subject to adjustment in certain circumstances, and expire when exercised in full, subject to certain conditions. All pre-funded warrants have been exercised for net proceeds of $0.11 million. In connection with the October 2020 Offering, we entered into a Purchase Agreement on October 22, 2020 with certain institutional investors. The Purchase Agreement contains customary representations and warranties of ours, termination rights of the parties, and certain indemnification obligations of ours. Warrants to purchase 125,641 ordinary shares, which represents a number of ordinary shares equal to 7.0% of the aggregate number of ordinary shares and pre-funded warrants sold in the October 2020 Offering, were issued to designees of the placement agent on closing of the October 2020 Offering. Upon closing, the warrants issued to such designees became exercisable immediately at an exercise price of $12.1875 per ordinary share and will expire on October 27, 2025.

February 2021 Underwritten Offering

On February 3, 2021, we entered into an underwriting agreement (the Underwriting Agreement) pursuant to which we issued and sold 2,318,840 ordinary shares, at a public offering price of $17.25 per ordinary share (the February 2021 Underwritten Offering). We offered the ordinary shares in the February 2021 Underwritten Offering pursuant to the 2019 Shelf Registration Statement. The February 2021 Underwritten Offering closed on February 8, 2021. Pursuant to the Underwriting Agreement, we granted the underwriter an option for a period of 30 days to purchase up to an additional 347,826 ordinary shares on the same terms and conditions, which the underwriter exercised in full on February 10, 2021. This increased the total number of ordinary shares we sold in the February 2021 Underwritten Offering to 2,666,666 shares, which resulted in aggregate net proceeds of $42.1 million after deducting underwriting discounts and commissions and offering expenses. In addition, pursuant to the Underwriting Agreement, we agreed to issue to the underwriter's designees warrants to purchase 186,665 ordinary shares, which is equal to 7.0% of the aggregate number of ordinary shares sold in the February 2021 Underwritten Offering, including the underwriter's option to purchase an additional 347,826 ordinary shares. The warrants issued to such designees of the underwriter have an exercise price of $21.5625 per ordinary share, were exercisable upon issuance and will expire on February 3, 2026.

2024 Rights Offering

On August 9, 2024, we sold an aggregate of 6,121,965 units (2024 Units) at a subscription price of $1.21 per whole 2024 Unit, consisting of (a) one ordinary share, (b) a warrant to purchase 0.50 ordinary shares, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration one year from the date of issuance (1-year warrants) and (c) a warrant to purchase one ordinary share, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration

five years from the date of issuance (the 5-year warrants and, together with the 1-year warrants, the warrants) (the 2024 Rights Offering). Our net proceeds from the 2024 Rights Offering, after deducting dealer-manager fees and other offering expenses payable by us, were approximately $5.4 million. The warrants are exercisable upon issuance at a price of $1.21 per ordinary share and the 1-year warrants expired on August 9, 2025 and the 5-year warrants will expire on August 9, 2029.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	(15,258)	(22,514)
Net cash (used in) / provided by investing activities	(14)	17,108
Net cash provided by financing activities	2,164	12,814
Effect of exchange rates on cash and cash equivalents	(20)	(73)
Net (decrease) / increase in cash, cash equivalents and restricted cash	$ (13,128)	$ 7,335

Operating Activities

During the nine months ended September 30, 2025, operating activities used $15.3 million of cash, resulting from our net loss of $20.4 million and net cash used by changes in our operating assets and liabilities of $1.4 million consisting primarily of an increase in accounts receivable, prepaid expenses and other current assets and inventory, partially offset by net non-cash charges of $6.5 million.

During the nine months ended September 30, 2024, operating activities used $22.5 million of cash, resulting from our net loss of $18.2 million and net cash used by changes in our operating assets and liabilities of $11.3 million consisting primarily of a decrease in accounts payable and accrued expenses, partially offset by net non-cash charges of $7.0 million.

Investing Activities

During the nine months ended September 30, 2025, a nominal amount of net cash was used by investing activities to purchase computer equipment.

During the nine months ended September 30, 2024, net cash provided by investing activities of $17.1 million was related to the proceeds from the sale of short-term investments of $29.5 million, partially offset by the purchase of short-term investments of $12.4 million.

Financing Activities

During the nine months ended September 30, 2025, net cash provided by financing activities of $2.2 million was primarily related to net proceeds from the sale of ordinary shares pursuant to the Sales Agreement with HC Wainwright of $12.7 million and net proceeds from the April 2025 Registered Direct Offering of $4.2 million, partially offset by the repayment of $14.7 million to the holders of Exchangeable Notes including accrued interest, which matured on January 31, 2025.

During the nine months ended September 30, 2024, net cash provided by financing activities of $12.8 million was primarily related to net proceeds from the sale of ordinary shares pursuant to the Sales Agreement of $7.4 million and net proceeds from the sale of ordinary shares in the 2024 Rights Offering of $5.4 million.

Funding Requirements

As of September 30, 2025, we had cash and cash equivalents of $11.0 million. Our expected cash usage for the next 12 months assumes that planned programs and expenditure continue and that we do not reduce or eliminate some or all of our commercialization efforts or research and development programs. Our future viability is dependent on our ability to obtain additional capital to finance our operations and support our business objectives, including the revenue growth rate of ORLYNVAH™.

We do not believe that our existing cash and cash equivalents will enable us to fund our operating expenses for the next 12 months from the date of this Quarterly Report on Form 10-Q. As such, we believe this condition raises substantial doubt about our ability to continue as a going concern for at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies. Additionally, the United States is experiencing a workforce shortage, which in turn has created a competitive wage environment that may also increase our operating costs in the future.

Our expenses will also increase substantially if and as we:

•initiate other studies as part of our sulopenem program, some of which may be required for regulatory approval of our product candidates;

•continue to build sales, marketing and distribution capabilities either directly or through a third-party, to commercialize ORLYNVAH™ in the United States;

•establish sales, marketing and distribution capabilities either directly or through a third-party, to commercialize oral sulopenem in additional indications, and/or future product candidates in the United States, if we obtain marketing approval from the FDA;

•establish manufacturing and supply chain capacity sufficient to provide commercial quantities of ORLYNVAH™ in additional indications, and/or future product candidates, if we obtain marketing approval, and undertake commercialization activities;

•pursue the development of our sulopenem program in additional indications;

•maintain, expand, defend and protect our intellectual property portfolio;

•hire additional clinical, scientific and commercial personnel;

•add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and

•acquire or in-license other product candidates or technologies.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

•the costs of commercialization activities for ORLYNVAH™ and any other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

•the revenue received from any potential commercial sales of ORLYNVAH™;

•the receipt of marketing approval and revenue received from any potential commercial sales of ORLYNVAH™ or future product candidates;

•the terms and timing of any future collaborations, licensing or other arrangements that we may establish;

•the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to the Pfizer License or other future license agreements;

•the amount and timing of any payments we may be required to make in connection with the RLNs;

•the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property related claims;

•the timing and costs of our clinical trials of our product candidates, including any clinical trials or non-clinical studies which may be required for regulatory approval of our product candidates;

•the timing of regulatory filings, review and potential approval of any product candidates;

•the initiation, progress, timing, costs and results of preclinical studies and clinical trials of other potential product candidates and of our current product and product candidates in additional indications;

•the amount of funding that we receive under government awards that we may apply for in the future;

•the number and characteristics of product candidates that we pursue;

•the outcome, timing and costs of seeking regulatory approvals;

•the costs of operating as a public company;

•the extent to which we in-license or acquire other products and technologies;

•the impact of general economic conditions, including inflation and tariffs; and

•the outcome, impacts, effects and results of any potential corporate, strategic, financial and financing transaction, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing transaction and our ability to complete one at all.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements, marketing and distribution arrangements or government funding. The disruption and volatility in the global and domestic capital markets resulting from heightened inflation, capital market volatility, interest rate and currency rate fluctuations, artificial intelligence, regulatory changes under the new Trump Administration, any potential economic slowdown or recession, including trade wars or civil or political unrest (such as the ongoing war between Ukraine and Russia, conflict in the Middle East, and tension between China and Taiwan) may increase the cost of capital and limit our ability to access capital.

This past spring, the U.S. government initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, President Trump issued an executive order announcing, a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the Trump administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement (USMCA), and tariffs equally 20% on China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the Trump administration delayed the effective date of such tariffs for all countries except China to August 1, 2025. Later, the U.S. and China reached a framework agreement that ultimately resulted in the suspension of the higher reciprocal tariffs on China until November 11, 2025. Since the April announcement, several countries including the European Union, Japan, South Korea and the United Kingdom, among others, have reached deals with the U.S. that include reduced tariff rates to varying levels and other measures. On July 31, 2025, President Trump issued an Executive Order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The new reciprocal rates, which are consistent with the rates reflected in the trade deals already announced, range from 10% to 41% with imports from Switzerland receiving a 39% rate. The new rates do not apply to Canada, China, Mexico and a few other countries. For China, the 10% baseline reciprocal tariff announced in April remains in effect, in addition to a minimum of an additional 20%., Regarding Canada and Mexico, the rate remains 25% for goods that are not covered by the USMCA for Mexico and, effective August 1, 2025, was increased to 35% on imports from Canada that are not covered by the USMCA. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CMOs and other service providers that operate in China. Certain countries have reached agreements with the U.S. that cap pharmaceutical tariffs at 15%. These include the European Union, Japan, South Korea and the United Kingdom

Separately, in April 2025, the U.S. Department of Commerce (Commerce Department) initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. At the same time, Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, Trump delayed the October 1st effective date of the tariffs on branded or patented pharmaceutical products announcing that the Administration had now "begun preparing" tariffs on manufacturers that don't build in the U.S. or enter into a most-favored-nation (MFN) drug pricing agreement with the Trump administration.

The extent and duration of increased tariffs and the resulting impact on general economic conditions and on our business are uncertain. The potential outcomes depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, availability and cost of alternative sources of supply, future demand for our product candidates in affected markets, and actions taken in response to the Commerce Department's investigatory report. We continue to monitor these developments closely and are actively considering contingency plans, including alternative sourcing strategies to support our ongoing product development and help mitigate potential future impacts.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our ordinary shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. The RLNs and the investor rights agreement we entered into in connection with the Private Placement each impose operating and other restrictions on us. Such restrictions may affect, and in many cases limit or prohibit, our ability to dispose of certain assets, pay dividends and incur additional indebtedness, among other things. In addition, in the A&R Note and the Letter Agreement we agreed not to, either directly or indirectly, (1) create, incur, assume, guaranty or otherwise become liable for any indebtedness that is senior in right of payment to the A&R Note, except for indebtedness incurred with the consent or waiver of Pfizer, or (2) create, grant or incur any lien on any of our property or assets, subject to specified exceptions (including liens securing permitted indebtedness and liens incurred with the consent or waiver of Pfizer).

If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. In addition, as described above, we are evaluating our corporate, strategic, financial and financing alternatives, with the goal of maximizing value for our shareholders while prudently managing our resources.

Contractual Obligations and Commitments

Under the Pfizer License, we have agreed to make certain regulatory and sales milestone payments. We are obligated to make a potential one-time payment related to sublicensing income that exceeds a certain threshold. We are also obligated to pay Pfizer sales milestones upon achievement of net sales ranging from $250.0 million to $1.0 billion for each product type, as well as royalties ranging from a single-digit to mid-teens percentage based on marginal net sales of each licensed product.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development, manufacturing and commercial activities. Expenditures to CROs, CMOs and other service providers represent significant costs in research and development and commercial activities. Subject to required notice periods and our obligations under binding purchase orders and any cancellation fees that we may be obligated to pay, we can elect to discontinue the work under these agreements at any time. In addition to the EVERSANA Agreement entered into with EVERSANA and the ACS Agreement we entered into with ACS Dobfar, we have and may also enter into additional collaborative research and development, contract research, commercialization, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Under the RLN Indenture, holders of RLNs are entitled to payments based solely on a percentage of our net revenues from U.S. sales of specified sulopenem products (Specified Net Revenues). Payments will be due within 75 days of the end of each six-month payment measuring period (Payment Measuring Period), beginning with the Payment Measuring Period ending June 30, 2020 until (i) the “Maximum Return” (as described below) has been paid in respect of the RLNs, or (ii) the “End Date” occurs, which is December 31, 2045. However, holders of RLNs will only be entitled to payments where the Company earns net revenues on such approved sulopenem product. The aggregate amount of payments in respect of all RLNs during each Payment Measuring Period will be equal to the product of total Specified Net Revenues earned during such period and the applicable payment rate (the Payment Rate), being 15%. There was no payment due for each of the Payment Measuring Periods through the payment measuring period ending June 30, 2025. Payment will be due for the payment measuring period ending December 31, 2025, following the commercial launch of ORLYNVAH™ in August 2025. Prior to the End Date, we are obligated to make payments on the RLNs from Specified Net Revenues until each RLN has received payments equal to $160.00 (or 4,000 times the principal amount of such RLN) (Maximum Return).

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of September 30, 2025, we had cash and cash equivalents of $11.0 million, consisting of cash and money market funds. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk.

We contract with CROs and CMOs globally. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of September 30, 2025 and December 31, 2024, substantially all of our liabilities were denominated in U.S. dollars. Realized net foreign currency gains and losses did not have a material effect on our results of operations for the nine months ended September 30, 2025 and 2024 or for the year ended December 31, 2024. We do not currently engage in any hedging activities against our foreign currency exchange rate risk.

Inflation generally affects us by increasing our cost of labor and research, manufacturing and development costs. We believe that inflation has not had a material effect on our financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, our operations may be adversely affected by inflation in the future.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

In August 2025, we commercially launched ORLYNVAH™ and in conjunction with beginning product sales we began recording product revenue and cost of goods sold. We enhanced our internal control over financial reporting by adding new processes and controls in these areas. We did not identify any material adverse impacts on our internal control over financial reporting as a result of the implementation of these new processes and controls.

There have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time and in the ordinary course of business, the Company has been subject to various claims, charges, and litigation. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the Securities and Exchange Commission (SEC) in evaluating our company and our business. Investing in our ordinary shares involves a high degree of risk. If any of the events described in the following Risk Factors and the risks described elsewhere in this Quarterly Report on Form 10-Q actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our ordinary shares could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Requirements

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We may be forced to delay or reduce the scope of our development programs, commercialization activities and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. As of September 30, 2025, we had $11.0 million of cash and cash equivalents. Subsequent to September 30, 2025, we have sold additional ordinary shares under the "at the market offering" agreement (the Sales Agreement), entered into on October 7, 2022, with H.C. Wainwright & Co. LLC (HC Wainwright), as agent, pursuant to which we may offer and sell our ordinary shares for aggregate gross proceeds of up to $20 million, subject to having sufficient authorized but unissued ordinary shares available for issuance, from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the Securities Act). Based on our available cash resources we do not believe that our existing cash and cash equivalents, including amounts raised under the Sales Agreement with HC Wainwright, will enable us to fund our operating expenses for the next 12 months from the date of filing this Quarterly Report on Form 10-Q.

This condition raises substantial doubt about our ability to continue as a going concern within one year after the date the financial statements included elsewhere in this Quarterly Report on Form 10-Q are issued. Management's plans in this regard are described in Note 1 to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, although Management intends to pursue plans to obtain additional funding to finance its operations, and the Company has successfully raised capital in the past, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

We currently have limited authorized share capital and authority to issue additional ordinary shares to raise capital.

We will need substantial additional funding to continue fund our operations, including the ongoing commercialization of ORLYNVAH™, which we may attempt to raise through public or private equity offerings, debt financings, and collaborative and licensing arrangements. We currently have limited ordinary shares available and authorized for issuance. Investors in prior transactions have purchased convertible notes and warrants convertible into our ordinary shares, for which we must reserve authorized but unissued ordinary shares. We therefore will likely need to increase the number of authorized ordinary shares and obtain the related shareholder authorization to allot and issue such additional ordinary shares and to disapply Irish statutory pre-emption rights on such an issuance, which requires shareholder approval. We will need to seek such shareholder approval in order to issue ordinary shares or securities convertible, exercisable or exchangeable into ordinary shares in an equity financing, to utilize the full amount available for issuance under the Sales Agreement or in other capital raising transactions.

If we are unable to increase our authorized shares available for issuance, we will be limited in our efforts to raise the additional capital needed to continue to fund our ongoing operations, including the commercialization of ORLYNVAH™ in the United States. This may have a negative effect on our financial condition and our ability to develop our sulopenem program and continue to commercialize ORLYNVAH™ and otherwise pursue our business strategy and we may be unable to continue as a going concern.

We have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses unless the continued commercialization of* ORLYNVAH™ *is successful.

We have a limited operating history and have incurred net losses in each year since our inception in 2015. As of September 30, 2025, we had an accumulated deficit of $506.5 million cash and cash equivalents of $11.0 million. On October 25, 2024, we received

approval of our New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections (uUTIs) caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options. ORLYNVAH™ was commercially launched in the United States in August 2025 and we expect modest sales in 2025 during the early stages of our commercialization efforts.

We have financed our operations to date primarily with the issuance of ordinary shares, nominal value $0.01 per ordinary share (the ordinary shares), and convertible preferred shares, pre-funded warrants and warrants, debt raised under a financing arrangement with Silicon Valley Bank (SVB), a sub-award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program and the proceeds of a private placement which closed in January 2020 (the Private Placement) and a subsequent rights offering (the 2020 Rights Offering) pursuant to which our wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda), sold units (Units) consisting of (i) 6.500% Exchangeable Senior Subordinated Notes due 2025 (Exchangeable Notes); and (ii) Limited Recourse Royalty-Linked Subordinated Notes (RLNs), to certain existing and new investors. In April 2018, we entered into a secured credit facility with SVB and made an initial drawdown of $15.0 million pursuant to a loan and security agreement. In April 2020, we entered into a note (PPP loan) with SVB of $0.7 million under the Paycheck Protection Program. In early June 2020, we issued and sold, in a registered direct offering (June 3, 2020 Offering), ordinary shares for aggregate gross proceeds to us of $5.0 million and net proceeds of $4.3 million after deducting fees payable to the placement agent and other offering expenses payable by us. In late June 2020, we issued and sold, in a registered direct offering (June 30, 2020 Offering), ordinary shares for aggregate gross proceeds to us of $5.0 million and net proceeds of $4.2 million after deducting fees payable to the placement agent and other offering expenses payable by us. In October 2020, we issued and sold, in a registered public offering (October 2020 Offering), ordinary shares and pre-funded warrants exercisable for ordinary shares, each offered together with warrants exercisable for ordinary shares, for aggregate gross proceeds to us of $17.4 million and net proceeds of $15.5 million after deducting fees payable to the placement agent and other offering expenses payable by us. On February 8 and February 10, 2021, we issued and sold, pursuant to an underwritten agreement and including the underwriter's exercise in full of its option to purchase additional ordinary shares (February 2021 Underwritten Offering), ordinary shares for aggregate gross proceeds to us of $46.0 million and net proceeds of $42.1 million after deducting fees payable to the underwriter and other offering expenses payable by us. On February 12, 2021, we issued and sold, in a registered public offering (February 2021 Registered Direct Offering), ordinary shares for aggregate gross proceeds to us of $35.0 million and net proceeds of $32.2 million after deducting fees payable to the placement agent and other offering expenses payable by us. On October 7, 2022, we entered into the Sales Agreement with HC Wainwright, as agent, pursuant to which we may offer and sell ordinary shares from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. On October 16, 2025 we filed a prospectus supplement with the SEC pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to an additional $20 million, subject to having sufficient authorized but unissued ordinary shares available for issuance, through HC Wainwright pursuant to the Sales Agreement. In August 2024, we completed a rights offering (the 2024 Rights Offering) in which we sold an aggregate of 12,243,930 non-transferable subscription rights to purchase an aggregate of 6,121,965 units (2024 Units) at a subscription price of $1.21 per whole 2024 Unit, consisting of (a) one ordinary share, (b) a warrant to purchase 0.50 ordinary shares, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration one year from the date of issuance and (c) a warrant to purchase one ordinary share, at an exercise price of $1.21 per whole ordinary share from the date of issuance through its expiration five years from the date of issuance. The net proceeds from the 2024 Rights Offering, after deducting dealer-manager fees and other offering expenses payable by us, were $5.4 million. On April 30, 2025, we issued and sold, in the April 2025 Registered Direct Offering, ordinary shares and pre-funded warrants for aggregate net proceeds to us of $4.2 million after deducting placement agent fees and other offering expenses payable by us. During the quarter ended September 30, 2025, we sold 862,995 ordinary shares under the Sales Agreement at an average net price of $1.07 per ordinary share for net proceeds of $925,617.75. As of September 30, 2025, net proceeds of $18.0 million have been received from the exercise of certain warrants issued as part of the June 30, 2020 Offering, October 2020 Offering, February 2021 Underwritten Offering and the 2024 Rights Offering. Up until the first quarter of 2025, we devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical development, for our sulopenem program. Since the first quarter of 2025, we have devoted the majority of our financial resources and efforts to pre-commercialization activities and commercialization activities in preparation for the upcoming commercial launch of ORLYNVAH™ in the United States. On January 31, 2025, our Exchangeable Notes matured and the aggregate outstanding principal amount of $11.1 million together with accrued and unpaid interest became due. We repaid the aggregate principal and accrued and unpaid interest to holders of the Exchangeable Notes in full on January 31, 2025.

Following receipt of FDA approval for ORLYNVAH™ in October 2024, we initially focused our efforts on a strategic process to sell, license, or otherwise dispose of our rights to sulopenem. This strategic process did not result in any type of transaction acceptable to our board of directors. While we continue to engage in business development discussions with other companies regarding the potential sale, licensing, or disposal by other means of our rights to sulopenem, we are now mainly focused on the commercialization of ORLYNVAH™ in the United States, with our commercialization partner, EVERSANA Life Science Services, LLC (EVERSANA), and other third-parties, and we expect to continue to incur significant expenses and increased operating losses as we incur significant expenses related to the commercialization of ORLYNVAH™ in the United States, seek marketing approval for other product candidates, if clinical trials are successful, and engage and pursue the development of our sulopenem program in

additional indications, including through preclinical and clinical development. Our expenses will also continue to increase substantially as we:

- establish and further develop sales, marketing and distribution capabilities through EVERSANA and/or other third-parties, to support the ongoing commercialization of ORLYNVAH™ in the United States;
- establish sales, marketing and distribution capabilities either directly or through a third-party, to commercialize oral sulopenem in additional indications and/or any future product candidates in the United States, if we obtain marketing approval from the FDA;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of ORLYNVAH™ and undertake commercialization activities;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of oral sulopenem in additional indications and/or any future product candidates, if we obtain marketing approval, and undertake commercialization activities;
- pursue the development of our sulopenem program in additional indications;
- maintain, expand, defend and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- acquire or in-license other product candidates or technologies; and
- initiate other studies as part of our sulopenem program, some of which may be required for regulatory approval of our product candidates.

We will require additional capital to fund our operations and support us through the commercial launch of ORLYNVAH™ and the ongoing clinical development related to our sulopenem program. If we fail to obtain financing when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing and commercializing pharmaceutical products, including conducting clinical trials and preparing for and executing a commercial launch, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect that additional capital will be required as we incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution of ORLYNVAH™ and continue our ongoing development of the sulopenem program. Furthermore, we continue and will continue to incur significant costs associated with operating as a public company.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Although we have successfully raised capital in the past, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to develop and commercialize our sulopenem program and otherwise pursue our business strategy. If we fail to obtain financing when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization of ORLYNVAH™ in the United States, which would have a negative effect on our financial condition and our ability to develop our sulopenem program and continue to commercialize ORLYNVAH™ and otherwise pursue our business strategy and we may be unable to continue as a going concern.

Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the costs of commercialization activities for ORLYNVAH™ including the costs and timing of establishing and expanding product sales, marketing, distribution and manufacturing capabilities;
- the costs of commercialization activities for sulopenem and other product candidates, if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the receipt of revenue received from any commercial sales of ORLYNVAH™;
- the receipt of revenue received from any commercial sales of sulopenem and other product candidates, if we receive marketing approval;
- the receipt of marketing approval and revenue received from any potential commercial sales of sulopenem;

•the terms and timing of any future collaborations, licensing or other arrangements that we may establish;

•the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to an exclusive license agreement with Pfizer Inc. (the Pfizer License) or other future license agreements;

•the amount and timing of any payments we may be required to make in connection with the RLNs;

•the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property related claims;

•the timing and costs of our clinical trials of our product candidates, including any clinical trials or non-clinical studies which may be required for regulatory approval of our product candidates;

•the timing of regulatory filings;

•the timing of regulatory review and potential approval of any product candidates;

•the initiation, progress, timing, costs and results of preclinical studies and clinical trials of other potential product candidates and of our current product candidates in additional indications;

•the amount of funding that we receive under government awards that we may apply for in the future;

•the number and characteristics of product candidates that we pursue;

•the outcome, timing and costs of seeking regulatory approvals;

•the costs of operating as a public company;

•the extent to which we in-license or acquire other products and technologies; and

•the outcome, impact, effects and results of our evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative and our ability to complete one at all.

Our financial statements include substantial non-operating gains or losses resulting from required quarterly revaluation under generally accepted accounting principles of our outstanding derivative instruments.

Generally accepted accounting principles in the United States require that we report the value of certain derivatives in instruments we have issued as liabilities on our balance sheet and changes in the value of these derivatives as non-operating gains or losses on our statement of operations. The value of the derivatives is required to be recalculated (and resulting non-operating gains or losses reflected in our statement of operations and resulting adjustments to the associated liability amounts reflected on our balance sheet) on a quarterly basis. The valuations are based upon a number of factors and estimates, including estimates based upon management's judgment. Due to the nature of the required calculations, changes in management's assumptions may result in significant changes in the value of the derivatives and resulting gains and losses on our statement of operations.

We are heavily dependent on the success of our sulopenem program, our ability to successfully commercialize ORLYNVAH™ and our ability to develop, obtain additional marketing approvals for and successfully commercialize oral sulopenem and IV sulopenem. If we are unable to achieve and sustain profitability, the market value of our ordinary shares will likely decline.

Our ability to become and remain profitable depends on our ability to generate revenue. To date, we have invested substantially all of our efforts and financial resources in the development of ORLYNVAH™ and sulopenem. Our prospects, including our ability to finance our operations and generate revenue from product sales, currently depend entirely on the development and commercialization of ORLYNVAH™. Following receipt of FDA approval for ORLYNVAH™ in October 2024, we initially focused our efforts on a strategic process to sell, license, or otherwise dispose of our rights to sulopenem and this strategic process did not result in any type of transaction acceptable to our board of directors. While we continue to engage in business development discussions with other companies regarding the potential sale, licensing, or disposition by other means of our rights to sulopenem, we are now focusing the majority of our efforts and resources on the commercialization of ORLYNVAH™ in the United States with our commercialization partner, EVERSANA, which we launched in August 2025 to ensure ORLYNVAH™ was brought to the United States market as soon as possible to serve patients with limited or no treatment options. Outside of the United States, we continue to evaluate the options to maximize the value of our sulopenem program.

Our ability to generate future revenue from product sales will require us to be successful in a range of challenging clinical and commercial activities, including:

•establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate commercial quantities of ORLYNVAH™, and that can support clinical development and provide adequate commercial quantities of sulopenem, if approved;

•establishing and expanding sales, marketing and distribution capabilities either directly or through a third-party, such as EVERSANA, to continue the commercialization of ORLYNVAH™ in the United States and/or entering into collaboration arrangements for the commercial launch of ORLYNVAH™ in other jurisdictions and/or to commercialize sulopenem in jurisdictions where we choose not to commercialize directly ourselves;

•obtaining market acceptance of ORLYNVAH™, and sulopenem, if approved, as viable treatment options;

•enrolling and successfully completing any clinical trials that may be required for regulatory approval of additional product candidates;

•applying for and obtaining marketing approval for IV sulopenem and/or oral sulopenem in additional indications; and

•protecting and maintaining our rights to our intellectual property portfolio related to our sulopenem program.

Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. Our expenses could increase if we are required by the FDA, the European Medicines Agency (EMA), or any comparable foreign regulatory authority, to perform different studies or studies in addition to those currently expected or if there are any delays in completing such studies or with the development of our sulopenem program or any future product candidates. We anticipate that significant costs will be associated with the ongoing commercialization of ORLYNVAH™ and/or the commercial launch of oral sulopenem in additional indications, if approved for commercial sale. Where we enter into collaboration arrangements with third-party collaborators for commercialization of ORLYNVAH™ or other product candidates, our product revenues or the profitability of these product revenues to us would likely be lower than if we were to directly market and sell products in those markets.

Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

Our indebtedness imposes certain operating and other restrictions on us and could adversely affect our ability to raise additional capital.

In the amended and restated promissory note (A&R Note) entered into between us, our subsidiary, Iterum Therapeutics International Limited, and Pfizer Inc. (Pfizer) and the letter agreement relating to the A&R Note, amending the Pfizer License Agreement in connection therewith (the Letter Agreement) we agreed not to, either directly or indirectly, (1) create, incur, assume, guaranty or otherwise become liable for any indebtedness that is senior in right of payment to the A&R Note, except for indebtedness incurred with the consent or waiver of Pfizer, or (2) create, grant or incur any lien on any of its property or assets, subject to specified exceptions (including liens securing permitted indebtedness and liens incurred with the consent or waiver of Pfizer).

The indenture governing the RLNs (the RLN Indenture) contains affirmative and negative covenants which impose operating and other restrictions on us, including, among other things, transferring any material assets. Moreover, obtaining a consent to a waiver of these terms is subject to a veto right of 30% of the outstanding RLNs, under the RLN Indenture, and must include Sarissa Capital Offshore Master Fund LP, Sarissa Capital Catapult Fund LLC and Sarissa Capital Hawkeye Fund LP (collectively with their affiliates, Sarissa) so long as Sarissa and its affiliates own at least 10% of the outstanding RLNs. This veto right could make it more difficult for us to obtain a waiver than would otherwise be the case.

In addition, the exercise price and the number of shares issuable under our outstanding warrants are subject to adjustment pursuant to the terms of the applicable warrant. This indebtedness could make it more difficult for us to raise additional capital to fund our operations.

We may incur substantially more debt or take other actions that would intensify the risks discussed above.

We and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our current and future debt instruments, some of which may be secured debt.

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

Unless and until we can generate a substantial amount of revenue from our sulopenem program or future product candidates, we expect to finance our future cash needs through equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements, marketing and distribution arrangements or government funding.

We may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

On February 7, 2025 we filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on February 19, 2025 (File No. 333-284774) (the 2025 Shelf Registration Statement), pursuant to which we registered for sale up to $150.0 million of any combination of debt securities, ordinary shares, preferred shares, subscription rights, purchase contracts, units and/or warrants from time to time and at prices and on terms that we may determine. The extent to which we are able to utilize a shelf registration statement as a source of funding will depend on a number of factors, including the prevailing market price of our ordinary shares, general market conditions and applicability, or not, of restrictions on our ability to utilize the shelf registration statement to sell more than one-third of the market value of our public float, meaning the aggregate market value of voting and non-voting ordinary shares held by non-affiliates, in any trailing 12-month period.

On October 7, 2022, we entered into the Sales Agreement with HC Wainwright, as agent, pursuant to which we may offer and sell ordinary shares for aggregate gross sales proceeds of up to $16.0 million (subject to the availability of ordinary shares), from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. On December 10, 2024, we filed a prospectus supplement to the 2022 Shelf Registration Statement (the 2024 Prospectus Supplement) with the SEC pursuant to which we could offer and sell ordinary shares having an aggregate offering price of up to an additional $25.0 million through HC Wainwright pursuant to the Sales Agreement. Further, on October 16, 2025, we filed a prospectus supplement to the 2025 Shelf Registration Statement (the 2025 Prospectus Supplement) with the SEC pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to $20.0 million, subject to having sufficient authorized but unissued ordinary shares available for issuance, through HC Wainwright pursuant to the Sales Agreement. The 2025 Prospectus Supplement superseded the 2024 Prospectus Supplement relating to the offer and sale of our ordinary shares in accordance with the Sales Agreement.

Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our ordinary shares to decline, and our shareholders may not agree with our financing plans or the terms of such financings. To the extent that we raise additional capital through the sale of ordinary shares, convertible securities or other equity securities, the ownership interests of our then existing shareholders may be materially diluted, and the terms of these securities could include liquidation or other preferences and antidilution protections that could adversely affect the rights of our then existing shareholders. Further debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely affect our ability to conduct our business. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

While we received approval for ORLYNVAH™ for the treatment of uUTIs caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options, due to a variety of factors, including those described in this "Risk Factors" section, we may nonetheless be delayed in obtaining or ultimately be unable to obtain FDA approval for oral sulopenem in additional indications or for any other product or to successfully commercialize ORLYNVAH™.

Because we have limited financial resources, we initially focused our sulopenem development program on the specific indications of uUTI, complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI), all of which are focused on what we believe to be the most pressing near-term medical needs, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other potential product candidates or developing our sulopenem program in other indications that may prove to have greater commercial potential. For example, while we believe that sulopenem has the potential to treat cIAIs and cUTIs in humans based on the results of prior preclinical studies and clinical trials, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy in our Phase 3 cIAI and cUTI clinical trials. While we believe the secondary supporting analyses and safety data in all three prior Phase 3 clinical trials support the potential of sulopenem in the treatment of multi-drug resistant infections, we cannot guarantee that these supporting analyses are indicative of efficacy of sulopenem in treating cIAIs or cUTIs.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other

royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We have broad discretion in the use of our funds and may not use them effectively.

We have broad discretion in the application of our available funds and could spend the funds in ways that do not improve our results of operations or enhance the value of our ordinary shares. Our failure to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ordinary shares to decline and delay the development of our product candidates. Pending their use, we may invest funds in a manner that does not produce income or that loses value.

We hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions. The balance held in these accounts typically exceeds the Federal Deposit Insurance Corporation (FDIC), standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

For example, on March 10, 2023, SVB and Signature Bank were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

We also maintain investment accounts with other financial institutions in which we hold our investments and, if access to the funds we use for working capital and operating expenses is impaired, we may not be able to open new operating accounts or to sell investments or transfer funds from our investment accounts to new operating accounts on a timely basis sufficient to meet our operating expense obligations.

Changes in and uncertainty surrounding trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.

Changes in and uncertainty surrounding U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners, including potentially Europe, where we are in the process of negotiating an agreement with a third-party contract manufacturer for the commercial production of ORLYNVAH™. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization

Following the commercial launch of ORLYNVAH™ in the United States in August 2025, we are heavily dependent on the success of the commercialization of ORLYNVAH™ in the U.S. Any failure of such ongoing commercialization of ORLYNVAH™ or significant delays in doing so, will materially harm our business.

We have invested a significant portion of our efforts and financial resources in the development of ORLYNVAH™. Following receipt of FDA approval for ORLYNVAH™ in October 2024, we initially prioritized our efforts to achieve a strategic transaction, which did not result in any type of transaction acceptable to our board of directors. We are now mainly focused on the ongoing commercialization of ORLYNVAH™ in the U.S., with our commercialization partner, EVERSANA, and other third-parties. There remains a risk that such commercialization of ORLYNVAH™ in the U.S. is not successful. Outside of the United States, we continue to evaluate the options to maximize the value of our sulopenem program.

Our ability to generate meaningful product revenues depends heavily on the success of the commercialization of ORLYNVAH™ and our obtaining marketing approval for oral sulopenem in additional indications and other product candidates. The success of ORLYNVAH™ and any other approved products, will depend on a number of factors, including the following:

•establishing and maintaining arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;

•receiving marketing approval from the FDA and/or other comparable foreign regulatory authority for IV sulopenem, oral sulopenem in additional indications and/or other product candidates;

•maintaining an effective sales and marketing organization to successfully generate recurring sales of ORLYNVAH™;

•receiving acceptance of ORLYNVAH™ by patients, the medical community and third-party payors, including hospital formularies;

•achieving approval of favorable prescribing information;

•effectively competing with other therapies;

•maintaining a continued acceptable safety profile of ORLYNVAH™;

•securing contracts to allow ORLYNVAH™ to be paid for by private and public health insurance plans;

•obtaining and maintaining patent and trade secret protection and regulatory exclusivity;

•protecting our rights in our intellectual property portfolio; and

•obtaining and maintaining adequate distribution levels of ORLYNVAH™ at all appropriate trade channels.

Successful development of ORLYNVAH™ and sulopenem for the treatment of additional indications, if any, or for use in other patient populations and our ability to broaden the label for ORLYNVAH™ will depend on similar factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize ORLYNVAH™ for uUTI or for any other indication, which would materially harm our business.

We obtained regulatory approval from the FDA for ORLYNVAH™, but have not yet demonstrated an ability to successfully conduct commercial activities.

We received FDA approval for ORLYNVAH™ for the treatment of uUTIs in adult women caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options on October 25, 2024. Prior to obtaining this approval, our operations were limited to financing and staffing our company, conducting preclinical research and clinical trials of our product candidates, pursuing a strategic transaction to sell, license or dispose of our rights to sulopenem, and more recently, preparing for the commercial launch of ORLYNVAH™. We have not received regulatory approval or commercialized any other product candidates to date and may never do so. While we commercially launched ORLYNVAH™ in the United States in August 2025, we are at a very early stage of our commercialization efforts. Accordingly, our shareholders should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to continue to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year.

Even though ORLYNVAH™ has obtained regulatory approval and we may obtain regulatory approval for other product candidates, they may never achieve the market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community that is necessary for commercial success, and the market opportunity may be smaller than we estimate.

Even though we have obtained FDA approval for ORLYNVAH™ and may obtain FDA or other regulatory approvals for sulopenem or any other product candidate and are able to launch ORLYNVAH™, sulopenem or any other product candidate commercially, they may not achieve market acceptance among physicians, patients, hospitals (including pharmacy directors) and third-party payors and, ultimately, may not be commercially successful. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Moreover, many antibiotics currently exist for the pathogens underlying uUTI, cUTI and cIAI. While many of those pathogens are resistant to certain drugs in the market, the selection is broad, and individual physicians' prescribing patterns vary widely and are affected by resistance rates in their geographies, whether their patients are at elevated risk, the ability of patients to afford branded drugs and concerns regarding generating resistance with specific classes of antibiotics.

Efforts to educate the medical community and third-party payors on the benefits of ORLYNVAH™ and any other product candidates that obtain approval may require significant resources and may not be successful. If ORLYNVAH™, sulopenem or any other product candidate that we develop does not achieve an adequate level of market acceptance, we may not generate significant

product revenues and, therefore, we may not become profitable. Market acceptance of ORLYNVAH™ and any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidate as demonstrated in clinical trials as compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- relative convenience and ease of administration;
- the clinical indications for which the product candidate is approved;
- the willingness of physicians to prescribe the product;
- the willingness of hospital pharmacy directors to purchase the product for their formularies;
- acceptance by physicians, patients, operators of hospitals and treatment facilities and parties responsible for coverage and reimbursement of the product;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the effectiveness of our sales and marketing efforts or those of collaborators, where we choose not to commercialize directly ourselves;
- the strength of marketing and distribution support;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved REMS;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;
- the emergence of bacterial resistance to the product; and
- the rate at which resistance to other drugs in the target infections grows.

In addition, the potential market opportunity for ORLYNVAH™ and additional sulopenem indications is difficult to estimate. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, then the actual market for ORLYNVAH™ and/or additional sulopenem indications could be smaller than our estimates of the potential market opportunity. If the actual market for ORLYNVAH™ and/or additional sulopenem indications is smaller than we expect, or if the product fails to achieve an adequate level of acceptance by physicians, health care payors, patients, hospitals and others in the medical community, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

We have a limited operating history and only a very recent history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We began operations in November 2015. Since our inception, we have devoted substantially all of our financial resources and efforts to organizing and staffing our company, business planning, raising capital, planning for the potential commercialization, and research and development, including preclinical and clinical development, for our sulopenem program. While the members of our development team have successfully developed and registered other antibiotics in past roles at different companies, our company and newly established commercial team have limited experience in and have not yet demonstrated an ability to successfully manufacture a commercial scale product (or arrange for a third party to do so on our behalf), or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. While we continue to engage in business development discussions with other companies regarding the potential sale, licensing, or disposition by other means of our rights to sulopenem, we commercially launched ORLYNVAH™ in the United States in August 2025, with our commercialization partner, EVERSANA. As we continue the commercialization of ORLYNVAH™ in the United States with EVERSANA and other third-parties, we are transitioning from a company with a research and development focus to a

company supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such an ongoing transition.

We currently have a limited commercial organization. If we are unable to establish and maintain sales, marketing and distribution capabilities, enter into sales, marketing and distribution agreements with third parties, or enter into a strategic transaction with a partner that has established commercial capabilities in the U.S., the ongoing commercialization of ORLYNVAH™ may not be successful.

Following receipt of FDA approval for ORLYNVAH™ in October 2024, efforts to achieve a strategic transaction were prioritized. As our strategic process did not result in any type of transaction acceptable to our board of directors, and while we continue to engage in business development discussions with other companies regarding the potential sale, licensing, or disposition by other means of our rights to sulopenem, we commercially launched ORLYNVAH™ in the United States in August 2025, with our commercialization partner, EVERSANA. Outside of the United States, we continue to evaluate the options to maximize the value of our sulopenem program. If we are unable to maintain and expand sales, marketing and distribution capabilities, enter into sales, marketing and distribution agreements with third parties or enter into a strategic transaction with a partner that has established commercial capabilities in the United States, the ongoing commercialization of ORLYNVAH™ may not be successful.

The ongoing development and expansion of sales, marketing and distribution capabilities for the commercialization of ORLYNVAH™ in the United States will require substantial resources and will be time-consuming. In addition, we may not be able to continue to hire or expand a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. If we are unable to maintain and expand our sales force and marketing and distribution capabilities, our operating results may be adversely affected. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates including the ongoing commercialization of ORLYNVAH™ in the United States.

Other factors that may inhibit our efforts to commercialize any product directly include:

•our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

•the inability of a health resources group to obtain access to educate physicians regarding the attributes of our future products;

•lack of adequate number of physicians to use or prescribe our products;

•the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

•costs and expenses associated with creating an independent sales and marketing organization;

•challenges in developing a commercialization strategy or launching new drug products using a traditional marketing model following a global health crisis or pandemic;

•our inability to reach a definitive agreement for commercialization services with respect to the potential commercialization of oral sulopenem in the United States or abroad, should we choose to outsource such services to a third party;

•our inability to complete a strategic transaction with a partner that has established commercial capabilities in the U.S.; and

•our ability to raise sufficient capital to fund operations.

For those countries in which we choose not to commercialize directly ourselves, we may use collaborators that have direct sales forces and established distribution systems to assist with the commercialization of ORLYNVAH™. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us would likely be lower than if we were to directly market and sell products in those markets.

Furthermore, while we are focusing on third party arrangements, we may be unsuccessful in entering into the necessary arrangements with third parties including strategic partners, or in obtaining all necessary approvals that may be required to enter into such arrangements or transactions, or may be unable to do so on terms that are favorable to us. In addition, we likely would have little control over such third parties, and any of them might fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, or we are not successful in completing a strategic transaction that has established commercial capabilities in the U.S., or at all, ORLYNVAH™ and any other product candidates will not be successfully commercialized.

We face substantial competition from other pharmaceutical and biotechnology companies and our business may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to oral sulopenem, sulopenem and other product candidates that we may seek to develop and commercialize in the future. There are a number of pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of multi-drug resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than oral sulopenem, sulopenem or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive.

There are a variety of available oral therapies marketed for the treatment of multi-drug resistant infections that we expect to compete with ORLYNVAH™ and would compete with oral sulopenem in additional indications, such as levofloxacin, ciprofloxacin, nitrofurantoin, fosfomycin, amoxicillin-clavulanate, cephalexin, trimethoprim-sulfamethoxazole, pivmecillinam and gepotidacin. Many of the available therapies are well established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products, for example in the fluoroquinolone class. Pricing of ORLYNVAH™, or sulopenem, if approved in additional indications, may be at a significant premium over other competitive products that are generic. This may make it difficult for ORLYNVAH™, or sulopenem, if approved in additional indications, to compete with these products.

There are several IV-administered products marketed for the treatment of infections resistant to first-line therapy for gram-negative infections, including Avycaz from AbbVie Inc. and Pfizer, Vabomere from CorMedix, Inc., Zerbaxa from Merck & Co., Zemdri from Cipla Limited, Xerava from Innovia, Inc., Recarbrio from Merck & Co, and Fetroja from Shionogi & Co., Ltd.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now Act (the GAIN Act). The GAIN Act is intended to provide incentives for the development of new, qualified infectious disease products (QIDP). One such incentive is that, once a product receives QIDP designation and completes the necessary clinical trials and is approved by the FDA, it will be given an additional five years of exclusivity regardless of whether it is protected by a patent, provided that it is already eligible for another type of regulatory exclusivity. The FDA has designated sulopenem and oral sulopenem as QIDPs for the indications of uUTI, cUTI, cIAI, community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease. Fast track designation for these seven indications in both the oral and intravenous formulations has also been granted. In October 2024, the FDA confirmed that an additional five years of marketing exclusivity under the GAIN Act will be added to the regulatory exclusivity granted upon approval of ORLYNVAH™, resulting in a total of ten years marketing exclusivity. In December 2016, the Cures Act was passed, providing additional support for the development of new infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of product candidates that could be competitive with oral sulopenem, sulopenem and our other product candidates.

Even if we are able to continue to commercialize ORLYNVAH™ in the U.S., oral sulopenem in additional indications or any other product candidate, the product may become subject to unfavorable pricing regulations, or third-party payor coverage and reimbursement policies that could harm our business.

Marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which may negatively affect the revenues that we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

The commercial success of ORLYNVAH™, and any future product candidates, if approved, will depend substantially, both in the United States and outside the United States, on the extent to which coverage and adequate reimbursement for the product and related treatments are available from government health programs, private health insurers and other third-party payors. If coverage is

not available, or reimbursement is limited, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investments. Government authorities and third-party payors, such as health insurers and managed care organizations, publish formularies that identify the medications they will cover and the related payment levels. The healthcare industry is focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably.

In the United States, sales of ORLYNVAH™, oral sulopenem in additional indications and any future product candidates will depend, in part, on the availability and extent of coverage and reimbursement by third-party payors, such as government health programs, including Medicare and Medicaid, commercial insurance and managed healthcare organizations. There is no uniform coverage and reimbursement policy among third-party payors; however, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Obtaining coverage and reimbursement approval for a product candidate from third-party payors is a time-consuming and costly process that may require the provision of supporting scientific, clinical and cost effectiveness data for the use of such product candidate to the third-party payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product candidate is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product candidate will be paid for in all cases or at a rate that covers operating costs, including research, development, intellectual property, manufacture, sales and distribution expenses. Reimbursement rates may vary according to the use of the product candidate and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. It is difficult to predict what third-party payors will decide with respect to coverage and reimbursement for our product candidates.

We currently expect that sulopenem, if approved, will be administered in a hospital setting, and that ORLYNVAH™ will be used in a community setting and possibly be administered in a hospital inpatient setting as well. In the United States, third-party payors generally reimburse hospitals a single bundled payment established on a prospective basis intended to cover all items and services provided to the patient during a single hospitalization. Hospitals bill third-party payors for all or a portion of the fees associated with the patient's hospitalization and bill patients for any deductibles or co-payments. Because there is typically no separate reimbursement for drugs administered in a hospital inpatient setting, some of our target customers may be unwilling to adopt our product candidates in light of the additional associated cost. If we are forced to lower the price we charge for ORLYNVAH™ and any other approved product candidates, our gross margins may decrease, which would adversely affect our ability to invest in and grow our business. Centers for Medicare and Medicaid Services (CMS) recently revised its reimbursement system for certain antibiotics in order to address challenges associated with antimicrobial resistance. Based on the final rule published on August 2, 2019, CMS is finalizing an alternative new technology add-on payment pathway (NTAP) for certain breakthrough devices, and under this policy, a QIDP product will be considered new and will not need to demonstrate that it meets the substantial clinical improvement criterion. Instead, it will only need to meet the cost criterion. CMS has also increased the NTAP percentage to 75 percent for an antimicrobial designated by the FDA as a QIDP. The potential impact of this rule on sulopenem has not yet been assessed.

On April 18, 2022, CMS released the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) proposed rule. Within each IPPS proposed rule, CMS assesses technologies that have been submitted for potential NTAP status and reconsiders the eligibility for technologies already so designated. In connection with this proposed rule, CMS assessed 13 technologies that were submitted for FY 2023 NTAP consideration through alternative application pathways. These pathways streamline the NTAP application process for (1) devices with FDA breakthrough designation, (2) drugs designated as qualified infectious disease products, and (3) technologies approved through the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs. CMS has once again proposed to approve these 13 technologies applying through the alternative pathway depending on FDA approval or clearance.

An inability to promptly obtain coverage and adequate payment rates from third-party payors for ORLYNVAH™ and any other approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We cannot predict whether bacteria may develop resistance to ORLYNVAH™ or sulopenem, which could affect their revenue potential.

We have developed ORLYNVAH™ for the treatment of uUTIs caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options and are developing sulopenem to treat additional drug-resistant bacterial infections. The bacteria responsible for these infections evolve quickly and readily transfer their resistance mechanisms within and between species. We cannot predict whether or when bacterial resistance to ORLYNVAH™ and sulopenem may develop.

As with some commercially available carbapenems, oral sulopenem and sulopenem are not active against organisms expressing a resistance mechanism mediated by enzymes known as carbapenemases. Although occurrence of this resistance mechanism is currently uncommon, we cannot predict whether carbapenemase-mediated resistance will become widespread in regions where we intend to market sulopenem if it is approved. The use of carbapenems or penems in areas with drug-resistant infections or in countries

with poor public health infrastructures, or the potentially extensive use of ORLYNVAH™ or sulopenem outside of controlled hospital settings or in the community, could contribute to the rise of resistance. In addition, prescribers may be less likely to prescribe ORLYNVAH™ and sulopenem if they are concerned about contributing to the rise of antibiotic resistance. If resistance to ORLYNVAH™ or sulopenem becomes prevalent, or concerns about such resistance are strong, our ability to generate revenue from ORLYNVAH™ and sulopenem could suffer.

If we are unable to establish, maintain and expand sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful with the ongoing commercialization of ORLYNVAH™ or the commercialization of sulopenem in additional indications and/or any future products, if approved.

Following the commercial launch of ORLYNVAH™ in August 2025, we are continuing to establish, maintain and expand a sales, marketing and distribution infrastructure for ORLYNVAH™ in the U.S., in collaboration with our commercial partner, EVERSANA, and other third-parties. The development of sales, marketing and distribution capabilities requires substantial resources and is time consuming. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

If we enter into arrangements with third parties, including EVERSANA, to perform sales, marketing and distribution services, our product revenues or the profitability of ORLYNVAH™ may be lower than if we were to directly market and sell ORLYNVAH™ in the U.S. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market ORLYNVAH™ effectively in the U.S.

We may seek to enter into collaborations that we believe may contribute to our ability to commercialize ORLYNVAH™ or to advance development and ultimately commercialize oral sulopenem in additional indications and/or any future product candidates. We may also seek to enter into collaborations where we believe that realizing the full commercial value of our development programs will require access to broader geographic markets or the pursuit of broader patient populations or indications. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our products, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

If we do not establish, maintain or expand sales, marketing and distribution capabilities, in collaboration with EVERSANA and/or other third parties, we will not be successful in commercializing ORLYNVAH™ or oral sulopenem in additional indications and/or any future product candidates that receive marketing approval.

Risks Related to Product Development

If clinical trials of sulopenem or any other product candidate that we may advance to clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or comparable foreign regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of sulopenem or any other product candidate.

While we received marketing approval from the FDA for ORLYNVAH™ for the treatment of uUTIs caused by the certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment option, we may not commercialize, market, promote, or sell ORLYNVAH™ for any additional indications or any other product candidate in the United States without obtaining marketing approval from the FDA or in other countries without obtaining approvals from comparable foreign regulatory authorities, such as the EMA, and we may never receive such approvals. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. While we received an approval for ORLYNVAH™ from the FDA in October 2024, we have not submitted an NDA to the FDA for any of our other product candidates or any similar applications to comparable foreign regulatory authorities for ORLYNVAH™ or any of our product candidates.

Our business currently heavily depends on the successful development, regulatory approval and commercialization of our sulopenem program. The continued clinical development of our sulopenem program, or any future product candidates, is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of severe adverse events, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier non-clinical studies or clinical trials. The results of preclinical and other non-clinical studies and/or early clinical trials of our product candidates or future product candidates may not be predictive of the results of later-stage clinical trials and interim results of a clinical trial do not necessarily predict final results. Notwithstanding any promising results in early non-clinical studies or clinical trials, we cannot be certain that we will not face similar setbacks.

Preclinical and clinical data are often susceptible to varying interpretations and analyses. Although data from clinical trials of oral sulopenem and sulopenem provides support for the overall safety profile of the product candidates, many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of our clinical trials warrant marketing approval, the FDA or

comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates. For example, while we ultimately received approval for ORLYNVAH™ (oral sulopenem) for the treatment of uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, we received a CRL from the FDA on July 23, 2021 for our NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen. The CRL provided that additional data are necessary to support approval of oral sulopenem for the treatment of adult women with uUTIs caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone and recommended that we conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. In July 2022 we reached an agreement with the FDA under the SPA process on the design, endpoints and statistical analysis of a Phase 3 clinical trial for oral sulopenem for the treatment of uUTIs and commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study was designed as a non-inferiority trial comparing oral sulopenem and Augmentin® (amoxicillin/clavulanate) in the Augmentin® susceptible population. In October 2023 we completed enrollment in the REASSURE clinical trial, enrolling 2,222 patients. In January 2024, we announced that ORLYNVAH™ met the primary endpoint of statistical non-inferiority to Augmentin® in the Augmentin®-susceptible population, and demonstrated statistically significant superiority versus Augmentin® in the Augmentin® susceptible population, in the REASSURE clinical trial. Additionally, though not an approvability issue, the FDA recommended in its CRL that we conduct additional non-clinical pharmacokinetic-pharmacodynamic (PK/PD) studies to support dose selection for the proposed treatment indication(s), which we completed as recommended by the FDA. We resubmitted our NDA to the FDA in April 2024 and received approval from the FDA for ORLYNVAH™ for the treatment of uncomplicated uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options in October 2024.

In some instances, there can be significant variability in safety and/or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants, among others. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one of the factors listed or otherwise. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of or intolerability of our product candidates or may determine that our product candidates are toxic or not well tolerated when that is not in fact the case. In the case of our clinical trials, results may differ on the basis of the type of bacteria with which patients are infected. We cannot assure our shareholders that any clinical trials that we are conducting or other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We may encounter unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent us from obtaining regulatory approval for oral sulopenem in additional indications or any of our other product candidates, including:

- we may not reach agreement on acceptable terms with all clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the FDA, the local National Health Authorities or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have to suspend or terminate clinical trials of a product candidate for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies; or
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of any product candidate beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any product candidate, we may:

•incur additional unplanned costs;

•be delayed in obtaining marketing approval for our product candidates;

•not obtain marketing approval at all;

•obtain approval for indications or patient populations that are not as broad as intended or desired;

•obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

•be subject to additional post-marketing testing or other requirements; or

•be required to remove the product from the market after obtaining marketing approval.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act (FDORA), Congress required sponsors to develop and submit a diversity action plan (DAP) for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

On January 27, 2025, in response to an executive order issued by President Trump on January 21, 2025, relating to Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the Trump administration's actions to remove these webpages, including the draft DAP guidance, is unlawful under the Administrative Procedure Act. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of NDAs and Biologics License Applications (BLAs).

In addition, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of oral sulopenem, sulopenem or any other product candidate.

If we experience delays or difficulties in the enrollment of patients in clinical trials, clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. While we successfully completed the REASSURE clinical trial, we may not be able to initiate and/or continue or complete other clinical trials for any other product candidate that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials as required by the FDA or

comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for participation in the clinical trial;
- the number of sites at which we conduct the trial and the speed at which we are able to open such sites;
- the prevalence of antibiotic resistance to pathogens where we conduct the clinical trial;
- the accuracy of certain estimates and assumptions upon which the design of the protocols are predicated;
- our ability to recruit clinical trial investigators with appropriate experience;
- the success of competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion.

The inclusion and exclusion criteria for any clinical trials of oral sulopenem in additional indications and sulopenem may adversely affect our enrollment rates for patients in those clinical trials. In addition, we may face competition in enrolling suitable patients as a result of other companies conducting clinical trials for antibiotic product candidates that are intended to treat similar infections, resulting in slower than anticipated enrollment in our clinical trials. Enrollment delays in our clinical trials may result in increased development costs for oral sulopenem in additional indications and/or sulopenem, or slow down or halt our product development for oral sulopenem in additional indications and/or sulopenem.

Accordingly, our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed. Furthermore, we rely on and expect to continue to rely on contract research organizations (CROs) and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we have limited influence over their performance.

Success in non-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot assure our shareholders that any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our sulopenem program in any additional indications.

Although we obtained approval from the FDA for ORLYNVAH™ for the treatment of uUTIs caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options in October 2024, we believe that oral sulopenem and sulopenem also have the potential to treat cUTIs and cIAIs in humans based on the results of prior preclinical studies and clinical trials. However, we cannot guarantee that oral sulopenem and/or sulopenem will demonstrate the expected efficacy in clinical trial patients to the satisfaction of the FDA and/or other regulators in those additional indications. We also cannot guarantee that the projections made from the pharmacokinetic and pharmacodynamic models that we developed from non-clinical and clinical oral sulopenem and sulopenem studies will be validated in these clinical trials. For example, while we believe that sulopenem has the potential to treat cIAIs and cUTIs in humans based on the results of prior preclinical studies and clinical trials, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy in our Phase 3 cIAI and cUTI clinical trials. While we believe the secondary supporting analyses and safety data in all three Phase 3 clinical trials support the potential of sulopenem in the treatment of multi-drug resistant infections, we cannot guarantee that these supporting analyses are indicative of efficacy of sulopenem in treating cIAIs or cUTIs.

Other companies in the pharmaceutical industry have frequently suffered significant setbacks in later clinical trials, even after achieving promising results in earlier non-clinical studies or clinical trials.

Serious adverse events or undesirable side effects or other unexpected properties of ORLYNVAH™, sulopenem or any other product candidate may be identified during development or after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an institutional review board (IRB), or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a

more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If ORLYNVAH™ or any product candidate is associated with serious or unexpected adverse events or undesirable side effects, the FDA or the IRBs at the institutions in which our studies are conducted, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

To date, sulopenem and sulopenem etzadroxil have generally been well tolerated in clinical trials conducted in healthy subjects and patients and there were no safety issues found in any patients treated with sulopenem in our prior Phase 3 clinical trials. During the development of oral sulopenem and sulopenem, patients have experienced drug-related side effects including diarrhea, temporary increases in hepatic enzymes, allergic reactions, and rash.

While the active pharmaceutical ingredient in the bilayer tablet is sulopenem etzadroxil, the combination product with probenecid has not yet been tested extensively in patients. In the cIAI trial, patients received either sulopenem IV followed by sulopenem etzadroxil or ertapenem followed by ciprofloxacin/metronidazole or amoxicillin-clavulanate. Among 668 treated patients, treatment-related adverse events were observed in 6.0% and 5.1% of patients on sulopenem and ertapenem, respectively, with the most commonly reported drug-related adverse event being diarrhea, which was observed in 4.5% and 2.4% of patients on sulopenem and ertapenem, respectively. Discontinuations from treatment were uncommon for both regimens, occurring in 1.5% of patients on sulopenem and 2.1% of patients on ertapenem. Serious adverse events unrelated to study treatment were seen in 7.5% of patients on sulopenem and 3.6% of patients on ertapenem. In the cUTI trial, patients received either sulopenem IV followed by sulopenem etzadroxil, if eligible for oral therapy, or ertapenem IV followed by ciprofloxacin or amoxicillin-clavulanate, if eligible for oral therapy. Among 1,392 treated patients, treatment-related adverse events were observed in 6.0% and 9.2% of patients on sulopenem and ertapenem, respectively, with the most commonly reported adverse events being headache (3.0% and 2.2%), diarrhea (2.7% and 3.0%) and nausea (1.% and 1.6%), on sulopenem and ertapenem, respectively. Discontinuations from treatment were uncommon for both regimens, occurring in 0.4% of patients on sulopenem and 0.6% of patients on ertapenem. Serious adverse events unrelated to study treatment were seen in 2.0% of patients on sulopenem and 0.9% of patients on ertapenem. In the uUTI trial known as known as Sulopenem for Resistant Enterobacteriaceae (SURE) 1, patients received either oral sulopenem or ciprofloxacin. Among 1,660 treated patients, treatment related adverse events were observed in 17.0% and 6.2% of patients on sulopenem and ciprofloxacin, respectively. The most commonly reported adverse events were diarrhea (12.4% and 2.5%), nausea (3.7% and 3.6%), and headache (2.2% and 2.2%), for sulopenem and ciprofloxacin patients, respectively. The difference in adverse events was driven by diarrhea which, in the majority of patients, was mild and self-limited. Overall discontinuations due to adverse events were uncommon on both regimens and were seen in 1.6% of patients on sulopenem and 1.0% of patients on ciprofloxacin. Serious adverse events were seen in 0.7% of patients on sulopenem with one drug-related serious adverse event due to transient angioedema and 0.2% of patients on ciprofloxacin with no drug-related serious adverse event. In the REASSURE clinical trial, patients received either ORLYNVAH™ or Augmentin®. Among 2,214 treated patients, treatment related adverse events were observed in 18.9% and 12.3% of patients on ORLYNVAH™ and Augmentin®, respectively. The most commonly reported adverse events were diarrhea (8.1% and 4.1%), nausea (4.3% and 2.9%), and headache (2.2% and 1.5%), for ORLYNVAH™ and Augmentin® patients, respectively. The difference in adverse events was driven by diarrhea which, in the majority of patients, was mild and self-limited. Overall discontinuations due to adverse events were uncommon on both regimens and were seen in 0.7% of patients on ORLYNVAH™ and 0.4% of patients on Augmentin®. Serious adverse events were seen in 0.0% of patients on ORLYNVAH™ and 0.5% of patients on Augmentin® with no drug-related serious adverse event.

While we believe these results support a positive safety and tolerability profile for sulopenem and there were no safety issues identified by the FDA in its review of ORLYNVAH™ prior to approval, in future trials there may be unforeseen serious adverse events or side effects that differ from those seen in our prior Phase 3 program. There may also be unexpected adverse events associated with probenecid that have not been seen to date. Following approval of ORLYNVAH™, we are required to report certain adverse reactions, if any, to the FDA as part of the post-marketing requirements.

If unexpected adverse events occur in any of our clinical trials, we may need to abandon development of our product candidates, or limit development to lower doses or to certain uses or subpopulations in which the undesirable side effects or other unfavorable characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevent further development of the compound.

Undesirable side effects or other unexpected adverse events or properties of sulopenem or any of our other future product candidates could arise or become known either during clinical development or, if approved, and in the case of ORLYNVAH™, after the approved product has been marketed. If such an event occurs during development, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or could deny approval of sulopenem or other product candidates. If such an event occurs after such product candidates are approved, a number of potentially significant negative consequences may result, including:

•regulatory authorities may withdraw the approval of such product;

•we may be required to recall a product or change the way such product is administered to patients;

•regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;

•regulatory authorities may require one or more post-marketing studies;

•regulatory authorities may require the addition of a "black box" warning;

•we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS), including the creation of a medication guide outlining the risks of such side effects for distribution to patients;

•we could be sued and held liable for harm caused to patients;

•our product may become less competitive; and

•our reputation may suffer.

Additionally, if the safety warnings in our product labels are not followed, adverse medical situations in patients may arise, resulting in negative publicity and potential lawsuits, even if our products worked as we described. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

We may be subject to costly product liability claims related to our clinical trials and the commercialization of ORLYNVAH™ and, if we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of our insurance coverage, a material liability claim could adversely affect our financial condition.

We face an inherent risk of product liability exposure related to the commercialization of ORLYNVAH™ and the testing of our product candidates in clinical trials and other research activities. Although we have product liability insurance, which is intended to cover claims related to our clinical trials and the commercial sale of ORLYNVAH™ for up to $10.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur a liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates or products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

•decreased demand for ORLYNVAH™ or any other product candidates we commercialize;

•withdrawal of clinical trial volunteers, investigators, patients or trial sites;

•the inability to commercialize any other product candidates that we may develop, if approved;

•regulatory investigations that could require costly recalls or product modifications;

•loss of revenue;

•substantial costs of litigation;

•liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;

•an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;

•the diversion of management's attention from our business; and

•damage to our reputation and the reputation of our products.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage,

handling, exposure, disposal and recordkeeping with respect to these materials. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of non-compliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials.

If we experience a significant disruption in our information technology systems, or breaches of data security, or become the target of a cyberattack, our business could be adversely affected.

We rely on information technology systems to keep financial records, capture laboratory data, maintain clinical trial data and corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including, but not limited to, natural disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could delay or negatively impact the development and commercialization of our sulopenem program and any future product candidates or technology, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches, whether by employees or others, which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees and others, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers, and other business partners, may become the target of cyberattacks or information security compromises or breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of private, proprietary, and other information, or could otherwise lead to the disruption of our business operations. Cyberattacks are becoming more sophisticated and certain cyber incidents, such as surveillance, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss due to remedial actions, loss of business, disruption of operations, damage to our reputation, or potential liability, including litigation and regulatory investigations and enforcement actions. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Furthermore, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks.

Moreover, a security breach, cyberattack or privacy violation that leads to disclosure or modification of, personally identifiable information, could harm our reputation, compel us to comply with applicable European, and United States federal and/or state, breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation and liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. In addition, a data security breach or cyberattack could result in loss of clinical trial data or damage to the integrity of that data. If we are unable to prevent such security breaches, attacks or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer reputational damage, financial loss and other negative consequences because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Risks Related to Our Dependence on Third Parties

If we fail to comply with our obligations in our agreement with Pfizer, we could lose such rights that are important to our business.

We rely heavily on the Pfizer License pursuant to which we exclusively in-license certain patent rights and know-how related to sulopenem etzadroxil and certain know-how related to the IV formulation of sulopenem. The Pfizer License imposes diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us, and we may enter into additional agreements, including license agreements, with other parties in the future which impose similar obligations.

The Pfizer License gives us exclusive worldwide rights to develop, manufacture, and commercialize sulopenem etzadroxil and sulopenem, or any other prodrug of sulopenem previously identified by Pfizer as well as the right to use relevant information and regulatory documentation developed by Pfizer to support any regulatory filing worldwide. In exchange for those rights, we are obligated to satisfy diligence requirements, including using commercially reasonable efforts to develop, obtain regulatory approval for and commercialize sulopenem etzadroxil and sulopenem by implementing a specified development plan and providing an update on progress on an annual basis. Under the Pfizer License, we paid Pfizer a one-time non-refundable upfront fee of $5.0 million, clinical milestone payments totaling $15.0 million, upon first patient dosing of oral sulopenem and sulopenem in a Phase 3 clinical trial, and are obligated to pay Pfizer milestone payments upon the achievement of other specified regulatory and sales milestones, including a regulatory milestone payment of $20.0 million which became due upon approval of oral sulopenem for commercial sale in the United States by the FDA. We deferred this payment for a two-year period, at an annual rate of eight percent on a daily compounded basis until paid in full, which was amended and restated on May 13, 2025 for an additional three-year deferral period, at an annual rate of ten percent for the extended deferral period, beginning on October 26, 2026, as permitted pursuant to the terms of the Pfizer License.

We are also obligated to pay Pfizer royalties ranging from a single-digit to mid-teens percentage based on the amount of marginal net sales of each licensed product. Pfizer also received 381,922 of our Series A preferred shares (which converted to 25,461 ordinary shares in connection with our initial public offering) as additional payment for the licensed rights.

If we fail to comply with our obligations to Pfizer under the Pfizer License, Pfizer may have the right to terminate the Pfizer License, in which event we would not be able to develop, obtain regulatory approval for, manufacture or market any product or product candidate that is covered by the Pfizer License, including ORLYNVAH™ and sulopenem, which would materially harm our business, financial condition, results of operations and growth prospects. Any termination of the Pfizer License or reduction or elimination of our rights thereunder may result in our having to negotiate new or reinstated agreements with less favorable terms. Any termination of the Pfizer License would cause us to lose our rights to important intellectual property or technology.

We depend on collaborations with third parties for the commercialization of products, including ORLYNVAH™, and the development and commercialization of product candidates in certain territories. Our prospects with respect to those product candidates will depend in part on the success of those collaborations.

Following the commercial launch of ORLYNVAH™ in the United States in August 2025, we have become reliant on various collaborations with third parties, including EVERSANA. Although we are focusing our initial commercial efforts on the United States market, which we believe represents the largest market opportunity for our sulopenem program, we are also evaluating our commercialization strategy both within and outside the United States. We have established a sales, marketing and distribution infrastructure for ORLYNVAH™ in the United States, in collaboration with EVERSANA and/or other third parties, however, do not have experience in the sales, marketing or distribution of pharmaceutical products to date. To achieve commercial success for ORLYNVAH™ and any approved product, we must either build our marketing, sales, distribution, managerial and other non-technical capabilities directly, or make arrangements to outsource those functions to a commercial partner, as we have done for the initial commercial launch of ORLYNVAH™ in the United States. For those other countries in which we may also choose not to commercialize directly ourselves or through a business development partner, we may seek to commercialize ORLYNVAH™ and/or sulopenem through further collaboration arrangements. In addition, we may seek third-party collaborators for development and commercialization of other product candidates in the United States and other territories. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements could include service providers to the pharmaceutical industry, large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We may derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of any product or product candidate that we license to a third party.

We face significant competition in seeking and obtaining appropriate collaborators. Collaborations involving our products and product candidates may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our products and product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of products

and product candidates, might lead to additional responsibilities for us with respect to products and product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

•collaborators may not properly maintain, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

•collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

•collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products and product candidates.

Collaboration agreements may not lead to development or commercialization of products and product candidates in the most efficient manner or at all. If a collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product or product candidate licensed to it by us.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay a product or product candidates' 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 fund and undertake development or commercialization activities on our own, we will need to obtain additional expertise and significant additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities directly ourselves or with a commercial partner, we may not be able to further develop our product candidates or bring any products to market including ORLYNVAH™ or continue to develop our product platform.

We rely on third parties, including EVERSANA, to perform many essential services for the ongoing commercialization of ORLYNVAH™ in the U.S., including services related to warehousing and inventory control, distribution, government price reporting, customer service, accounts receivable management, cash collection, and pharmacovigilance and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize ORLYNVAH™ in the U.S. will be significantly impacted and we may be subject to regulatory sanctions.

We have engaged third-party service providers, including EVERSANA, to perform a variety of functions related to the sale and distribution of ORLYNVAH™ in the U.S., key aspects of which are out of our direct control. These service providers will provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management, and cash collection. As we engage a service provider, such as EVERSANA, we substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action. In addition, we are engaging third parties to perform various other services for us relating to pharmacovigilance and adverse event reporting, safety database management, fulfillment of requests for medical information regarding ORLYNVAH™ and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements, we could be subject to regulatory sanctions. Additionally, we have contracted with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required, or errors in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates or commercialize any of our products or product candidates. If they do not perform satisfactorily, our business may be materially harmed.

We do not independently conduct non-clinical studies that comply with good laboratory practice (GLP) requirements. We also do not have the ability to independently conduct clinical trials of any of our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators to conduct our clinical trials of oral sulopenem and sulopenem and expect to rely on these third parties to conduct clinical trials of any potential product candidates. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities limits our control over these activities but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a clinical trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and

protocols for the clinical trial. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP studies and our clinical trials play a significant role in the conduct of these studies and clinical trials and the subsequent collection and analysis of data.

Although we rely on these third parties to conduct our GLP-compliant non-clinical studies and clinical trials, we remain responsible for ensuring that each of our non-clinical studies and clinical trials are conducted in accordance with applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. The FDA and regulatory authorities in other jurisdictions also require us to comply with standards, commonly referred to as good clinical practices (GCPs), for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot assure our shareholders that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time and resources to our development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for oral sulopenem, sulopenem or other product candidates could be harmed, our costs could increase and our ability to generate revenue could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

We contract with third parties, including ACS Dobfar S.p.A., for the manufacture of preclinical and clinical supplies of oral sulopenem, sulopenem and the ORLYNVAH™ bilayer tablet for commercial supply, and expect to continue to do so in connection with any future clinical trials and commercialization of our products and product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our products and/or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have the internal infrastructure or capability to manufacture sulopenem for use in the conduct of our preclinical research or clinical trials or to manufacture ORLYNVAH™ for commercialization. We rely on third-party contract manufacturers to manufacture supplies of sulopenem, and we rely/expect to rely on third-party contract manufacturers to manufacture commercial quantities of ORLYNVAH™, and any product candidate that we commercialize following approval for marketing by applicable regulatory authorities, if any. Reliance on third-party manufacturers entails risks, including:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our products and/or product candidates or otherwise do not satisfactorily perform according to the terms of their agreement with us;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We currently rely on a small number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials.

In July 2025, we entered into a manufacturing and supply agreement with ACS Dobfar, S.p.A. (ACS Dobfar) to manufacture and supply to us finished product, being the ORLYNVAH™ bilayer tablet, and/or sulopenem etzadroxil bulk drug substance, in each case, for commercial purposes. We currently depend entirely on ACS Dobfar to manufacture the ORLYNVAH™ bilayer tablet for commercial sale, and if ACS Dobfar should become unavailable to us for any reason, we may incur delays in identifying or qualifying replacements.

In addition, we recently entered and are in the process of negotiating agreements with third-party contract manufacturers for the manufacture and supply of raw materials required for the commercial production of ORLYNVAH™. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under current Good Manufacturing Practices (cGMPs), that are capable of manufacturing certain of these components for ORLYNVAH™. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could negatively impact our commercial efforts.

Third-party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States. Facilities used by our third-party manufacturers must be approved by the FDA after we submit an NDA(s) and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in countries outside of the United States. We have no direct control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel, and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate or adversely affect supplies of ORLYNVAH™ or product candidates. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and have a material adverse effect on our business, financial condition and results of operations.

We and our third-party suppliers also continue to refine and improve the manufacturing process, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes, particularly as we seek to significantly increase our capacity to commercialize ORLYNVAH™ and/or sulopenem. Our reliance on contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

As drug candidates are developed through non-clinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, methods of making drug formulations, and drug formulations, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our drug candidates to perform differently and affect the results of clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require us to conduct bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commence sales and generate revenue.

While no issues with regard to third-party manufacturers or the manufacturing process were identified as part of the FDA review prior to approval of ORLYNVAH™, there can be no assurance that issues will not be identified in the future or that our third-party manufacturers will continue to maintain adequate quality control, quality assurance and qualified personnel and/or will continue to comply with the applicable regulatory requirements for the manufacture of our products and product candidates.

Our current and anticipated future dependence upon others for the manufacture of ORLYNVAH™ and sulopenem and any future product candidates may adversely affect our future profit margins and our ability to continue to commercialize ORLYNVAH™ and any products for which we receive marketing approval on a timely and competitive basis.

Risks Related to Our Intellectual Property

We rely heavily on the Pfizer License for the patent rights and know-how required for the development of oral sulopenem and to commercialize ORLYNVAH™ and the know-how required to develop the IV formulation of sulopenem.

We rely heavily on the Pfizer License for intellectual property rights that are important or necessary for the development of oral sulopenem and to commercialize ORLYNVAH™. We do not own or license any patent rights that cover the IV formulation of sulopenem. In addition, all patents directed to sulopenem expired prior to us entering into the Pfizer License. Licenses to additional third-party intellectual property, technology and materials that may be required for the development and commercialization of our sulopenem program or any other product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our sulopenem program and any other product candidates or technology we may obtain in the future or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize ORLYNVAH™, sulopenem or other future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

Under the Pfizer License, and we expect under certain of our future license agreements, we are responsible for prosecution and maintenance of the licensed patents and for bringing any actions against any third party for infringing on such patents. In addition, the Pfizer License requires, and we expect certain of our future license agreements would also require, us to meet certain development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. In addition, such license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Disputes may arise regarding intellectual property subject to the Pfizer License or any of our future license agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In spite of our best efforts, Pfizer and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and growth prospects.

If we are unable to obtain and maintain patent protection or other intellectual property rights for ORLYNVAH™ or our other technology and product candidates, or if the scope of the patent protection or intellectual property rights we obtain is not sufficiently broad, we may not be able to successfully commercialize ORLYNVAH™ or develop and commercialize any other product candidates or technology or otherwise compete effectively in our markets.

We rely upon a combination of patents, trademarks, trade secret protection, confidentiality agreements and other proprietary rights to protect the intellectual property related to our development programs and product candidates. Our success depends, in part, on obtaining and maintaining patent protection and successfully enforcing these patents and defending them against third-party challenges in the United States and other countries. If we or our licensors are unable to obtain or maintain patent protection with respect to ORLYNVAH™ or any other product candidates or technology we develop, our business, financial condition, results of operations and growth prospects could be materially harmed.

We have sought to protect our proprietary position by in-licensing patents in the United States and abroad related to oral sulopenem. Further, we own four U.S. patents, one Canadian, one Chinese patent, one Japanese patent, one Korean patent, one Mexican and two Australian patents, with one U.S. patent, the Canadian patent, the Japanese patent, the Korean patent, the Mexican patent and one Australian patent directed to the composition of the bilayer tablet of oral sulopenem and its related preparations and/or uses, two U.S. patents and one Australian patent directed to the method of use of oral sulopenem in treating multiple diseases, including uUTIs, and one U.S. patent and the Chinese patent directed to the method of use of sulopenem etzadroxil, probenecid, and valproic acid in treating multiple diseases. We also own three pending U.S. patent applications, and 23 pending foreign patent applications, which collectively cover uses of sulopenem etzadroxil and probenecid and bilayer tablets of sulopenem etzadroxil and probenecid.

Moreover, although we control prosecution of the patents we have licensed from Pfizer related to our sulopenem program, we may not always have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce or defend the patents, covering technology that we may license from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained, enforced or defended in a manner consistent with the best interests of our business.

If any patent applications we own or may own or in-license in the future with respect to our development programs or product candidates fail to issue, if their breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our current and future product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Any such outcome could materially harm our competitive position, business, financial condition, results of operations and growth prospects.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of countries outside the United States may not protect our rights to the same extent as the laws of the United States. For example, European Union (EU) patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. In addition, publications of discoveries in scientific literature often lag behind the actual discoveries, patent applications in the United States and other jurisdictions remain confidential for a period after filing, and some remain so until issued. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in the patents or pending patent applications we currently own, license or may own or license in the future, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patent rights has been found, and such prior art could potentially invalidate one or more of the patents we currently license or may own or license in the future or prevent a patent from issuing from one or more pending patent applications we own or may own or license in the future. There is also no assurance that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patent rights, may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Even if patents do successfully issue and even if such patents cover our current and future products and product candidates, third parties may challenge their ownership, validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Any successful opposition to these patents or any other patents owned by us in the future or licensed to us could deprive us of rights necessary for the successful commercialization of any products and product candidates that we may develop. Furthermore, even if they are unchallenged, our patents rights may not adequately protect our products, product candidates and technology, provide exclusivity for our products and product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patent rights or narrow the scope of our patent protection.

We cannot offer any assurances about whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful challenge or opposition to patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products or product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Furthermore, our patent rights may be subject to a reservation of rights by one or more third parties. For example, certain research we conducted was funded in part by the U.S. government. As a result, the U.S. government may have certain march-in rights to patents and technology arising out of such research, if any. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products and product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercial launch of our products and product candidates in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products and product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products and product candidates or the use of our products and product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and product candidates. We may incorrectly determine that our products and product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products and product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates.

The patent protection for our products and product candidates may expire before we are able to maximize their commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, 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. The patents for ORLYNVAH™ have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, our licensed U.S. patent claim for a composition of matter patent for oral sulopenem is due to expire in 2029, subject to potential extension to 2034 under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and our patent directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid is due to expire no earlier than 2039, absent any extensions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent rights may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

The FDA designated sulopenem and oral sulopenem as QIDPs for the indications of uUTI, cUTI, cIAI, community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease. Fast track designation for these seven indications in both the oral and intravenous formulations has also been granted. QIDP status provides the potential for a more rapid review cycle for an NDA and could add five years to any regulatory exclusivity period that we may be granted. While the FDA confirmed that an additional five years of marketing exclusivity was granted upon approval of ORLYNVAH™, resulting in a total of ten years marketing exclusivity, that does not guarantee that we will receive any regulatory exclusivity for any other product candidates or that any such exclusivity will be for a period sufficient to provide us with any commercial advantage. Moreover, we do not own or license any patent directed to sulopenem.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of the U.S. patents we currently license and/or own may be eligible for limited patent term extension under the Hatch-Waxman Act, and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of the relevant patents or otherwise fail to satisfy applicable requirements and the length of the extension could be less than we request. To the extent we wish to pursue patent term extension based on a patent that we in-license from Pfizer or another third party, we would need the cooperation of Pfizer or the third party. Moreover, similar extensions may be available in some of the larger economic territories but may not be available in all of our markets of interest.

If we are unable to obtain patent term extension/restoration or some other exclusivity, or the term of any such extension is less than we request, the period during which we can enforce our exclusive rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patent rights. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would materially harm our business, financial condition, results of operations and growth prospects.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to oral sulopenem and sulopenem compounds or formulations but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;

•others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

•it is possible our pending patent applications, and any future patent applications, will not lead to issued patents or afford meaningful protection for our products and product candidates;

•issued patents that we may own in the future or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

•our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

•third parties performing manufacturing or testing for us using our products, product candidates or technologies could use the intellectual property of others without obtaining a proper license; and

•we may not develop additional proprietary technologies that are patentable.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products and product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological complexity and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (the AIA) was signed into law on September 16, 2011, and many of its substantive changes became effective on March 16, 2013.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office (USPTO) after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO, including through post-issuance patent review procedures such as inter partes review, post-grant review and covered business methods. This applies to all U.S. patents, including those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The USPTO has developed regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. Accordingly, it is not clear what, if any, impact the AIA will have on the operation of our business and this may not be known until such time as we, or our licensors or collaboration partners, are filing patent applications for an invention or seeking to defend issued patents. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, the standards that the USPTO and foreign patent office's use to grant patents are not always applied predictably or uniformly and can change. Consequently, any patents we currently license or may own or license in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the ownership, validity, enforceability or term of patents we currently license or may own or license in the future.

For example, the U.S. Supreme Court's rulings on several patent cases, such as Association for Molecular Pathology v. Myriad Genetics, Inc., Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank

International, either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. These changes could limit our ability to obtain new patents in the future that may be important for our business.

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, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability, and the ability of our future collaborators, to develop, manufacture, market and sell ORLYNVAH™, sulopenem and any future product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to ORLYNVAH™, sulopenem or any future product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, e.g., to challenge the validity or scope of intellectual property rights controlled by third parties. In order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court would invalidate the claims of any such U.S. patent. Moreover, third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to

engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such products and/or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product and/or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our products and/or product candidates at issue, which could harm our business significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to commercialize ORLYNVAH™, or further develop and commercialize one or more of our future product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other adversarial proceedings such as proceedings before the Patent Trial and Appeal Board and opposition proceedings in the European Patent Office regarding intellectual property rights with respect to our products and technology.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our products, product candidates or intellectual property could be diminished. Accordingly, the market price of our ordinary shares may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, ability to compete in the marketplace, financial condition, results of operations and growth prospects.

We may not be able to protect our intellectual property rights globally, which could negatively impact our business.

Filing, prosecuting and defending patents covering ORLYNVAH™, sulopenem and any future product candidates globally would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States 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 United States. These products may compete with our ORLYNVAH™ and other 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, 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 any current or future patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our ORLYNVAH™ or other product candidates. Accordingly, our efforts

to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize ORLYNVAH™ or any other product candidates in all of our expected significant foreign markets.

In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, thereby increasing the uncertainty of any potential litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable to challenges in all participating jurisdictions when challenged in a single participating jurisdiction. Given the present uncertainty, we plan to opt out of the UPC where we are able.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which 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. Non-compliance events that could result in abandonment or lapse of a patent or a patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents covering our products, our

competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We, as well as our licensors, also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. For example, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We have not yet registered our trademarks in certain jurisdictions. Failure to secure those registrations could adversely affect our business.

We have registered trademarks for “Iterum” as well as trademarks for oral sulopenem and other potential product candidates in various jurisdictions including the United States, United Kingdom, European Union, Japan, Switzerland and Canada. If we are unable to secure registrations for our trademarks in other countries, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. Any trademark applications we have filed for our products or product candidates or may file in the future are not guaranteed to be allowed for registration, and even if they are, we may fail to maintain or enforce such registered trademarks. During trademark registration proceedings in any jurisdiction, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks.

Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

In addition, any proprietary name we propose to use with product candidates in the United States must be approved by the FDA, and in Europe by the EMA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA and the EMA each typically conduct a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or EMA objects to any proposed proprietary product name for any future product candidates, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under

applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA.

Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our business, financial condition, results of operations and growth prospects.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize future product candidates, and our ability to generate revenue will be materially impaired.

ORLYNVAH™, sulopenem and future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. ORLYNVAH™ is currently our only product approved for sale in the United States.

Although we have QIDP status and fast track designation for sulopenem and oral sulopenem for the indications of uUTI, cUTI and cIAI (and for the indications of community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease) which may provide for a more rapid NDA review cycle, the time required to obtain approval, if any, by the FDA and comparable foreign authorities is unpredictable and typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may also change during the course of a product candidate's clinical development and may vary among jurisdictions. While we have obtained regulatory approval for ORLYNVAH™ for the treatment of uUTIs caused certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, it is possible that we will not be able to obtain regulatory approval for sulopenem or any other product candidates or other indications that we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we or they receive regulatory approval of an NDA(s) from the FDA.

In order to obtain approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe that the non-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities.

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the CMC for the product candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The FDA has substantial discretion in the review and approval process and may refuse to accept for filing any application or may decide that our data is insufficient for approval and require additional non-clinical, clinical or other studies. Foreign regulatory authorities have differing requirements for approval of drugs with which we must comply prior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively affect our ability to obtain marketing approval in other jurisdictions. The FDA or any foreign regulatory body can delay, limit or deny approval of our product candidates or require us to conduct additional non-clinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency's disagreement with the design or implementation of our clinical trials, such as the FDA stating in the CRL received in July 2021 that additional data are necessary to support approval of oral sulopenem, approval of which was ultimately obtained in October 2024;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication(s);
- the FDA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from non-clinical studies or clinical trials;

•our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;

•the FDA's or the applicable foreign regulatory agency's requirement for additional non-clinical studies or clinical trials, such as the FDA's request for additional clinical trial work in the CRL received in July 2021;

•the FDA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling and/or the specifications for our product candidates; or

•the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

Further, under the Pediatric Research Equity Act (PREA), a Biologics License Application (BLA), or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

While we received approval of ORLYNVAH™ for the treatment of uUTIs caused certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options without such contingencies, if we receive approval of an NDA or foreign marketing application for our future product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, often referred to as Phase 4 clinical trials, and the FDA may require the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act (APA). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various

measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the district court in Texas challenging FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the district court declined to dismiss the case and, instead, transferred it to federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and could materially adversely impact our business and prospects.

Disruptions in the FDA 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, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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 and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018, 2019 and 2025 the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, disruptions may result also events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

If a prolonged government shutdown or other disruption 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. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development programs and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the European Medicines Agency and Committee for Medicinal Products for Human Use, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including investigational new drug applications (INDs), requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the recent loss and retirement of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, or review and approval of our product candidates. Pursuant to President Trump's E.O. 14210, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Secretary of the Department of Health and Human Services (HHS) announced on March 27, 2025, a reorganization and reduction in force across HHS of approximately 20,000 employees (82,000 to 62,000), with FDA's workforce of approximately 20,000 to decrease by 3,500 full-time employees. Subsequently, the FDA indicated that roughly a quarter of those employees who received reduction in force notices had been reinstated. On July 14, 2025, following litigation reaching the U.S. Supreme Court, the administration began to carry out these layoffs across HHS, including the FDA. There are also ongoing deliberations within the administration and Congress over potentially substantial proposed cuts to the overall budget for HHS and funding of the FDA for the 2026 federal fiscal year.

Further, while the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under the Prescription Drug User Fee Act (PDUFA), it remains unclear how the administration's reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. For example, while the FDA reduction in force did not reportedly specifically target

FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. There have been several reports in which the FDA failed to meet a PDUFA goal date for approval of a New Drug Application (NDA) or BLA due to heavy workload and limited resources. In addition, while currently unclear, there is a risk that the reduction in force and budget cutbacks could threaten the integrity of the PDUFA program itself. That is because, for the FDA to obligate user fees collected under PDUFA in the first place, a certain amount of non-user fee appropriations must be spent on the process for the review of applications plus certain other costs during the same fiscal year.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, the President has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency" Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention and FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the U.S., and threatening access to federal agency contracts and other funding awards based on companies' otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

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. During 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 and could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs and NDAs or biologics license applications, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

If we are unable to obtain marketing approval in jurisdictions outside the United States, we will not be able to market any product or product candidates outside of the United States.

In order to market and sell ORLYNVAH™, sulopenem or our other future product candidates in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. While we received approval by the FDA for ORLYNVAH™ for the treatment of uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required

to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis or at all.

For example, we obtained scientific advice from the EMA for each of the prior Phase 3 clinical trials in the uUTI, cUTI and cIAI indications, as well as to gain alignment on non-clinical supportive information required for EMA submission. We are not in alignment with regard to the comparator agent selected for the cUTI clinical trial and would need to consider other options to accommodate a European filing for this indication. The EMA may request that we conduct one or more additional clinical trials or non-clinical studies to support potential approval for oral sulopenem and sulopenem for the cUTI indication. We cannot predict how the EMA will interpret the data and results from our Phase 3 clinical trial and other elements of our development program, or whether oral sulopenem or sulopenem will receive any regulatory approvals in the European Union.

Outside of the United States, we continue to evaluate the options to maximize the value of our sulopenem program. We believe that in addition to the United States, Europe represents a significant market opportunity because of rising rates of extended spectrum ß-lactamases (ESBL) resistance.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the U.K. as a result of the withdrawal of the U.K. from the EU, commonly referred to as Brexit. The U.K. is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain (GB) and Northern Ireland). At the same time, a new international recognition procedure (IRP) will apply, which intends to facilitate approval of pharmaceutical products in the U.K. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators (RRs). The RRs notably include EMA and regulators in the EU/European Economic Area (EEA) member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term. In June 2025, after almost two years of negotiations among the European Union Member States, the Council of the European Union adopted its position on the proposed overhaul of the European Union general pharmaceutical legislative framework, which is known as the new Pharma Package. This proposal will now be the subject of additional negotiations and technical meetings, with the objective of reaching agreement on issues such as the regulatory data protection framework and the access and supply obligations. At this point, it appears that the period of market exclusivity for innovator products may be reduced from two years to one, exclusions from patent infringement for studies and trials will likely expand, and there will be a new obligation to ensure sufficient supply of medicines. The revisions may have a significant impact on the pharmaceutical industry and our business in the long term.

The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

While we have received regulatory approval from the FDA for ORLYNVAH™ for the treatment of uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, we will be subject to ongoing obligations and continuing regulatory review, which may result in significant additional expense. Additionally, ORLYNVAH™ and any other product candidates, including sulopenem, if approved, could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with ORLYNVAH™ or any of our product candidates, when and if approved.

ORLYNVAH™ and any other product candidate, including sulopenem, for which we obtain marketing approval will also be subject to ongoing regulatory requirements for labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post marketing information. For example, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to

report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. For example, in addition to reporting of adverse reactions to ORLYNVAH™, post marketing requirements for ORLYNVAH™ also include conducting a U.S. surveillance study over a five-year period after the introduction of ORLYNVAH™ to the market to determine if resistance has increased or decreased susceptibility to ORLYNVAH™ is occurring in the target population of bacteria identified in the approved label for ORLYNVAH™.

In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, may be subject to significant conditions of approval or may impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us. In addition, if any product fails to comply with applicable regulatory requirements, a regulatory agency may:

•issue fines, warning letters, untitled letters or impose holds on clinical trials if any are still ongoing;

•mandate modifications to promotional materials or require provision of corrective information to healthcare practitioners;

•impose restrictions on the product or its manufacturers or manufacturing processes;

•impose restrictions on the labeling or marketing of the product;

•impose restrictions on product distribution or use;

•require post-marketing clinical trials;

•require withdrawal of the product from the market;

•refuse to approve pending applications or supplements to approved applications that we submit;

•require recall of the product;

•require entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;

•suspend or withdraw marketing approvals;

•refuse to permit the import or export of the product;

•seize or detain supplies of the product; or

•issue injunctions or impose civil or criminal penalties.

Similar restrictions apply to the approval of our products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to EU Member State laws.

Accordingly, in connection with our currently approved product and assuming we, or our collaborators, receive marketing approval for one or more other product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe

the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act (PIE Act) signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission (FTC), and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

Further, on September 9, 2025, the President issued a Memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer ("DTC") prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." The same day, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA issued a generic "notice letter" to a substantial number of companies directing such companies to "remove any noncompliant advertising and bring all promotional communications into compliance." We will need to maintain a robust compliance program and processes designed to ensure that all such advertising activities are performed in a legal and compliant manners and anticipated rule changes at the FDA and possibly other agencies.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Any relationships we may have with customers, healthcare providers and professionals and third-party payors, among others, will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we are able to obtain marketing approval. Any arrangements we have with healthcare providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws and

regulations may constrain the business or financial arrangements and relationships through which we conduct clinical research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

- *Anti-Kickback Statute*. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward or in return for, either the referral of an individual for or the purchase, lease or order of a good, facility, item or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid.

- *False Claims Laws.* The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions against individuals or entities for, among other things, knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties.

- *Health Insurance Portability and Accountability Act of 1996 (HIPAA).* HIPAA imposes criminal and civil liability for, among other things, executing a scheme or making materially false statements in connection with the delivery of or payment for health care benefits, items or services. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.

- *Transparency Requirements.* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

- *Analogous State and Foreign Laws.* Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that any business arrangements we have with third parties and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm and the curtailment or restructuring of our operations. Defending against any such actions can be costly, 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States. In addition, payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct,

applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative and regulatory changes, and proposed changes, that could affect the future results of our business and operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. For example, in March 2010 the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act) (ACA) was enacted, which has substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws 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.

Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO), sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriation Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (TCJA), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the PPACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment (HTA), amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop

and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when approved.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, the Department of Health and Human Services (HHS) and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program (SIP), to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America (PhRMA) but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2025, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA. Vermont has submitted a concept letter to the HHS. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it did not originally apply to drugs and biologics that have been approved for a single rare disease or condition. With passage of the One Big Beautiful Bill Act, or OBBBA, on July 3, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. While there had been some questions about the Trump administration's position on this program, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. This second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the new legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions

until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce (Chamber), Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal and, on October 30, 2024, the Court of Appeals for the Third Circuit heard oral argument in three of these cases. In April 2025, the U.S. Court of Appeals for the Second Circuit and the U.S. Court of Appeals for the Third Circuit heard argument in an additional three cases. On May 8, 2025, the Third Circuit rejected AstraZeneca's challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. On May 8, 2025, the Third Circuit rejected AstraZeneca's challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care organizations 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Finally, in the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve

subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company's financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs.

Additionally, if a pharmaceutical company overcharges the government in connection with the Family Self-Sufficiency Program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against a company under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (FCPA), the Irish Criminal Justice (Corruption Offenses) Act 2018, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in that existing laws might be administered or interpreted.

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.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the trade control laws. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

There is no assurance that we will be effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including trade control laws. If we are not in compliance with the FCPA and other anti-corruption

laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We are subject to various laws protecting the confidentiality of certain patient health information, and our failure to comply could result in penalties and reputational damage. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (GDPR), which took effect across all member states of the EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data (including health and other sensitive data), including the following: to provide information to individuals regarding data processing activities; to implement safeguards to protect the security and confidentiality of personal data; to make a mandatory breach notification in certain circumstances; and to take certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities, among other things, to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater. The GDPR also confers a private right of action on data subjects to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data adding to the complexity of processing personal data in the European Union.

In July 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-US Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. One activist has already taken a legal challenge against the EU-U.S.
Data Privacy Framework, which was heard by the EU General Court in April 2025, with the judgment still awaited. The Trump
Administration has also taken various actions which have the potential to call into question the ongoing availability and effectiveness
of the EU-U.S. Data Privacy Framework, such as removing personnel from the Privacy and Civil Liberties Oversight Board and the
FTC. The European Commission is closely following these political developments and has the power to propose the suspension of the
framework if it does not consider that the required level of protection is ensured. In November 2024, the European Data Protection
Board recommended that the European Commission review the EU-U.S. Data Privacy Framework within three years or less. The uncertainty around this issue has the potential to impact our business at the international level.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General are all aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act—which went into effect on January 1, 2020—is creating similar risks and obligations as those created by GDPR, though the Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations

into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

In addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond, including New Hampshire and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that regulates the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2025. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

If we fail to comply with applicable privacy laws, including applicable the federal HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In recent months, the Officer of Civil Rights (OCR) has been especially active in enforcing the HIPAA rules. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Additionally, OCR is looking to amend the HIPAA Security Rule, which (if and when finalized) could create additional compliance obligations and risk for our business.

In addition to potential enforcement by the HHS, we could also be potentially subject to privacy enforcement from the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly. Finally, both the FTC and HHS's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the U.S. to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive US data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities, and could lead to government enforcement actions, private litigation and significant fines and penalties against us, all of which could increase our cost of doing business and have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these

issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Further, we cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Changes in and uncertainty surrounding U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

This past spring, the U.S. government initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, President Trump issued an executive order announcing a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the Trump administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement, or USMCA, and tariffs equaling 20% on China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the Trump administration delayed the effective date of such tariffs for all countries except China to August 1, 2025. Later, the United States and China reached a framework agreement that ultimately resulted in the suspension of the higher reciprocal tariffs on China until November 11, 2025. Since the April announcement, several countries including the European Union, Japan, South Korea, and the United Kingdom, among others, have reached deals with the U.S. that include reduced tariff rates to varying levels and other measures. On July 31, 2025, President Trump issued an Executive Order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The new reciprocal rates, which are consistent with the rates reflected in the trade deals already announced, range from 10% to 41% with imports from Switzerland receiving a 39% rate. The new rates do not apply to Canada, China, Mexico and a few other countries. For China, the 10% baseline reciprocal tariff announced in April remains in effect, in addition to a minimum of an additional 20%., Regarding Canada and Mexico, the rate remains 25%for goods that are not covered by the USMCA for Mexico and, effective August 1, 2025, was increased to 35% on imports from Canada that are not covered by the USMCA. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CMOs and other service providers that operate in China. Certain countries have reached agreements with the U.S. that cap pharmaceutical tariffs at 15%. These include the European Union, Japan, South Korea and the United Kingdom.

Separately, in April 2025, the Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. At the same time, Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, Trump delayed the October 1st effective date of the tariffs on branded or patented pharmaceutical products announcing that the Administration had now "begun preparing" tariffs on manufacturers that don't build in the U.S. or enter into a most-favored-nation (MFN) drug pricing agreement with the Trump administration.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Further, some of our manufacturers and suppliers are located in China. Trade tensions and conflicts between the United States and China have been escalated in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For

example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military.

In addition, in 2024, the U.S. Congress considered legislation referred to as the BIOSECURE Act. If this legislation had been enacted into law, it would have prohibited, subject to limited exceptions, the direct or indirect use of U.S. federal government contract, grant, and loan funds for purchasing biotechnology equipment and services from certain Chinese biotechnology companies, possibly including WuXi entities. On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE legislation as part of its National Defense Authorization Act for FY 2026. Instead of specifying particular Chinese entities for restrictions, the Senate bill would initially target biotechnology companies that have been identified on the so-called 1260H List by the U.S. Department of Defense as Chinese Military Companies Operating in the United States. This list currently includes BGI Group, BGI Genomics Co., Ltd. (BGI), Forensic Genomics International (FGI), and MGI Tech Co., Ltd. (MGI), but does not include WuXi entities. The legislation would allow for other biotechnology companies, possibly including WuXi entities, to be added to the federal funding prohibitions at a later time. The U.S. House of Representatives has passed a version of the bill that does not contain similar biotechnology provisions, so it is not currently known whether the House or Senate language or other language or neither may become law.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our product candidates (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidates used in our preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries, in particular, China, will impose and maintain quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, curtailment of our operations, contractual damages, reputational harm, and diminished potential profits and future earnings, any of which could adversely affect our business, financial condition, results of operations or growth prospects.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our Chief Executive Officer and other key executives and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Corey N. Fishman, our Chief Executive Officer, as well as the other principal members of our management team. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain “key man” insurance with respect to any of our executive officers or key employees.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. 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 develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is

intense, and we may be unable to hire, train, retain or motivate these additional 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. In addition, we have in the past, and may continue to do so in the future, relied on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

We may encounter difficulties in managing growth, which could disrupt our operations.

We could experience growth in the number of our employees and the scope of our operations particularly in the areas of manufacturing, regulatory affairs, sales, marketing and health resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage any expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any growth experienced 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 such growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

In addition, we have and may continue to need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses.

If approvals are obtained outside of the United States, we will be subject to additional risks in conducting business in those markets.

Even if we are able to obtain approval for commercialization of a product candidate in a country outside of the United States, we will be subject to additional risks related to international business operations, including:

- potentially reduced protection for intellectual property rights;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a market outside of the United States (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular economies and markets;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting a product candidate and/or finished drug product supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires, public health crises, or pandemics; and
- failure to comply with Office of Foreign Asset Control rules and regulations and the FCPA.

These and other risks may materially adversely affect our ability to attain or sustain revenue from markets outside of the United States.

We may engage in acquisitions that could disrupt our business, cause dilution to our shareholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. Any such proposed acquisitions may be subject to the consent of certain holders of the RLNs in accordance with the terms and conditions of the RLN Indenture. If we do identify suitable candidates for acquisition, we may not be able to make such acquisitions on favorable terms, or at all, and we may not be able to obtain approval of or consent to such acquisitions from holders of the RLNs. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our ordinary shares or other equity securities to the shareholders of the acquired company, which would reduce the percentage ownership of our then current shareholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In

addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Taxation

As used in this section, Risks Related to Taxation, the term "U.S. Holder" means a beneficial owner of our ordinary shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia or otherwise treated as a "domestic corporation" for such purposes, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust. If a partnership or other pass-through entity holds our ordinary shares, the U.S. federal income tax treatment of a partner in that partnership or entity generally will depend upon the status of that partner and the activities of that partnership or entity.

We have been a passive foreign investment company for U.S. federal income tax purposes in the past and we could be a passive foreign investment company in the future, which could subject U.S. Holders to adverse U.S. federal income tax consequences.

We were a passive foreign investment company (PFIC) for U.S. federal income tax purposes for our taxable year ended December 31, 2017. Based on our gross income and average value of our gross assets, we do not believe we (or our wholly owned non-U.S. subsidiaries) were a PFIC for the taxable year ended December 31, 2018 or for any subsequent completed taxable year. We do not expect to be a PFIC for the taxable year ending December 31, 2025; however, our status, and the status of our non-U.S. subsidiaries, in any taxable year will depend on our assets and activities as determined at various times throughout that taxable year. As our PFIC status is a factual determination made annually after the end of each taxable year, there can be no assurances as to that status for the current taxable year or any future taxable year.

We will be a PFIC in any taxable year if at least (i) 75% of our gross income is "passive income" or (ii) 50% of the average gross value of our assets, determined on a quarterly basis, is attributable to assets that produce, or are held for the production of, passive income. We refer to the passive income test as the "PFIC Income Test" and the asset test as the "PFIC Asset Test".

If we are a PFIC in any taxable year in which a U.S. Holder holds the shares of our stock, subject to the next sentence, we always will be a PFIC with respect to those shares, regardless of the results of the PFIC Income Test or the PFIC Asset Test as applied to us in subsequent taxable years. However, under applicable Treasury regulations, if the preceding sentence applies to a U.S. Holder we will cease to be treated as a PFIC with respect to that U.S. Holder if, in the manner and at the time required by those regulations, the U.S. Holder elects to recognize (and pay tax on, in the manner described in the next paragraph) any unrealized gain in the shares of our stock owned by that U.S. Holder.

If we are a PFIC and a U.S. Holder does not make a mark-to-market election (discussed below) with respect to our ordinary shares, under the so-called "excess distribution" regime that U.S. Holder may be subject to adverse tax consequences, including deferred tax and interest charges, with respect to certain distributions on our ordinary shares, any gain realized on a disposition of our ordinary shares and certain other events. The effect of these tax consequences could be materially adverse to the shareholder. If, in any taxable year during which a U.S. Holder holds our ordinary shares and any of our non-U.S. subsidiaries is a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions.

If a U.S. Holder makes a valid and timely mark-to-market election with respect to our ordinary shares, that U.S. Holder will recognize as ordinary income or loss in each taxable year that we meet the PFIC Income Test or PFIC Asset Test an amount equal to the difference between that U.S. Holder's adjusted basis in our ordinary shares and the fair market value of the ordinary shares, thus also possibly giving rise to phantom income and a potential out-of-pocket tax liability. Ordinary loss generally is recognized only to the extent of net mark-to-market gains previously included in income. The mark-to-market election generally will not be available with respect to any of our subsidiaries that is a PFIC and gain recognized on the sale of our ordinary shares that is attributable to a subsidiary that is a PFIC may result in such gain being subject to deferred tax and interest charges.

In certain circumstances a U.S. Holder may make a qualified electing fund (QEF election), under the U.S. federal income tax laws with respect to that holder's interest in a PFIC. Such an election may mitigate some of the adverse U.S. federal income tax consequences that could otherwise apply to a U.S. Holder under the excess distribution regime. However, we do not expect to provide

U.S. Holders with the information necessary to make a valid QEF election, and U.S. Holders should therefore assume that a QEF election will not be available.

If the IRS determines that we are not a PFIC, and a U.S. Holder previously paid taxes pursuant to a mark-to-market election, that holder may have paid more taxes than the holder legally owed.

If the U.S. Internal Revenue Service (IRS) makes a determination that we were not a PFIC in a prior taxable year and a U.S. Holder previously paid taxes pursuant to a mark-to-market election, that U.S. Holder may have paid more taxes than were legally owed due to such election. If such U.S. Holder does not, or is not able to, file a refund claim before the expiration of the applicable statute of limitations, that U.S. Holder will not be able to claim a refund for those taxes.

Changes to U.S. federal income tax laws could have material consequences for us and U.S. Holders of our ordinary shares.

Future U.S. legislation, U.S. Treasury regulations, judicial decisions and IRS rulings could affect the U.S. federal income tax treatment of us and U.S. Holders of our ordinary shares, possibly with retroactive effect.

Changes in U.S. tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Income, sales, use or other U.S. tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, and cash tax obligations in the U.S. For example, the IRA, was signed into law in August 2022, and the One Big Beautiful Bill Act (OBBBA), was signed into law in July 2025. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a *de minimis* exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules, and the international tax framework. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation.

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

Transfers of our ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company (DTC) should not be subject to Irish stamp duty. Where the ordinary shares are traded through DTC through brokers who hold such ordinary shares on behalf of customers an exemption should be available because our ordinary shares are traded on a recognized stock exchange in the U.S. However, if a shareholder holds their ordinary shares directly rather than beneficially through DTC through a broker, any transfer of their ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty to arise could adversely affect the price of our ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

We have never declared or paid cash dividends on our ordinary shares and we do not expect to pay dividends for the foreseeable future. To the extent that we do make dividend payments (or other returns to shareholders that are treated as "distributions" for Irish tax purposes), it should be noted that, in certain limited circumstances, dividend withholding tax (currently at a rate of 25%) may arise in respect of dividends paid on our ordinary shares. A number of exemptions from dividend withholding tax exist, such that shareholders resident in EU member states (other than Ireland) or other countries with which Ireland has signed a double tax treaty, which includes the United States, should generally be entitled to exemptions from dividend withholding tax provided that the appropriate documentation is in place. The ability of a U.S. Holder to credit any Irish dividend withholding tax against that U.S. Holder's tentative U.S. federal tax liability may be subject to limitations.

Dividends received by Irish residents and certain other shareholders may be subject to Irish income tax.

We have never declared or paid cash dividends on our ordinary shares and we do not expect to pay dividends for the foreseeable future. To the extent that we do make dividend payments (or other returns to shareholders that are treated as "distributions" for Irish tax purposes), it should be noted that shareholders who are entitled to an exemption from Irish dividend withholding tax on dividends received from us will not be subject to Irish income tax in respect of those dividends, unless they have some connection with Ireland other than their shareholding in Iterum Therapeutics plc (for example, they are resident in Ireland) or they hold their ordinary shares through a branch or agency in Ireland which carries out a trade of their behalf. Shareholders who are not resident nor ordinarily

resident in Ireland, but who are not entitled to an exemption from Irish dividend withholding tax, will generally have no further liability to Irish income tax on those dividends which suffer dividend withholding tax.

Our ordinary shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.

Irish capital acquisitions tax (CAT) could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares will be regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

Risks Related to Our Ordinary Shares

An active trading market for our ordinary shares may not be sustained.

Our ordinary shares began trading on the Nasdaq Global Market on May 25, 2018 and on December 23, 2020, we transferred the listing of our ordinary shares to The Nasdaq Capital Market. Given the relatively limited trading history of our ordinary shares and the intermittent volume of trading of our ordinary shares during that time, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our ordinary shares and thereby affect the ability of shareholders to sell their shares. An inactive trading market for our ordinary shares may also impair our ability to raise capital to continue to fund our operations by issuing shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our ordinary shares has been volatile and could be subject to volatility related or unrelated to our operations and our shareholders' investment in us could suffer a decline in value.

Our share price has been and may continue to be volatile. The daily closing market price for our ordinary shares has varied between a high price of $2.91 on December 9, 2025, and a low price of $0.58 on November 6, 2025, in the twelve-month period ending on November 12, 2025. During this time, the price per ordinary share has ranged from an intra-day low of $0.57 per ordinary share to an intra-day high of $3.02 per ordinary share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ordinary shares at or above the price paid for the shares.

We may continue to incur rapid and substantial increases or decreases in our stock price in the foreseeable future that may not coincide in timing with the disclosure of news or developments by or affecting us. Accordingly, the market price of our ordinary shares may fluctuate dramatically, and may decline rapidly, regardless of any developments in our business.

The trading price of our ordinary shares could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The market price for our ordinary shares may be influenced by those factors discussed elsewhere in this "Risk Factors" section of this document and others, such as:

- a failure to maintain or expand our sales force, marketing and/or distribution capabilities in respect of the ongoing commercialization of ORLYNVAH™ in the United States;
- results from, and any delays in, clinical trials;
- announcements of regulatory approval, failure to obtain regulatory approvals or receipt of a "complete response letter" from the FDA with respect to any of our product candidates;
- our need to raise additional funds;
- announcements relating to changes to our capital structure including a reorganization, recapitalization, share split or reverse share split, exchange of shares, or any similar equity restructuring transaction;
- the sentiment of retail investors including the perception of our clinical trial results by such retail investors, which investors may be subject to the influence of information provided by social media, third party investor websites and independent authors distributing information on the internet;
- manufacturing and supply issues related to our development programs and commercialization of ORLYNVAH™, sulopenem or any of our future product candidates;
- quarterly variations in our results of operations or those of our competitors;
- changes in our earnings estimates or recommendations, or withdrawal of coverage, by securities analysts;
- announcements by us or our competitors of new product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- announcements relating to future development or license agreements including termination of such agreements;
- adverse developments with respect to our intellectual property rights or those of our principal collaborators;

•commencement of litigation involving us or our competitors;

•changes in our board of directors, management, or key scientific personnel;

•new legislation in the United States relating to the prescription, sale, distribution or pricing of drugs;

•product liability claims, other litigation or public concern about the safety of ORLYNVAH™, sulopenem or future products;

•failure to comply with the Nasdaq Capital Market continued listing requirements;

•market conditions in the healthcare market in general, or in the antibiotics segment in particular, including performance of our competitors;

•publication of research reports about us or our industry, or antibiotics in particular;

•changes in the market valuations of similar companies;

•sales of large blocks of our ordinary shares by our existing shareholders; and

•general economic conditions in the United States and abroad, including resulting from geo-political actions, including war and terrorism, natural disasters, including earthquakes, hurricanes, typhoons, floods and fires, public health crises, or pandemics.

In addition, the stock market in general, or the market for equity securities in our industry, may experience extreme volatility unrelated to our operating performance. In recent years, the market for pharmaceutical and biotechnology companies in particular has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose shares are experiencing those price and volume fluctuations. These broad market fluctuations may adversely affect the trading price or liquidity of our ordinary shares regardless of our actual operating performance. Any sudden decline in the market price of our ordinary shares could trigger securities class-action lawsuits against us. If any of our shareholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the time and attention of our management would be diverted from our business and operations. We also could be subject to damages claims if we are found to be at fault in connection with a decline in our share price.

The volatility of our shares and shareholder base may hinder or prevent us from engaging in beneficial corporate initiatives.

Our shareholder base is comprised of a large number of retail (or non-institutional) investors, which creates more volatility since shares change hands frequently. In accordance with our governing documents and applicable laws, there are a number of initiatives that require the approval of shareholders at an annual or extraordinary general meeting of shareholders. To hold a valid meeting, a quorum comprised of one or more Members (as defined in our Amended and Restated Constitution) whose name is entered in our register of members as a registered holder of our ordinary shares, present in person or by proxy (whether or not such Member actually exercises his voting rights in whole, in part or at all), holding not less than a majority of our issued and outstanding ordinary shares entitled to vote at a meeting of shareholders, is required. A record date is established to determine which shareholders are eligible to vote at the meeting, which record date must not be more than 60 days prior to the date of the meeting. Since our shares change hands frequently, there can be a significant turnover of shareholders between the record date and the meeting date which makes it harder to get shareholders to vote. While we make every effort to engage retail investors, such efforts can be expensive and the frequent turnover creates logistical issues for obtaining shareholder approval. Further, retail investors tend to be less likely to vote in comparison to institutional investors. Failure to secure sufficient votes may impede our ability to move forward with initiatives that are intended to grow the business and create shareholder value or prevent us from engaging in such initiatives at all. If we find it necessary to delay or adjourn meetings or to hold multiple meetings to secure sufficient shareholder votes, it will be time consuming and we will incur additional costs. For example, at our annual general meeting of shareholders held on September 10, 2025, proposals to increase our authorized share capital (the Share Capital Increase) and provide authority for our board of directors to issue ordinary shares (the Share Issuance Authority) were not passed with the requisite majority of votes, despite the Share Capital Increase and the Share Issuance Authority being needed to allow us to issue additional ordinary shares in capital raising transactions, to continue to fund our operations and implement our business plans, including the ongoing commercialization of ORLYNVAH™ in the United States.

If we fail to comply with the listing requirements of the Nasdaq Capital Market, we may be delisted and the price of our ordinary shares, our ability to access the capital markets and our financial condition could be negatively impacted and the delisting of our ordinary shares would result in an event of default and/or fundamental change under our debt instruments.

Our ordinary shares are currently listed for quotation on the Nasdaq Capital Market. To maintain the listing of our ordinary shares on the Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others:

•a minimum closing bid price of $1.00 per share, and

•a market value of publicly held shares (excluding shares held by our officers, directors and 10% or more shareholders) of at least $1.0 million.

In addition to the above requirements, we must meet at least one of the following requirements:

•shareholders' equity of at least $2.5 million; or

•a market value of listed securities of at least $35 million; or

•net income from continuing operations of $500,000.

On August 25, 2025, we received a letter from the Listing Qualifications Department of Nasdaq, indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), which requires us to maintain a minimum bid price of $1.00 per share, or the Bid Price Rule, for continued listing on the Nasdaq Capital Market. The notice does not result in the immediate delisting of our ordinary shares from the Nasdaq Capital Market. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until February 23, 2026, to regain compliance with the Bid Price Rule. To regain compliance during this 180-day compliance period, the closing bid price of our ordinary shares must be at least $1.00 for a minimum of 10 consecutive business days.

In the event that we do not regain compliance with the Bid Price Rule prior to the expiration of the 180-day compliance period, we may be eligible for an additional 180-day compliance period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Bid Price Rule, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse share split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not otherwise eligible, Nasdaq will provide notice that our ordinary shares are to be subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. However, there can be no assurance that, if we appeal any delisting determination by Nasdaq to the panel, such appeal would be successful.

We intend to actively monitor the closing bid price of our ordinary shares and, as appropriate, will consider all available options to resolve the deficiency and regain compliance with the Bid Price Rule and remain listed on the Nasdaq Capital Market. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule during the 180-day compliance period, secure an additional 180-day compliance period, maintain compliance with the other Nasdaq listing requirements or be successful in appealing any delisting determination.

Although we have been able to regain compliance with Nasdaq listing requirements within the manner and time periods prescribed by Nasdaq in the past, there can be no assurance that we will be able to maintain compliance with the Nasdaq Capital Market continued listing requirements in the future or regain compliance with respect to any future deficiencies. This could impair the liquidity and market price of our ordinary shares. In addition, the delisting of our ordinary shares from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our ordinary shares as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

Through the RLNs, we transferred to the holders thereof rights to receive certain payments in connection with commercial sales of sulopenem, which may reduce our ability to realize potential future revenue from such sales.

As part of the Private Placement and subsequent 2020 Rights Offering, Iterum Bermuda issued RLNs which entitle the holders thereof to certain payments in connection with commercial sales of sulopenem. Holders of RLNs are entitled to payments based solely on a percentage of our net revenues from U.S. sales of specified sulopenem products (Specified Net Revenues). Payments will be due within 75 days of the end of each six-month payment measuring period (each, a Payment Measuring Period), beginning with the Payment Measuring Period ending June 30, 2020 until (i) the "Maximum Return" (as defined below) has been paid in respect of the RLNs, or (ii) December 31, 2045 (the End Date) but will not entitle the holders thereof to any payments unless the Company earns net revenues on such approved sulopenem product. The aggregate amount of payments in respect of all RLNs during each Payment Measuring Period will be equal to the product of total Specified Net Revenues earned during such period and the applicable payment rate, being 15%.

Prior to the End Date, Iterum Bermuda will be obligated to make payments on the RLNs from Specified Net Revenues until each RLN has received payments equal to $160.00 (or 4,000 times the principal amount of such RLN) (the Maximum Return). The principal amount of the RLNs, equal to $0.04 per RLN, is the last portion of the Maximum Return amount to which payments from Specified Net Revenue are applied. If any portion of the principal amount of the outstanding RLNs has not been paid as of the End Date, Iterum Bermuda must pay the unpaid portion of the principal amount. If Iterum Bermuda fails to pay any amounts on the RLNs that are due and payable, such defaulted amounts will accrue default interest at a rate per annum equal to the prime rate plus three percent (3.00%). Default interest will also accrue on the Principal Amount Multiple (as defined in the RLN Indenture) as a result of certain other defaults under the RLN Indenture at a rate per annum equal to four percent (4.00%).

Iterum Bermuda may at any time redeem for cash all, but not less than all, of the RLNs, at its option. The redemption price per RLN will be equal to the Maximum Return for each RLN, less payments made through and including the redemption date, plus certain

accrued but unpaid default interest (if any). Upon a change of control of our company, we will require the ultimate beneficial owner or owners controlling the acquiring person or persons to guarantee the obligations of Iterum Bermuda under the RLN Indenture.

The payment obligations under the RLNs will reduce the revenue we are able to derive from commercial sales of ORLYNVAH™ and a redemption of the RLNs would require us to use our cash resources, which could adversely affect the value of our company and the prices that investors are willing to pay for our ordinary shares and could adversely affect our business, financial condition and results of operations.

If securities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our ordinary shares, our share price and trading volume could decline.

The trading market for our ordinary shares relies, in part, on the research and reports that industry or financial analysts publish about our company. If no, or only a few, analysts publish research or reports about our company, the market price for our ordinary shares may be adversely affected. Our share price also may decline if any analyst who covers us issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our share performance, or if our pivotal safety and efficacy studies and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

The issuance of additional ordinary shares may dilute our existing shareholders' level of ownership in our Company or require us to relinquish rights.

Any issuance of securities we may undertake, whether in the future to raise additional capital or upon exchange or exercise of outstanding convertible securities, could cause the price of our ordinary shares to decline, or require us to issue shares at a price that is lower than that paid by holders of our ordinary shares in the past, which would result in those newly issued shares being dilutive.

The outstanding warrants (including any pre-funded warrants) that we issued the purchasers and/or the designees of the placement agent and underwriter, as applicable, in connection with the February 2021 Underwritten Offering, the February 2021 Registered Direct Offering and the 2024 Rights Offering are exercisable at any time until a specified expiration date, and any exercise of outstanding warrants will increase the number of shares outstanding, which may dilute the ownership percentage or voting power of our shareholders.

Similarly, the outstanding warrants that we issued SVB and Life Sciences Fund II LLC in connection with the secured credit facility we had in place with SVB are exercisable at any time until April 27, 2028, and any exercise of such warrants will increase the number of shares outstanding, which may dilute the ownership percentage or voting power of our shareholders. Additionally, the exercise of outstanding options and vesting of restricted share units under our equity incentive plans or equity inducement incentive plan or exercise of other outstanding warrants for ordinary shares may also dilute the ownership percentage or voting power of our shareholders.

Further, if we obtain funds through the sale of equity or a debt financing or through the issuance of convertible debt or preference securities, these securities would likely have rights senior to the rights of our ordinary shareholder, which could impair the value of our ordinary shares. Any debt financing we enter into may include covenants that limit our flexibility in conducting our business. We also could be required to seek funds through arrangements with collaborators or others, which might require us to relinquish valuable rights to our intellectual property or product candidates that we would have otherwise retained.

Sales of a substantial number of our ordinary shares in the public market, or the perception that these sales could occur, could cause our share price to fall.

A substantial portion of our outstanding ordinary shares can be traded without restriction at any time. If our current shareholders sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of our ordinary shares could decline.

A portion of our outstanding ordinary shares is currently restricted as a result of federal securities laws but can be sold at any time subject to applicable volume limitations.

In addition, on October 7, 2022, we entered into the Sales Agreement with HC Wainwright, as agent, pursuant to which we may offer and sell ordinary shares from time to time through HC Wainwright by any method permitted that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. On October 16, 2025 we filed a prospectus supplement with the SEC pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to $20.0 million through HC Wainwright pursuant to the Sales Agreement. We cannot predict if and when shares sold pursuant to the Sales Agreement, if any, will be resold in the public markets. Any of our outstanding shares that are not restricted as a result of securities laws may be resold in the public market without restriction unless purchased by our affiliates.

Furthermore, ordinary shares that are issuable upon exercise of outstanding options or reserved for future issuance under our equity incentive plans and equity inducement plan or are issuable upon exercise of our outstanding warrants and pre-funded warrants will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules or

performance criteria, and applicable securities laws. If any of these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.

Shareholders may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if a shareholder sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider:

•that it did not have jurisdiction;

•that it was not the appropriate forum for such proceedings;

•that, applying Irish conflict of law rules, U.S. law (including U.S. securities laws) did not apply to the relationship between the shareholder and us or our directors and officers; or

•that the U.S. securities laws were of a penal nature and violated Irish public policy and should not be enforced by the Irish court.

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

A judgment obtained against us will be enforced by the courts of Ireland only if the following general requirements are met:

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

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

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

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

•the judgment was obtained by fraud;

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

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

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

As an Irish company, we are governed by the Irish Companies Act 2014 (the Irish Companies Act), which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

Our shareholders should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time and attention to our public reporting obligations.

As a publicly traded company, we have incurred and will continue to incur significant additional legal, accounting and other expenses compared to historical levels. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations

promulgated and to be promulgated thereunder, as well as under the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) and the rules and regulations of the SEC and the Nasdaq Capital Market, have created uncertainty for public companies and increased our costs and time that our board of directors and management must devote to complying with these rules and regulations. We expect these rules and regulations to continue to increase our legal and financial compliance costs substantially and lead to diversion of management time and attention from revenue-generating activities.

We are an "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our ordinary shares less attractive to investors.

We are a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). We may remain a smaller reporting company until we have a non-affiliate public float of at least $250 million and annual revenues of at least $100 million or a non-affiliate public float of at least $700 million, each as determined on an annual basis. For so long as we remain a smaller reporting company, we are permitted to take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, on the design and effectiveness of our internal controls over financial reporting; and
- reduced disclosure about our executive compensation arrangements.

Investors may find our ordinary shares less attractive if we rely on certain or all of these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may decline or become more volatile.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of the applicable listing standards of the Nasdaq Capital Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our consolidated financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our ordinary shares. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Capital Market.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a smaller reporting company with less than $100 million in revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404, we engaged and continue to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Additionally, we will be unable to issue securities in the public markets through the use of a shelf registration if we are not in compliance with Section 404.

Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our ordinary shares.

We have never paid cash dividends, do not anticipate paying any cash dividends and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.

We have never declared or paid cash dividends on our ordinary shares and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Any determination to pay dividends in the future will be at the sole discretion of our board of

directors after considering our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors our board of directors deems relevant, and subject to compliance with applicable laws, including the Irish Companies Act which requires Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. Distributable reserves are the accumulated realized profits of the company that have not previously been utilized in a distribution or capitalization less accumulated realized losses that have not previously been written off in a reduction or reorganization of capital. Unless the company creates sufficient distributable reserves from its business activities, the creation of such distributable reserves would involve a reduction of the company's share premium account, which would require the approval of (i) 75% of our shareholders present and voting at a shareholder meeting, and (ii) the Irish High Court. In the event that we do not undertake a reduction of capital to create distributable reserves, no distributions by way of dividends, share repurchases or otherwise will be permitted under Irish law until such time as the company has created sufficient distributable reserves from its business activities.

Accordingly, the only opportunity for a shareholder to achieve a return on their investment in our company is expected to be if the market price of our ordinary shares appreciates and they sell their ordinary shares at a profit.

Anti-takeover provisions in our Articles of Association and under Irish law could make an acquisition of us more difficult, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

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

- dividing our board of directors into three classes, with each class serving a staggered three-year term;
- permitting our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- permitting our board of directors to issue preference shares, with such rights, preferences and privileges as they may designate;
- establishing an advance notice procedure for shareholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; and
- imposing particular approval and other requirements in relation to certain business combinations.

These provisions would apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Provisions in the RLN Indenture may deter or prevent a business combination that may be favorable to the holders of our ordinary shares.

The RLN Indenture prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the RLNs, the RLN Indenture and the guarantees and the RLN Indenture prohibits us from selling, transferring or assigning certain assets and prohibits Iterum Bermuda, the Guarantors or any of our significant subsidiaries from undergoing a change of control, other than in connection with a change of control of us. These and other provisions in the RLN Indenture could deter or prevent a third party from acquiring us even when the acquisition may be favorable to the holders of our ordinary shares.

Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

Following the authorization for trading of our ordinary shares on the Nasdaq Global Market on May 25, 2018, we became subject to the Irish Takeover Panel Act, 1997, Irish Takeover Rules 2022 (Irish Takeover Rules). Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options, restricted share units or convertible securities, (ii) the redemption or repurchase of securities by the Company (save in certain circumstances), (iii) material acquisitions or disposals, (iv) entering into contracts other than in the ordinary course of business, or (v) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in a jurisdiction of the United States.

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

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of the company, then the acquirer and/or, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for all of the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months (known as a mandatory cash offer). This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company, if the effect of such acquisition was to increase that person's percentage of the voting rights by 0.05% within any 12 month period.

Under the Irish Takeover Rules, certain separate concert parties are presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of our shares. The application of these presumptions may result in restrictions upon the ability of any such concert parties and/or members of our board of directors to acquire more of our securities, including under any executive incentive arrangements. We, or any such holders, may consult with the Irish Takeover Panel from time to time with respect to the application of this presumption and the restrictions on the ability to acquire further securities, although we are unable to provide any assurance as to whether the Irish Takeover Panel would overrule this presumption. Accordingly, the application of the Irish Takeover Rules may restrict the ability of certain of our shareholders and directors to acquire our ordinary shares.

As an Irish public limited company, certain capital structure decisions require shareholder approval, which may limit our flexibility to manage our capital structure.

Under Irish law, our authorized share capital can be increased by an ordinary resolution of our shareholders and the directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our Articles of Association or by a resolution approved by not less than 50% of the votes cast at a general meeting of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory pre-emption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory pre-emption rights either in our Articles of Association or by way of a resolution approved by not less than 75% of the votes cast at a general meeting of our shareholders. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, at an extraordinary meeting of our shareholders on October 8, 2024, our shareholders authorized the board to issue new shares, and to disapply statutory pre-emption rights for such issuances up to the amount of our authorized but unissued share capital until May 3, 2028. The authorization of the directors to issue shares and the disapplication of statutory pre-emption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, or be approved without limitations, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

We could be subject to securities class action litigation that could divert management's attention and harm our business.

In the past, securities class action litigation has often been brought against a company following a significant business transaction, such as the announcement of a financing or a strategic transaction, or the announcement of a negative event, such as a negative regulatory decision. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our cash resources and/or our ability to consummate a potential strategic transaction.

Item 5. Other Information

Securities Trading Plans of Directors and Executive Officers

During the three months ended September 30, 2025, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

The following is a list of exhibits filed or furnished as part of this Quarterly Report on Form 10-Q:

Exhibit No.	Description of Document	Filed with this report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File Number
10.1†	Commercial Manufacturing and Supply Agreement, dated July 18, 2025, by and between Iterum Therapeutics International Limited and ACS Dobfar S.p.A.	X			
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	Inline XBRL Instance Document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)	X			

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

ITERUM THERAPEUTICS PLC

Date: November 14, 2025	By:	/s/ Corey Fishman **Corey Fishman** President and Chief Executive Officer
Date: November 14, 2025	By:	/s/ Judith Matthews **Judith Matthews** Chief Financial Officer

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

COMMERCIAL MANUFACTURING AND SUPPLY AGREEMENT

This Commercial Manufacturing and Supply Agreement (this ***"Agreement"***) is made as of this 18th day of July, 2025 by and between Iterum Therapeutics International Limited, having its registered office address at 25 North Wall Quay, Dublin 1, D01 104, Ireland (***"Iterum"***) and **ACS Dobfar S.p.A**, having a principal place of business at Viale Addetta 2/12, 20067 Tribiano, Milan, Italy, together with its Affiliates (***"Supplier"***).

WITNESSETH:

WHEREAS, Iterum owns rights to the Products (as defined below) and wishes to engage Supplier for the commercial manufacture and supply of the Products; and

WHEREAS, Supplier is willing to manufacture and supply the Products for and to Iterum on the terms and conditions set out in this Agreement

NOW, THEREFORE, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are recited herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The following words and phrases when used herein with capital letters shall have the meanings set forth or referenced below:

1.1*"Additional Advance Payment Invoice"* means an invoice issued by Supplier to Iterum in accordance with Section 5.2 (b);

1.2"***Advance Payment***" means a payment made by Iterum on an Advance Payment Invoice or an Additional Advance Payment Invoice issued in accordance with Section 5.2 (a) and/or Section 5.2 (b), as the context so requires;

1.3"***Advance Payment Invoice***" means an invoice issued by Supplier to Iterum in accordance with Section 5.2 (a);

1.4*"Affiliate"* means, with respect to a Party, any corporation, partnership, joint venture and/or firm which controls, is controlled by or is under common control with such Party. As used in this Section 1.5, ***"control"*** means: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors; and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity;

1.5 *"Applicable Law"* means all applicable ordinances, rules, regulations, laws, guidelines, requirements and court orders of any kind whatsoever of any national (e.g., the FDA, EPA, etc.), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity of the US or EU, including, but not limited to, the U.S. Federal Food, Drug, and Cosmetic Act, as amended (the "***Act***"), and the regulations promulgated thereunder; European Directive 2003/94/EC and 2001/83/EC, and any amendments thereto and related legislation (if and when applicable); and all applicable cGMP;

1.6*"Batch"* means a specific quantity of the Products that is intended to have a uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture;

1.7*"Business Day"* means a day which is not a Saturday or Sunday or a bank or public holiday in the Republic of Ireland and/or Italy;

1.8*"Certificate of Analysis"* or ***"CoA"*** means a document, signed by an authorized representative of Supplier, describing (a) the Product Specifications; and (b) testing methods applied to the Product in order to verify compliance with the Product Specifications, and the results thereof;

1.9*"Certificate of Compliance"* means a document, signed by an authorized representative of Supplier, attesting that a particular Batch was manufactured in accordance with cGMP, Applicable Law, and the Product Specifications. The Certificate of Compliance may be included within the Certificate of Analysis, or separately, if required by Iterum for regulatory purposes or Applicable Law;

1.10*"cGMP"* means those principles and guidelines of good manufacturing practices, including as set forth in: (a) the U.S. Food, Drug & Cosmetics Act (21 U.S.C. § 301 *et seq.*) and related U.S. regulations, including 21 Code of Federal Regulations (Chapters 210, 211, 600 and 610) and other FDA regulations, policies, or guidelines in effect at a particular time for the manufacture, testing and quality control of investigational drugs; (b) EudraLex Volume 4; (c) the ICH guide Q7 "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients;" and (d) any other laws, regulations and statutes set forth by a government authority applicable to the manufacture of compounds and products by Supplier under this Agreement;

1.11"***Competing Product***" means, for the purposes of Article 8 (Intellectual Property Rights), any products substantially similar to Sulopenem and/or sulopenem etzadroxil at the signature date of this Agreement. For the purposes of the Agreement, a product will be considered to be substantially similar to Sulopenem if [**] and shall be part of an oral antibiotic developed for the treatment of multi-drug resistant infections;

1.12*"Components"* means collectively, all raw materials, intermediates, excipients and other components to manufacture the Products in accordance with the Product Specifications, including, for the avoidance of doubt, the Iterum Components;

1.13*"Confidential Information"* means all information provided by or on behalf of one Party (the ***"Disclosing Party"***) to the other Party ("***Receiving Party***") in connection with this Agreement or the MSA, including, without limitation, all data, inventions and information developed in or as a result of the performance of this Agreement, whether in oral, written, graphic or electronic form, except any portion thereof which:

(a) is known to the Receiving Party at the time of the disclosure, as evidenced by its written records or other competent evidence;

(b) is disclosed to the Receiving Party by a Third Party lawfully in possession of such information and not under an obligation of nondisclosure;

(c) is or becomes patented, published or otherwise part of the public domain through no fault of the Receiving Party or its Affiliates; or

(d) is developed by or for the Receiving Party without access to or use of the disclosing Party's Confidential Information, as evidenced by the recipient's written records;

1.14 "***Effective Date***" means the later of (i) date of issue of the first Purchase Order by Iterum pursuant to Section 3.2 of this Agreement, or (ii) July 14, 2025;

1.15*"EMA"* means the European Medicines Agency and any successor organization;

1.16"***Expiration Event***" shall have the meaning given to that term in Section 2.5 (c);

1.17*"Facilities"* means Supplier's facilities at *[**]*, or such other manufacturing site agreed to by the Parties in writing;

1.18*"FDA"* means the United States Food and Drug Administration or any successor organization;

1.19 "***Final Invoice***" means the final invoice issued by Supplier to Iterum in accordance with Section 5.2 (c);

1.20"***Forecasts***" shall have the meaning given to that term in Section 3.1;

1.21*"Intellectual Property"* means all patents, copyrights, trade secrets, know-how and all other intellectual property rights, anywhere in the world, including all applications and registrations with respect thereto, but excluding all trademarks, trade names, service marks, logos and other corporate identifiers;

1.22"***Iterum Components***" means those components forming part of the Components to be procured by Supplier in accordance with Section 2.5 (b), as set forth in Exhibit C hereto and the Product Specifications, and as may be changed from time to time as agreed between the Parties;

1.23"***Iterum Components Purchasing Plan***" means the Iterum Components to be purchased by Supplier under Iterum's contracted conditions with suppliers of Iterum Components as instructed by Iterum on delivery of the Forecast (as defined in Section 3.1);

1.24 *"Iterum Intellectual Property"* means all Intellectual Property and trademarks owned or controlled by Iterum as of the date of this Agreement or developed or acquired by Iterum outside of the performance of this Agreement after the date of this Agreement. For purposes of this definition, "controlled by" means possession of the right to grant a license or sublicense without violating (a) any law or governmental regulation applicable to such license or sublicense or (b) the terms of any agreement or other arrangement with any Third Party;

1.25"***LOI***" means the binding letter of intent entered into between the Parties, dated [**] setting out the intention of the parties to enter into commercial arrangements for the supply and manufacture of the Products as amended and supplemented from time to time;

1.26"***Manufacture***" or "***Manufacturing***" means all steps and activities necessary to produce the Products to be performed by Supplier, including, without limitation and as applicable, the manufacturing, formulation, filling, packaging, inspection, labeling (including serialization), testing, quality control and release;

1.27*"Manufacturing Process"* means the Manufacturing process for the Products;

1.28*"Master Batch Record"* means the document that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the manufacture and testing of the Products, which may be amended in writing from time to time by mutual agreement of the Parties;

1.29"***MSA***" means the Master Services Agreement entered into by the Parties, dated [**].

1.30*"Party"* means Supplier or Iterum. "***Parties***" means Supplier and Iterum.

1.31"***Product A***" shall have the meaning given to that term in Exhibit A;

1.32"***Product B***" shall have the meaning given to that term in Exhibit A;

1.33"***Product C***" shall have the meaning given to that term in Exhibit A and, for the avoidance of doubt, shall be ordered by Iterum for the purpose of further processing by the Supplier in the manufacture of Product B;

1.34"***Products"*** means Product A, Product B and Product C described in Exhibit A which are to be manufactured and/or supplied by Supplier pursuant to this Agreement and "***Product***" shall mean any one of them;

1.35*"Product Specifications"* means those products, labeling and performance (including release testing) specifications for the Products as set out in the Quality Agreement.

1.36*"Purchase Order"* shall have the meaning given to that term in Section 3.2;

1.37"***Quality Agreement***" means the quality agreement entered into between the Parties, dated [**], ensuring that the Products ordered by Iterum conform to accepted cGMPs and other quality assurance standards, as may be amended from time to time.

1.38*"Regulatory Authority"* means any federal, state or local or other regulatory agency, department, bureau or other governmental entity, (including the FDA, the EMA and the Italian competent authority), which is responsible for issuing approvals, licenses, registrations or authorizations necessary for the manufacture, use, storage, import, transport, sale and use of the Products in any applicable regulatory jurisdiction;

1.39*"Supplier Intellectual Property"* means all Intellectual Property owned or controlled by Supplier as of the date of this Agreement or developed or acquired by Supplier outside of this Agreement subsequent to the date of this Agreement. For purposes of this definition, ***"controlled by"*** means possession of the right to grant a license or sublicense without violating (a) any law or governmental regulation applicable to such license or sublicense or (b) the terms of any agreement or other arrangement with any Third Party.; and

1.40*"Third Party"* means a party other than Supplier or Iterum and their respective Affiliates.

ARTICLE 2
MANUFACTURE AND SUPPLY OF PRODUCTS

2.1*Supply of Products*. During the Term and subject to the terms and conditions of this Agreement Supplier shall manufacture for and supply Iterum with the Products.

2.2*Manufacturing Standards*. Supplier shall manufacture the Products in accordance with the Product Specifications, the Manufacturing Process and all Applicable Laws ("***Manufacturing Standards***"). The Parties may amend the Product Specifications from time to time by written agreement without amending this Agreement. Further, all Products manufactured for Iterum hereunder shall be manufactured by Supplier at the Facilities.

2.3*Government Approvals; Regulatory Matters*. Supplier shall secure and maintain in good order, at its sole cost and expense, such current governmental registrations, permits and licenses as are required by Regulatory Authorities and make all such filings and submissions, including any applicable drug master file ("***DMF***") to the extent required to be filed by the Supplier under local law, in order for Supplier to perform all of its obligations under this Agreement. Supplier shall be solely responsible for all scheduling related to the Facilities and for the operation of the Facilities.

2.4*Components*.

(a)Supplier shall be responsible for the procurement and qualification of the Components (excluding the Iterum Components) required for the manufacture of the Products. Supplier will source all such components from suppliers listed in the Product Specifications that have been approved and qualified by Supplier in accordance with Supplier's internal vendor qualification and approval processes which have also been approved by Iterum prior to the entry into of this Agreement.

(b)Supplier shall order sufficient quantities of all Components (excluding the Iterum Components) to enable Supplier to manufacture and deliver at least [**] percent ([**]%) of the Products under Iterum's then current Forecast (as defined in Section 3.1) in accordance with Section 3.1.

2.5*Iterum Components*.

(a)Supplier shall order Iterum Components as instructed by Iterum pursuant to the Iterum Components Purchasing Plan.

(b)The purchase of Iterum Components by Supplier shall be made under Iterum's contracted conditions with suppliers of Iterum Components and as instructed by Iterum pursuant to the Iterum Components Purchasing Plan. On receipt of the Iterum Components, Supplier agrees to carry out release testing of relevant batches in accordance with the contracted conditions with suppliers of Iterum Components within the timeframes set out in Exhibit D. Iterum shall be responsible for necessary audits of suppliers of Iterum Components and the cost of any such audits, the frequency of such audits to be based upon site and regulatory requirements. To the extent requested by Supplier, Iterum shall make every effort to allow Supplier qualified personnel to participate in such audits of suppliers of Iterum Components. In the event a Supplier qualified person is prohibited from participating in such an audit, Supplier will provide audit requirements and templates that can be substituted such that Supplier can meet its vendor qualification obligation. Iterum agrees to use commercially reasonable efforts to conduct an audit of the suppliers of Iterum Components or procure that an audit can be conducted via an independent third party on behalf of Supplier for confidentiality reasons, at Suppliers request if Iterum has the right to do so under the applicable contracted conditions with such supplier of Iterum Components. Each Party shall be responsible for their respective costs and expenses in connection with an audit. Notwithstanding the foregoing, in the event that an independent third party is engaged to conduct an audit, the Party who has engaged such independent third party shall be responsible for the costs and expenses in connection therewith, save that in the event an independent third party is engaged for confidentiality reasons, Iterum and Supplier shall cover all such costs and expenses in connection therewith in equal proportions. Iterum shall provide to Supplier a copy of any reports of deficiencies discovered as a result of an audit of any suppliers of Iterum Components or otherwise and shall provide a written action plan for the prompt resolution of any such deficiencies and/or a report of the full resolution of same. For the avoidance of doubt, both Parties shall mutually agree the corrective actions to be taken by any supplier of Iterum Components as a result of any such audit.

(c)To the extent that Supplier has procured the Iterum Components pursuant to the Iterum Purchasing Plan on Iterum's contracted conditions in accordance with Section 2.5(a), save in the event of negligence on the part of Supplier, Supplier shall not be responsible in the event that the shelf life of any such Iterum Components purchased in accordance with the Iterum Purchasing Plan expires following the date of such procurement, prior to use in the normal course to satisfy a Purchase Order ("***Expiration Event***"). For the avoidance of doubt, there shall be no refund to Iterum of any Advance Payments made to Supplier under this Agreement following an Expiration Event. Save in the event of negligence of Supplier, Iterum shall be responsible for any costs associated with any additional Iterum Components required as a result of an Expiration Event.

(d)With the exception of an Expiration Event and subject to Section 2.5 (c), Supplier shall reimburse Iterum for any Iterum Components required during the manufacturing process, which (i) as a result of negligence or omission of Supplier or breach of this Agreement or the Quality Agreement by Supplier, cannot be used in the manufacture of any Product, or (ii) which have been used in the manufacture of a Product but has not resulted in a Product being free from all defects, including, without limitation any Iterum Components used in failed or rejected Batches or in a defective product. Iterum shall also be reimbursed for any direct fees associated with such Iterum Components, including transportation fees, insurance and disposal costs.

(e)In lieu of reimbursement in accordance with Section 2.5 (b), at its absolute discretion, Iterum may agree that Supplier can rework or reprocess any Iterum Components and/or Product(s) with the result that (i) some or all of such Iterum Components can be used in the manufacture of a Product and/or (ii) the failed or rejected Batches can be deemed to have been manufactured in compliance with Manufacturing Standards. In such circumstances, Supplier shall be responsible for all costs associated with any such rework and/or reprocessing and shall compensate Iterum for any reduced yield as a result of such rework or reprocessing and or any Iterum Components which remain unusable after such rework or reprocessing. Any rework and reprocessing activities to be conducted shall be agreed in advance with Iterum, completed as soon as reasonably possible and carried out in accordance with all Applicable Laws.

(f)For the avoidance of doubt, Supplier shall be in the importer of record for all Iterum Components.

2.6*Exclusivity*. During the Term, Supplier shall not, directly or indirectly, manufacture for, or supply any of the Products to, any Third Party or for the benefit of Supplier or its Affiliates.

2.7*Project Management*.

(a)Each Party shall, within [**] after the date of this Agreement, appoint up to [**] individuals each to act as project leaders ("***Project Managers***") who shall be responsible for leading and coordinating the day to day operation of the Parties' activities under this Agreement. The Project Managers shall (i) manage the relationship between the Parties, (ii) oversee the performance of the services hereunder, (iii) undertake actions delegated to them by the Parties; and (iv) be the principal point of contact for the services hereunder. The Project Managers shall meet upon reasonable request either in person or by telephone or video-conference and each Party shall bear its own costs for attending such meetings.

(b)In addition, within [**] after the date of this Agreement, each Party shall select [**] of their senior technical staff or such additional number of people from each Party's senior technical staff as may be required from time to time to address specific topics (each a "***Project Team Member***"), one or more of whom (for each Party) may be a Project Manager, to form the project team who shall have responsibility for providing leadership and oversight of the activities under this Agreement ("***Project Team***"). The Project Team shall be responsible for (i) reviewing the decisions of the Project Managers, (ii) providing a forum for the Parties to exchange information and coordinate their respective activities regarding the services, any cost reduction opportunities identified in accordance with Section 5.3, and reporting on inventions developed in the course of Supplier's manufacture of the Products, (iii) providing a forum to discuss any technical difficulties or changes to services or Batch Price triggered by a change to the Services or in accordance with Section 5.3; (iv) resolving any disputes or disagreements before escalation to the dispute resolution provided for in Section 11.4, and (v) ensure that intent of this Agreement is maintained throughout the Term. The Project Team shall meet on a reasonably regular basis during the Term, either in person or by telephone or video-conference and each Party shall bear its own costs for attending such meetings.

ARTICLE 3
ORDERS AND FORECASTS

3.1*Product Supply Forecast*.

(a)For capacity planning purposes, commencing on the Effective Date, Iterum shall submit to Supplier on a [**] basis on or before the first business day of each [**] an [**] non-binding rolling forecast that sets forth the total quantity of each Product for commercial supply that Iterum either has ordered, desires to order, or expects to order from the Supplier (the "***Forecast***").

(b)Commencing on the Effective Date and for a period of [**] from the date thereof, the first [**] of the Forecast shall be binding on Iterum and constitute a firm order. The subsequent [**] of the Forecast submitted by Iterum in the [**] of supply shall be for planning purposes only, and thus shall not be binding. Iterum may adjust the Forecast with respect to the [**] of the Forecast by up to [**] percent ([**]%) and Supplier shall use commercially reasonable efforts to produce and deliver to Iterum any said additional quantities in accordance with any applicable Purchase Order issued by Iterum. If, for any reason, the Forecast contains a zero quantity order of any Product(s) in a given month, Iterum shall be entitled to adjust such zero Forecast up to the quantity in the preceding month having a non-zero Forecast, and Supplier shall use commercially reasonable efforts to produce and deliver to Iterum any said additional quantities in accordance with any applicable Purchase Order issued by Iterum.

(c)From the first anniversary of the Effective Date, the first [**] of each Forecast submitted shall be binding on Iterum and constitute a firm order. The remaining [**] of each Forecast submitted by Iterum shall be for planning purposes only, and thus shall not be binding. Iterum may adjust the Forecast with respect to the [**] of the Forecast by up to [**] percent ([**]%) and Supplier shall use commercially reasonable efforts to produce and deliver to Iterum any said additional quantities in accordance with any applicable Purchase Order (issued by Iterum).

(d)Commencing on the Effective Date, Supplier shall reserve sufficient capacity at the Facilities to manufacture at least [**] percent ([**]%) of each Product under Iterum's then current Forecast, which shall include, where the context so requires, capacity to manufacture any Components required to be manufactured by the Supplier in accordance with the Product Specifications.

3.2*Purchase Orders*. Iterum shall submit a purchase order (***"Purchase Order"***) to Supplier at least [**] prior to the requested delivery date of the Products. Each Purchase Order shall reference this Agreement and shall be governed exclusively by the terms contained herein. Any terms or conditions contained in a Purchase Order that are inconsistent or in conflict with this Agreement shall be deemed not to be a part of such Purchase Order. Following the date the Parties enter into this Agreement, the Parties agree that the Purchase Order dated [**], issued initially under the MSA, will be governed solely by this Agreement and any remaining fees to be paid under such Purchase Order shall be invoiced and paid pursuant to Section 5.1 and Section 5.2 of this Agreement.

3.3*Purchase Order Acceptance*. Each Purchase Order shall specify the Products ordered and the time, manner and address of delivery, all of which shall be subject to this Article 3. Supplier shall notify Iterum as to whether any Purchase Order delivered pursuant to this Section 3.3 has been accepted or rejected within [**] following Supplier's receipt of such order; provided that Supplier may only reject a Purchase Order which fails to comply with the requirements of this Article 3. Supplier's failure to affirmatively reject a Purchase Order within the [**] period shall be deemed an acceptance of such Purchase Order, notwithstanding the Purchase Order's failure to comply with the requirements of this Article 3. In the event that Supplier rejects a Purchase Order hereunder, Supplier shall notify Iterum in writing within [**] of the reasons why such order was rejected by Supplier. Iterum may, at its option, submit a revised Purchase Order.

3.4*Shortage of Supply; Supply Failure*.

(a)In the event that Supplier is unable to manufacture and supply the Products in accordance with Iterum's Purchase Orders, Supplier shall notify Iterum promptly. If the inability is not: (i) caused by an event of *force majeure*; or (ii) primarily attributable to Iterum's acts or omissions or breach of its obligations under this Agreement, then Supplier shall be solely responsible for undertaking all commercially reasonable measures to minimize any possible shortage of Products to Iterum as a result of its manufacturing issues. If Supplier cannot undertake such measures promptly, then either Party may request that the Parties convene a meeting to discuss possible remedial action. For the sake of clarity, the provisions of this Section 3.4 are not Iterum's sole remedy in the event of Supplier's inability to supply the Products in accordance with the Purchase Order.

(b)In the event Supplier is aware of possible delays in the fulfilment of any of the Iterum's Purchase Orders or if the Supplier is unable to manufacture and supply the Products in accordance with Section 3.4 (a), Supplier shall promptly inform Iterum and shall make its best efforts to ensure the Purchase Order is fulfilled within the expected date of delivery of the Product indicated in the Purchase Order. In the event that the Purchase Order is not fulfilled within [**] of the due date of delivery of the Product indicated in the Purchase Order and where the delay is attributable to Supplier, without limiting Supplier's liability hereunder and without prejudice to any other remedy Iterum may be entitled to pursue, the price to be paid by Iterum pursuant to the relevant Purchase Order shall be reduced by an amount of [**] percent ([**]%) of the overall value of such Purchase Order. The price of the Purchase Order shall be reduced by further amounts of [**] percent ([**]%) of

the overall value of the Purchase Order for every [**] of delay in the delivery of the Product, up to a maximum of [**] percent ([**]%) of total reduction.

3.5*Alternative Supplier*.

(a)Nothing in this Agreement shall preclude Iterum, at any time during this Agreement, from qualifying an alternate supplier to provide manufacturing services for the Products; *provided, however*, that Iterum will be responsible for all of the costs and expenses of such qualification.

(b)If Iterum exercises its option to transfer the manufacture of the Products to an alternate supplier in accordance with Article 3.5 (a), Supplier shall reasonably assist Iterum for a reasonable period of time in such transfer (including conducting a technology transfer consistent with the transfer of information described in Section 9.7) at Iterum's costs.

(c)In the event that Iterum should validate an alternative supplier after the date of this Agreement, Iterum will guarantee to Supplier the following minimum quantities of supply volumes:

(i)in respect of Product B, [**]% of Iterum's commercial requirements of Product B as set out in the then current Forecast; and

(ii)in respect of Product C, [**]% of Iterum's commercial requirements of Product C as set out in the then current Forecast.

3.6*Title and Delivery Terms*.

(a)Supplier shall ship all accepted Product A and Product B to Iterum or to Iterum's designated consignee or otherwise deal with accepted Product A and Product B in accordance with instructions received from Iterum from time to time. For the avoidance of doubt, Supplier shall be the exporter of record on all shipments of Product A and Product B.

(b)Title to Product A and Product B shall transfer to Iterum upon fulfilment by Supplier of its obligations in accordance with the relevant Incoterm set out in Section 3.6(c) or as defined in the relevant Purchase Order, [**]. For the avoidance of doubt, title to Product C, which shall be used by Supplier in the manufacture of Product B, will be retained by Supplier for onward processing and Supplier shall be responsible for all risks related thereto including insurance covering damage or loss while in either of the Facilities and any transport costs to transport Product C between the Facilities.

(c)Product A and Product B shall be shipped EXW or FCA Supplier's Facility (Incoterm 2020), by a common carrier designated by Iterum. Supplier will charge all reasonable costs of shipping and transit insurance to Iterum. Iterum shall have the right to request that any Product(s) be shipped under different Incoterms at any time during the term of the Agreement provided that the parties shall agree who will be responsible for shipping and transit insurance prior to shipment.

3.7*Shipping Instructions*. Iterum will provide Supplier with packaging and shipping instructions including temperature requirements, temperature monitoring instructions and packaging specifications. Notwithstanding any other provision of this Agreement, Supplier will not be liable for any loss or damage caused solely by Supplier's compliance with Iterum's packaging and shipping instructions or any loss or damage caused by Iterum's carrier.

3.8*Quality; Inspection; Nonconforming Shipment*.

(a) ***Inspection; Rejection***. Upon completion of the manufacture of each Batch, Supplier will provide Iterum with a copy of the Master Batch Record and all other documents and records as required by

the Quality Agreements for release of Products to be delivered to Iterum, including an appropriate Certificate of Analysis and Certificate of Compliance. In addition, Supplier shall, as requested upon reasonable written notice by Iterum, provide Iterum with Product samples from the relevant Batch. In respect of Product A and Product C, Iterum shall have a period of [**] from the date of its receipt of all such documentation and samples to inspect, and accept or reject, the corresponding Batch as conforming or non-conforming with the Manufacturing Standards. In respect of Product B, Iterum shall have a period of [**] from the date of its receipt of all such documentation and samples to inspect, and accept or reject, the corresponding Batch as conforming or non-conforming with the Manufacturing Standards. If Iterum rejects any Batch of Product(s), it shall promptly so notify Supplier. If, as a result of further review and testing, Supplier determines that the Batch does conform to the Manufacturing Standards, the Parties shall submit samples of such Batch to a mutually acceptable laboratory for independent testing.

(b)***Testing***. If such independent laboratory determines that the shipment conformed to the Manufacturing Standards, Iterum shall bear all expenses of shipping and testing such shipment samples. In relation to Product A and Product C, if Supplier or such independent laboratory confirms that such shipment did not meet the Manufacturing Standards, Supplier shall rework or reprocess that portion of the Product A/Product C shipment which does not conform to the Manufacturing Standards as soon as reasonably possible, at Suppliers cost and expense so that the Batch can be deemed to have been manufactured in compliance with Manufacturing Standards. If the reworked or reprocessed Product A/Product C cannot conform to Manufacturing Standards, Supplier shall replace, at no cost to Iterum, that portion of the Product A/Product C shipment which does not conform to the Manufacturing Standards and shall bear all expenses of shipping and testing the shipment samples. In relation to Product B, if Supplier or such independent laboratory confirms that such shipment did not meet the Manufacturing Standards, Supplier shall replace[**] that portion of the Product B shipment which does not conform to the Manufacturing Standards and shall bear all expenses of shipping and testing the shipment samples. Iterum shall dispose of any nonconforming portion of any shipment of Product A or Product B (as the case may be) as directed by Supplier, at Supplier's expense.

(c)***Deemed Acceptance; Latent Defects***. Any Product(s) that Iterum does not reject pursuant to this Section 3.8 shall be deemed accepted, except as to latent defects which are not discoverable by the exercise of ordinary diligence and reasonable care and render the Product(s) not conforming to the Manufacturing Standards at the time of delivery to Iterum. In the event that a latent defect is discovered at any time during the then shelf life of the Products, the Parties shall consult to confirm the cause of the latent defect. If the Parties do not agree as to whether the Product(s) is non-conforming the Parties shall submit samples of such Product(s) to a mutually acceptable independent laboratory for testing in accordance with Section 3.8 ((b) above. If it is confirmed that the cause of the defect is attributable to Supplier, then Supplier will replace [**] all such defective Products with Products that meet the Manufacturing Standards and the other relevant provisions of Section 3.8 shall apply.

ARTICLE 4
QUALITY; REGULATORY MATTERS

4.1*Quality Agreements*. The Parties covenant and agree to use commercially reasonable efforts to update and revise the Quality Agreements as appropriate for the commercial manufacture and supply of the Products pursuant to this Agreement within [**] after the date of this Agreement or such later date as may be agreed between the Parties.

4.2*Audit Rights; Regulatory Authority Inspections*

(a)***General Audit***. Upon [**] prior written notice to Supplier, Iterum shall have the right to have representatives visit the Facility during normal business hours to review Supplier's manufacturing operations relating to the Products and assess its compliance with Applicable Laws, cGMP, the Product Specifications, this Agreement and the Quality Agreements and to discuss any related issues with Supplier's

manufacturing and management personnel. Supplier shall provide Iterum with copies of all relevant documentation for the purposes of assuring Product quality and compliance with agreed-upon manufacturing procedures. To the extent that documentation provided as part of a general audit contains Confidential Information of the Supplier which is not relevant to the Products or the Manufacturing Process, this will be available for review at the Facility, but copies may only be taken by Iterum to the extent that such Confidential Information has been redacted. Such general audits may be conducted not more than [**].

(b)***For Cause Audits***. Iterum shall also have the right to conduct "for-cause" audits to address Products or safety concerns as discovered through Product failures related to Supplier's manufacture of the Products and/or quality issues identified by Iterum or any Regulatory Authority in any audit or inspection conducted in accordance with this Section 4.2. Product failures would include issues related to stability, out of specification, labeling or container integrity where there is reason to believe such Product failures are related to Supplier's manufacture of the Products or issues arising from Supplier activities. Iterum shall notify Supplier in writing in advance of the audit and thereafter, Iterum and Supplier shall mutually determine the timing of the audit.

(c)***Observation Rights.*** Iterum shall have the right, at Iterum's sole cost and expense, during normal business hours and upon reasonable notice, to visit the Facility to observe the Manufacturing of the Products. At all times while in attendance at the Facility, Iterum agrees to comply with all Supplier policies and procedures applicable to visitation of the Facility as notified by Supplier to Iterum prior to or during such attendance. Such visits shall not unreasonably interfere with Supplier's operations and shall not exceed [**] occurrences in any year or such additional number as may be reasonable given the volume of Manufacturing runs during the particular year.

(d)***Regulatory Authority Inspections***. Supplier agrees to allow Regulatory Authorities to conduct inspections related to the manufacture of the Products which such Regulatory Authority requires, and Supplier agrees to reasonably cooperate with such Regulatory Authority in connection with such inspection. The provisions contained in the Quality Agreements relating to Regulatory Authority inspections shall apply.

4.3*Regulatory Filings*. Supplier will provide Iterum with a copy of any submissions it is obligated to make to any Regulatory Authorities relating to the Products or the services hereunder prior to its submission to the relevant Regulatory Authorities and shall consider and reasonably incorporate Iterum's comments thereto. Supplier grants Iterum the right to use or refer to any and all information contained therein, including without limitation a right of reference to the Product DMF filed by Supplier (to the extent such DMF filing is required to be made by the Supplier pursuant to local laws) and Iterum shall provide Supplier with details of any submissions made to Regulatory Authorities which include reference Supplier.

4.4*Record Keeping*. Supplier shall retain all records relating to the manufacture of each Batch of Product for not less than [**] from the date of release, unless required to retain such records for longer under Applicable Law. Records shall be stored by Supplier in accordance with the provisions of the Quality Agreements. Thereafter, Supplier shall not destroy such records without giving Iterum prior written notice and the opportunity to further store such records or have such records shipped to Iterum, at Iterum's cost and expense.

4.5 *Product Recalls.*

(a)If either Party becomes aware of information about distributed Products indicating that it may be non-conforming with respect to the Product Specifications or that there is potential adulteration, misbranding, serialization errors and/or any potential issues regarding safety or effectiveness with respect to the Products, it shall promptly serve written notice to that effect on the other Party. If such issue relates to the manufacture of the Products or the Manufacturing Process, Supplier shall initiate an investigation and assessment of such circumstances and shall provide Iterum a written report of its findings and any proposed course of action to remedy such issue.

(b)In the event: (i) any Regulatory Authority or other national government authority issues a request, directive or order that Product be recalled; (ii) a court of competent jurisdiction orders such a recall; or (iii) Iterum reasonably determines that a Product should be recalled, the Parties shall take all appropriate corrective actions and shall cooperate in any governmental investigations surrounding the recall. In the event Supplier reasonably determines that a Product should be recalled, Supplier shall provide notice to Iterum including all relevant information that supports such determination by Supplier. Iterum shall reasonably consider such information; provided that the institution of a recall shall be in Iterum's sole discretion. Iterum will have the responsibility for all communications with Regulatory Authorities and customers regarding any recall of Products. Supplier will give Iterum any assistance that Iterum may reasonably require to handle any recall.

(c)In the event: (i) any Regulatory Authority or other national government authority issues a request, directive or order that Product be recalled; (ii) a court of competent jurisdiction orders such a recall; or (iii) Iterum reasonably determines that a Product should be recalled, the Parties shall take all appropriate corrective actions and shall cooperate in any governmental investigations surrounding the recall. In the event Supplier reasonably determines that a Product should be recalled, Supplier shall provide notice to Iterum including all relevant information that supports such determination by Supplier. Iterum shall reasonably consider such information; provided that the institution of a recall shall be in Iterum's sole discretion. Iterum will have the responsibility for all communications with Regulatory Authorities and customers regarding any recall of Products. Iterum will consult with Supplier in relation to any other appropriate corrective actions to be taken by Supplier in connection with a recall and will consider Supplier's comments in good faith before including details of such corrective actions in any communications with Regulatory Authorities. Supplier will give Iterum any assistance that Iterum may reasonably require to handle any recall.

ARTICLE 5

Price and Payment.

5.1*Price*.

(a)Supplier shall invoice Iterum for each of Product A and Product B delivered by Supplier at the price as set forth on Exhibit B, less any Advance Payments made by Iterum in accordance with Section 5.2.

(b) Each Final Invoice for Product A and Product B shall reference the relevant price of the tier/volume in effect on the date of Supplier's invoice and any credit for the Advance Payment and/or the Additional Advance Payment applied in accordance with Section 5.2.

(c) The Parties agree that the price set out in Exhibit B shall be reviewed [**] and updated to reflect any changes agreed between the Parties and/or any cost reductions identified in accordance with Section 5.3 ("***Exhibit B Amendment***"). An Exhibit B Amendment shall be effective without amending this Agreement if it is evidenced in writing and is signed by the Parties and any such Exhibit B Amendment shall automatically replace the then current Exhibit B. The revised price will be applied starting from the delivery requested from [**], unless otherwise agreed. Notwithstanding the provisions of this Section 5.1 (c), the prices set out in Exhibit B on the Effective Date shall not be amended prior to [**].

5.2*Payment*.

(a)Within [**] of receipt of an invoice for Iterum Components (the "***Third Party Invoice***") ordered in accordance with Section 2.5 from a Third-Party supplier of Iterum Components to be used in the various steps of the supply chain, Supplier shall issue an invoice to Iterum for an Advance Payment (the "***Advance Payment Invoice***") equaling the cost of such Iterum Components in accordance with the Third Party Invoice, which shall be credited against the cost of Product B or Product A, as applicable, to be purchased by Iterum pursuant to a Purchase Order accepted by Supplier in accordance with Section 3.3. The amount of the credit to be applied shall be based on the cost of the Iterum Components required in the manufacture of the relevant Product(s) set out in the applicable Purchase Order (calculated in accordance with Exhibit B).

Notwithstanding the foregoing, the Parties agree that any additional costs incurred by Supplier in connection with the purchase of the Iterum Components, including any transport costs, duties or taxes, shall be invoiced separately by Supplier to the Iterum and shall not be subject to credit. The invoice for the Advance Payment will be issued in EURO currency using the applicable USD exchange rate on Euro foreign exchange reference rates on the date of the issuance of the Third-Party Invoice.

(b)Where it is necessary to manufacture Product C for use in the manufacture of Product B for a particular Purchase Order, Supplier will issue an invoice for an additional advance payment (the "***Additional Advance Payment***") equaling the "Product C Conversion Cost" computation set forth in Section 2 of Exhibit B(an "***Additional Advance Payment Invoice***").

The Additional Advance Payment shall be credited against the cost of Product B to be purchased by Iterum pursuant to a Purchase Order accepted by Supplier in accordance with Section 3.3 based on the amount of Product C required in the manufacture of the relevant Product(s) set out in the applicable Purchase Order.

(c)The Final Invoice for the balance of payment due in respect of each Purchase Order for Product B and/or Product A accepted in accordance with Section 3.3 taking into account the Advance Payment already made in accordance with Section 5.2 (a) and any Additional Advance Payment, if any, made in accordance with Section 5.2 (b), shall be issued by Supplier to Iterum upon shipment of Product B.

(d)With the exception of the Advance Payment Invoice, Iterum shall make payment on all undisputed invoices within [**] after the date of receipt of Supplier's invoice. With respect to the Advance Payment Invoice, Iterum shall make payment on all undisputed Advance Payment Invoices within the later of (i) [**] after the date of receipt of Supplier's invoice and (ii) the date on which Supplier approves batch conformance in respect of the applicable Iterum Components, being within [**] after receipt of such Iterum Components. For the avoidance of doubt, an Advance Payment Invoice will not be issued where Supplier has not approved batch conformance for the applicable Iterum Components.

5.3 Supplier shall, on an ongoing basis, use commercially reasonable efforts to identify opportunities to reduce the cost of manufacturing the Products (***"Cost Reduction Program"***). The Cost Reduction Program shall include [**]. Supplier shall notify Iterum of any such cost reduction opportunities identified. The Parties, through the Project Team, shall discuss any cost reducing opportunities identified through the Cost Reduction Program or otherwise (including opportunities independently identified or developed by Iterum) and shall confer in good faith to (i) capitalize on such opportunities by sharing in the cost of implementation; and (ii) adjust the price of Products paid under this Agreement in proportion [**] to the benefit of such improvement by reducing the price of the Products by [**]% of the cost savings achieved. For the avoidance of doubt, no changes shall be implemented until such time as Iterum has had an opportunity to consider the impact of any proposed changes in accordance with the terms of the Quality Agreements.

5.4*Taxes*. Any federal, state, county or municipal sales or use tax, excise, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against income), license, fee or other charge (other than that assessed against Supplier's net income) lawfully assessed or charged on the manufacture, sale or transportation of Products sold pursuant to this Agreement, and all government license filing fees and Prescription Drug User (PDUFA) annual establishment fees, with respect to all Products shall be paid by Iterum.

ARTICLE 6
WARRANTIES AND COVENANTS

6.1*Supplier's Warranties and Covenants*. Supplier represents and warrants to Iterum that:

(a)all Products delivered to Iterum pursuant to this Agreement shall, at the time of delivery, not be adulterated or misbranded within the meaning of the Act or within the meaning of all Applicable Law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, as the Act and such laws are constituted and effective at the time of delivery, and will not be an article which may not under the provisions of Sections 404 and 505 of the Act be introduced into interstate commerce;

(b)all Products delivered to Iterum pursuant to this Agreement shall, at the time of delivery, be free from defects in material and workmanship and shall be: (i) manufactured and tested in accordance and conformity with the Product Specifications, Manufacturing Process and the Master Batch Record; (ii) manufactured in compliance with all Applicable Laws, including those relating to the environment, food or drugs and occupational health and safety, including those enforced or promulgated by the FDA (including compliance with cGMP); and (iii) transferred to Iterum free and clear of any liens or encumbrances of any kind;

(c)Supplier owns or lawfully controls the Facility, has the permits required to operate the Facility, and the Facility shall be maintained in accordance with cGMP and in such condition as will allow Supplier to manufacture the Products in compliance with cGMP, in conformance with the Master Batch Record, and in compliance with all Applicable Laws;

(d)In its performance of its obligations under this Agreement, Supplier will not knowingly incorporate into the Manufacturing Process any patents or know-how of a Third Party for which it does not have a license that permits it to do so and/or to be able to grant to Iterum the licenses and other rights otherwise required to be granted to Iterum hereunder;

(e)Supplier's performance of its obligations under this Agreement will not result in a material violation or breach of any agreement, contract, commitment or obligation to which Supplier is a party or by which it is bound and will not conflict with or constitute a default under its corporate charter or bylaws; and

(f)Neither it, nor any of its officers, directors or employees expected to perform services hereunder has been debarred or convicted of a crime which could lead to debarment under 21 U.S.C. Section 335a and 335b and that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b).

6.2*Disclaimer of Warranties*. EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER ITERUM NOR SUPPLIER MAKES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS OR OTHERWISE UNDER THIS AGREEMENT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY SUPPLIER AND ITERUM.

ARTICLE 7
INDEMNIFICATION AND LIABILITY

7.1*Indemnification by Supplier*. Supplier shall indemnify and hold harmless Iterum, its Affiliates, officers, directors and employees from and against all claims, causes of action, suits, costs and expenses (including reasonable attorney's fees), losses or liabilities of any kind related to this Agreement and asserted by Third Parties ("Losses") to the extent such arise out of or are attributable to: (a) Supplier's breach of this Agreement; (b) any violation of any proprietary right of any Third Party relating to Supplier's manufacturing processes used in the manufacture of the Products pursuant to this Agreement; or (c) any negligent or wrongful act or omission or willful misconduct on the part of Supplier, its employees, agents or representatives. Notwithstanding anything to the contrary herein, the foregoing indemnity shall not apply to the extent such

Losses arise out of or result from any material breach of this Agreement by Iterum, or the negligent or wrongful acts or omissions or willful misconduct of Iterum or its employees, agents or representatives.

7.2*Indemnification by Iterum*. Iterum shall indemnify and hold harmless Supplier, its Affiliates, officers, directors and employees from and against all Losses to the extent such arise out of or are attributable to: (a) Iterum's breach of this Agreement; (b) the use of the Products; or (c) any negligent or wrongful act or omission or willful misconduct the part of Iterum, its employees, agents or representatives and which relate to Iterum's performance hereunder. Notwithstanding anything to the contrary herein, the foregoing indemnity shall not apply to the extent such Losses arise out of or result from any material breach of this Agreement by Supplier, or the negligent or wrongful acts or omissions or willful misconduct Supplier or its employees, agents or representatives.

7.3*Conditions of Indemnification.* If either Party seeks indemnification from the other hereunder, it shall promptly give notice to the other Party of any such claim or suit threatened, made or filed against it which forms the basis for such claim of indemnification and shall cooperate fully with the other Party in the investigation and defense of all such claims or suits. The indemnifying Party shall have the option to assume the other Party's defense in any such claim or suit with counsel reasonably satisfactory to the other Party. In the event the indemnifying Party assumes such defense, the indemnified Party shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense. No settlement or compromise shall be binding on a Party hereto without its prior written consent, such consent not to be unreasonably withheld.

7.4*No Consequential Damages*. EXCEPT WITH RESPECT TO THE INDEMNIFICATION OBLIGATIONS OF SECTIONS 7.1 OR 7.2 OR A BREACH OF THE CONFIDENTIALITY OBLIGATIONS OF ARTICLE 10, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR LOST PROFITS RESULTING FROM ANY BREACH OF THIS AGREEMENT, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

7.5*Insurance*.

(a)Each party shall procure and maintain during the Term and through the date that is [**] after the expiration date of all Products Manufactured under this Agreement; (i) Commercial General Liability insurance of not less than "$[**] for each occurrence for bodily injury liability, property damage liability, contractual liability, and not less than $[**] annual aggregate limit, (ii) Professional Liability insurance with not less than $[**] per occurrence and $[**] aggregate, (iii) Products Liability insurance with not less than $[**] per occurrence and $[**] aggregate. Each Party shall promptly deliver a certificate of Insurance to the other Party evidencing such coverage.

(b)Supplier shall use commercially reasonable efforts to procure and ensure it maintains during the Term and through the date that is [**] after the expiration date of all Products Manufactured under this Agreement, Network Security and Privacy Liability with not less than $[**] per occurrence and $[**] aggregate (the "***IT Security Insurance Coverage***"). Supplier shall promptly deliver a certificate of Insurance to Iterum evidencing such coverage. In the event that Supplier fails to procure the IT Security Insurance Coverage within [**] of entering into this Agreement, Supplier shall notify Iterum of such failure and provide an update on the reason(s) Supplier has not been able to procure such coverage. For the avoidance of doubt, Supplier's failure to comply with Section 7.5(b) shall not be deemed a breach of this Agreement.

ARTICLE 8
INTELLECTUAL PROPERTY RIGHTS

8.1*Ownership of Intellectual Property Developed under this Agreement*.

(a)Iterum shall be the sole owner of any technology, inventions, know-how or other proprietary rights that are made, conceived or reduced to practice by Supplier in connection with the performance of this Agreement that pertain to a Product (***"Project Inventions"***) and Supplier shall and hereby does assign all of its right, title and interest in Project Inventions, and all Intellectual Property therein, to Iterum. Iterum shall be entitled to apply for patent protection on such Project Inventions at Iterum's expense and risk. Supplier agrees to execute such assignments and other documents, to cause its employees, consultants and subcontractors to execute such assignments and other documents, and to take such other actions as may be reasonably requested by Iterum from time to time in order to effect to the ownership provisions of this Section 8.1(a).

(b)With respect to all other technology, inventions, know-how or other proprietary rights that are made, conceived or reduced to practice in connection with the performance of this Agreement, the following terms of ownership shall apply: Iterum shall solely own all know-how and inventions made solely by employees, consultants and/or subcontractors of Iterum (the ***"Iterum Project IP"***) and Supplier shall solely own know-how made and inventions made solely by employees, consultants and/or subcontractors of Supplier (the ***"Supplier Project IP"***). The Parties shall jointly own any know-how and inventions made, developed or reduced to practice jointly by employees, consultants and/or subcontractors of Iterum and employees, consultants and/or subcontractors of Supplier in the course of their performance of this Agreement (the ***"Joint Project IP"***). Each Party shall have the right to exploit and license the Joint Project IP without the prior consent of the other Party; provided that Supplier shall not, without the express written consent of Iterum which shall not unreasonably be withheld or delayed, exploit, use or license the Joint Project IP to manufacture, develop or commercialize any Competing Product. Iterum shall control the filing, prosecution, maintenance and enforcement of any patents or patent applications covering the Joint Project IP and shall keep Supplier regularly informed with respect to such activities, The costs of any such filings, prosecution, maintenance and enforcement shall be borne by Iterum. Supplier shall, at Iterum's request, reasonably assist and cooperate in the filing, prosecution, maintenance and enforcement of any Joint Project IP. For the avoidance of doubt, this Section 8.1 (b) is subject always to the provisions of Section 8.1 (a).

(c)Supplier shall promptly provide Iterum written notice of technology, inventions, know-how or other proprietary rights that are made, conceived or reduced to practice during the performance of this Agreement. The Project Team shall discuss such disclosures to ensure that all Project Inventions, Iterum Project IP, Supplier Project IP and Joint Project IP are appropriately identified.

8.2*License Grants*.

(a)***License to Supplier***. During the Term, Iterum hereby grants to Supplier a fully paid, non-exclusive license under any and all Iterum Intellectual Property, Project Inventions and Iterum Project IP that is necessary for Supplier to perform its obligations under this Agreement, for the sole and limited purpose of Supplier's performing its obligations under the Project Plan and this Agreement.

(b)***License to Iterum***. Supplier hereby grants to Iterum an irrevocable, fully paid, royalty-free, perpetual, worldwide, non-exclusive license, with the right to grant and authorize sublicenses, under any and all Supplier Intellectual Property or Supplier Project IP that Supplier incorporates into the Manufacturing Process or that is otherwise necessary for the practice of the Manufacturing Process, for the sole and limited purpose of manufacturing, or having manufactured, the Products.

ARTICLE 9
TERM AND TERMINATION

9.1*Term*. This Agreement shall commence on the date of this Agreement and, unless earlier terminated as provided below, shall expire at the end of the fifth (5th) year after the Effective Date (***"Initial Term"***) and shall thereafter automatically renew for additional two (2) year periods (each a "***Renewal Term"*** and together with the Initial Term, the ***"Term***"). Notwithstanding any of the foregoing, either Party may terminate this Agreement *provided, however*, that it has given the other Party at least twenty-four (24) months

("***Notice Termination Period***") prior written notice of termination and provided that such notice shall not be given before the third (3rd) year anniversary of the Effective Date.

9.2*General Termination Rights*. Either Party may terminate this Agreement as follows:

(a) Immediately by providing written notice to the other Party (i) if proceedings in voluntary or involuntary bankruptcy are initiated by, on behalf of or against the other Party (and, in the case of any such involuntary proceeding, not dismissed within [**]), or (ii) if the other Party is adjudicated bankrupt, files a petition under insolvency Laws, is dissolved or has a receiver appointed for substantially all of its property; or

(b)Upon the material breach of any provision of this Agreement by the other party if such breach is not cured by the breaching party within [**] after receipt by the breaching party of written notice of such breach.

(c)Upon notice to the other Party should the other Party continue to be unable to perform its obligations under this Agreement for a period in excess of [**] by reason of *force majeure*, in accordance with Section 11.1.

9.3*Supply*. Unless Supplier has terminated this Agreement pursuant to Section 9.2(a) and 9.2(b), notwithstanding the termination of this Agreement, Iterum shall have the right, upon written notice to Supplier within [**] of the effective date of such termination, to provide Supplier with its total need of the upcoming [**]. Supplier has the right to manufacture and invoice the full requested quantity during the Notice Termination Period and Iterum shall pay the total quantity according to the terms of this Agreement. The delivery date for such additional Product(s) shall be mutually agreed by the Parties. Notwithstanding the foregoing, Iterum may request Supplier to keep in stock the undelivered quantity up to [**] following the Termination Period ("***Extended Storage Term***") at Iterum's expense. For the avoidance of doubt, notwithstanding termination of this Agreement, all of the terms of this Agreement reasonably expected to apply to such manufacture and supply during the Notice Termination Period and Extended Storage Term shall continue to apply to the manufacture and supply of the Product(s) during the Notice Termination Period and Extended Storage Term.

9.4*Accrued Payment Obligations*. Upon termination by Iterum pursuant to Section 9.2:

(a)Iterum shall reimburse Supplier for Supplier's cost of all Components purchased and on hand or non-cancellable Components on order, in both cases in reliance on binding Forecasts provided by Iterum or otherwise agreed in writing with Iterum in accordance with section 2.4, if such Components cannot be reasonably used by Supplier for other purposes and, if so directed, shall deliver such Components to Iterum or an Iterum designee as instructed. No amounts shall be due with respect to Iterum Components where Supplier has issued an Advance Payment Invoice in accordance with Section 5.2 (a) and/or an Additional Advance Payment Invoice in accordance with Section 5.2 (b), in each case, covering the cost of such Iterum Components and such amounts have been paid by Iterum. Following termination of this Agreement, Iterum shall collect, or at its discretion, arrange for the destruction of, any and all undelivered Products, Iterum Components, and any other material in any form used for the purposes of manufacturing the Products pursuant to this Agreement.

9.5*Return of Inventory*. In the event of any expiration or termination of this Agreement, Supplier shall, if so requested by Iterum, return any remaining inventory of Products and/or any Components paid for by Iterum pursuant to this Agreement, to Iterum at Iterum's expense, unless such termination shall have been as a result of a breach of this Agreement by Supplier, in which case such inventory and Components (if so requested) shall be returned at Supplier's expense.

9.6*Return of Confidential Information*. Upon expiration or termination of this Agreement for any reason, the receiving Party shall immediately return to the disclosing Party all of the disclosing Party's Confidential Information, in any form or medium disclosed by the disclosing Party (or upon the disclosing Party's instructions in writing, destroy the same and certify its destruction), provided, however, that (a) the

receiving Party shall be allowed to retain one (1) copy of the disclosing Party's Confidential Information to ensure continuing compliance with Article 10; and (b) Iterum shall be allowed to retain Supplier's Confidential Information as necessary to exploit the license granted to Iterum pursuant to Section 8.2(b).

9.7*Technology Transfer*. Upon (a) termination or during the notice period regarding termination of this Agreement, other than where termination is for material breach by Iterum, or (ii) on expiry of this Agreement; Iterum may by written notice to Supplier seek assistance from Supplier with respect to the transfer to another manufacturer of the then-current Process and test methods solely for the purpose of manufacturing and testing the Products ("***Technology Transfer***"). Following Supplier's receipt of such notice, the Parties will establish, in good faith, a schedule and plan for effecting such transfer and Supplier will thereafter co-operate with Iterum in implementing such plan as agreed by the Parties and at Iterum's sole cost. As part of the Technology Transfer, Supplier will make available for collection all documentation (to the extent not previously delivered to Iterum) generated pursuant to this Agreement up to the date of termination or expiry including batch records, development and validation reports and production process documentation, test method SOPs and method development and validation reports. All such documentation shall be provided in English.

9.8*Survival*. Expiration or early termination of this Agreement shall not relieve either Party of any obligations that it may have incurred prior to expiration or early termination. The provisions of Articles 7, 8, 10 and 11 and Sections 2.7, 3.8, 4.3, 4.4, 4.5, 9.3, 9.4, 9.5, 9.6, 9.7 and 9.8 and any other provisions reasonably expected to survive termination including during the Extended Supply Term, shall survive expiration or termination of this Agreement in accordance with their terms.

ARTICLE 10
CONFIDENTIAL INFORMATION

10.1*Nondisclosure*. It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other. Supplier agrees that, except as expressly provided herein, it shall not disclose Confidential Information received from Iterum, and shall not use Confidential Information disclosed to it by Iterum, for any purpose other than to fulfill Supplier's obligations or exercise Supplier's rights hereunder. Iterum agrees that, except as expressly provided herein, it shall not disclose Confidential Information received from Supplier, and shall not use Confidential Information disclosed to it by Supplier, for any purpose other than to fulfill Iterum's obligations or exercise Iterum's rights hereunder. Each Party shall use reasonable and customary precautions to safeguard the other Party's Confidential Information, including ensuring that it will limit the permitted disclosures of the other's Confidential Information only to those persons who have a "need to know" such Confidential Information and ensuring that all employees, consultants and agents who are given access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have contractual or professional confidentiality and non-use obligations that are at least as restrictive as those contained in this Agreement.

10.2*Exceptions to Duty of Nondisclosure*.

(a)Notwithstanding the above, nothing contained in this Agreement shall preclude Iterum from utilizing Supplier's Confidential Information in the following circumstances: as may be necessary in prosecuting the patent and other Intellectual Property rights of Iterum pursuant to Article 8, obtaining governmental regulatory approvals, manufacturing Products subject to the terms and conditions of this Agreement, or complying with applicable laws or court orders provided, however, that Iterum uses reasonable efforts to seek confidential treatment of such information, except as required to file and prosecute such patent applications.

(b)The restrictions set forth in this Article 10 shall not apply to any of the disclosing Party's Confidential Information that the receiving Party is required to disclose under applicable laws or to defend or prosecute litigation, provided that the receiving Party: (i) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (ii) if legally permitted, affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure, and (iii) if the

disclosing Party is unsuccessful in its efforts pursuant to subsection (ii), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose.

(c)A Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances: to its Affiliates, and to prospective and actual acquirers, licensees, sublicensees, employees, consultants, agents, accountants, lawyers, advisors and investors, on a need to know basis, each of whom prior to disclosure must be bound by written or professional ethical obligations of confidentiality and non-use at least as restrictive in scope as those set forth in this Article 10 and that are of equivalent or greater duration in view of the circumstances of the disclosure;

(d)Each Party may disclose the terms of this Agreement to the extent such Party is advised by counsel that such disclosure is required by applicable law (including by rules or regulations of the United States Securities and Exchange Commission (***"SEC"***), any other relevant securities commission in any country, any securities exchange or NASDAQ); *provided*, that, (i) prior to such disclosure, to the extent permitted by applicable law or such rules or regulations, the disclosing Party promptly notifies the other Party of such requirement and the disclosing Party furnishes only those terms of this Agreement that the disclosing Party is legally required to furnish, and (ii) specifically with respect to a filing of this Agreement pursuant to the rules or regulations of the SEC, any other securities commission, any securities exchange or NASDAQ, the disclosing Party shall request, and use commercially reasonable efforts to obtain, confidential treatment of terms permitted to be redacted from the forms of such agreements so filed under the applicable rules and regulations of the SEC, such securities commission, any securities exchange or NASDAQ, as applicable. Each Party shall, to the extent permitted under the relevant law or rules, give the other Party a reasonable opportunity to review those portions of all filings with the SEC (or any other relevant securities commission in any country, any securities exchange or NASDAQ) describing the terms of this Agreement (including any filings of this Agreement) prior to submission of such filings, and shall give due consideration to any reasonable and timely comments by the non-filing Party relating to such filing, including the provisions of this Agreement for which confidential treatment should be sought; provided that each Party will ultimately retain control over what information that Party discloses to their relevant securities commission or exchange.

10.3*Public Announcements*. Neither Party shall make any public announcement concerning the transactions contemplated herein, or make any public statement which includes the name of the other Party or any of its Affiliates, or otherwise use the name of the other Party or any of its Affiliates in any public statement or document, except as may be required by law or judicial order, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.

10.4*Injunctive Relief*. The Parties acknowledge that either Party's breach of this Article 10 may cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the non-breaching Party may be entitled to injunctive relief in addition to any other remedies it may have at law or in equity.

10.5*Survival*. The obligations of the Parties relating to Confidential Information shall expire [**] after the expiration or termination of this Agreement.

ARTICLE 11
MISCELLANEOUS

11.1*Force Majeure*. Neither Party shall be considered to be in breach of this Agreement for a delay in the performance of any of its duties or obligations hereunder caused by any reason beyond the reasonable control and without the fault or negligence of the Party affected thereby, including an act of God, acts of a public enemy, insurrections, riots, embargoes, labor disputes, boycotts, fires, explosions, floods or shortages of material or energy (each an event of ***"Force Majeure"***). The performance of the affected Party shall be extended for a period equal to the period of such delay; provided, however, that affected Party shall give prompt notice to the other Party of such cause and shall take promptly whatever reasonable steps are necessary to relieve the effect of such cause and resume compliance with this Agreement as soon as possible. Should the event of *Force*

Majeure continue for a period longer than [**], the Party not so affected may terminate this Agreement in accordance with Section 9.2(c).

11.2*Notices*. All notices hereunder shall be delivered as follows: (a) personally; (b) by email and confirmed by first class mail (postage prepaid); (c) by registered or certified mail (postage prepaid); or (d) by overnight courier service, to the following addresses of the respective Parties:

If to Iterum:

Iterum Therapeutics International Limited
25 North Wall Quay
Dublin 1, D01 H104, Ireland
Attention: [**]

With copy to

Legal Department
[**]

If to Supplier:

ACS Dobfar S.p.A.
Centro Direzionale Colleoni
Viale Bartolomeo Colleoni
Palazzo Pegaso 3, 3rd Floor
20864 Agrate Brianza, MB, Italy
Attention: [**]

With copy to

[**]

11.3

Notices shall be effective upon receipt if personally delivered or delivered by email and confirmed by first class mail, on the third business day following the date of registered or certified mailing or on the first business day following the date of or delivery to the overnight courier. A Party may change its address listed above by written notice to the other Party.

11.4*Choice of Law and Jurisdiction*. This Agreement shall be construed, interpreted and governed by the laws of the State of New York, excluding its choice of law provisions and its conflict of law provisions. The Parties irrevocably (a) submit to the non-exclusive jurisdiction of any New York State court sitting in New York City or the United States District Court for the Southern District of New York in any action or proceeding arising out of or relating to this Agreement, (b) waive, to the fullest extent they may effectively do so, any defense based on inconvenient forum, improper venue or lack of jurisdiction to the maintenance of any such action or proceeding, and (c) waive all right to trial by jury in any action, proceeding or counterclaim arising out of this Agreement or the transactions contemplated hereby. The United Nations Convention on the International Sale of Goods is hereby expressly excluded.

11.5*Dispute Resolution*. The Parties recognize that bona fide disputes may arise from time to time which relate to the Parties' rights and obligations under this Agreement (***"Dispute"***). If such a Dispute arises, the Parties shall first try to solve it amicably. In this regard, any Party may send a notice of Dispute to the other, and each Party shall appoint, within [**] from receipt of such notice of Dispute, a single representative having full power and authority to solve the Dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If a Party fails to appoint a representative within the [**] period set forth above, or if these representatives are unable to settle the dispute within [**] of the Notice of Dispute, such dispute shall immediately be referred to the president or a senior executive (or such other officer as they may designate) of each Party (***"Senior Executives"***) who will meet as necessary to resolve the dispute amicably. If the Senior Executives fail to meet or to resolve the Dispute within [**] of the referral to such Senior Executives, either Party may pursue any court, administrative or other action to resolve such Dispute.

11.6*Assignment*. Neither Party shall assign this Agreement nor any part thereof without the prior written consent of the other Party; provided, however, that: (a) either Party may assign this Agreement to one of its Affiliates without such consent; and (b) either Party, without such consent, may assign this Agreement in connection with the transfer, sale or divestiture of substantially all of its business to which this Agreement pertains or in connection with a merger or consolidation of such Party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any accrued obligation which such Party then has hereunder. Any assignment made in violation of this Section shall be void.

11.7*Entire Agreement*. This Agreement together with the Exhibits referenced and incorporated herein, the MSA and the Quality Agreements constitute the entire agreement between the Parties concerning the subject matter hereof and supersede all written or oral prior agreements or understandings with respect thereto. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and the Quality Agreements regards to quality assurance, the Quality Agreements will control; in all other cases, this Agreement will control.

11.8*Severability*. This Agreement is subject to the restrictions, limitations, terms and conditions of all applicable governmental regulations, approvals and clearances. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

11.9*Waiver-Modification of Agreement*. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any such rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

11.10*Construction*. All Exhibits referred to herein are hereby incorporated by reference. In construing this Agreement, unless expressly specified otherwise; (a) references to Articles, Sections and Exhibits are to articles, sections of, and exhibits to, this Agreement; (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa; (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement; (d) any list or examples following the word “including” shall be interpreted without limitation to the generality of the preceding words; (e) except where the context otherwise requires, the word “or” is used in the inclusive sense; (f) all references to “dollars” or “$” herein shall mean U.S. Dollars; and (g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. Any terms or conditions contained in an invoice that are inconsistent or in conflict with this Agreement shall be deemed not to be a part of such invoice.

11.11*Counterparts and Facsimile Signatures*. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

IN WITNESS WHEREOF, the parties hereto have each caused this Agreement to be executed by their duly-authorized representatives as of the date above.

Iterum Therapeutics International Limited **ACS Dobfar S.p.A.**

By: /s/ Corey Fishman By: _/s/ Marco Falciani_____

Name: Corey Fishman Name: Marco Falciani

Title: Director Title: President

Execution Version

Exhibit A

Product A

[**]

Product B

[**]

Product C

[**]

Execution Version

Exhibit B

Price

Section 1) Product A price

The Product A Price will be calculated as per following Formula: [**].

Section 2) Product C price

[**].

Section 3) Product B price

Product B Price will be calculated as per the following Formula:
[**].

Section 4) Price adjustment

This Section 4) is applicable to the above Section 1), 2) and 3).

[**].

Execution Version

Exhibit C

Iterum Components

[**]

Execution Version

Exhibit D

Iterum Components – Timeframe for Release Testing

[**]	Within [**] of date of receipt of batch(es)
[**]	Within [**] of date of receipt of batch(es)
[**]	Within [**] of date of receipt of batch(es)
[**]	Within [**] of date of receipt of batch(es)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Corey Fishman, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Iterum Therapeutics plc;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

By: /s/ Corey Fishman
Corey Fishman
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Judith Matthews, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Iterum Therapeutics plc;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

By: /s/ Judith Matthews
Judith Matthews
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Iterum Therapeutics plc (the "Company") for the period ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Corey Fishman, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2025

By: /s/ Corey Fishman
Corey Fishman
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Iterum Therapeutics plc under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Iterum Therapeutics plc (the "Company") for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Judith Matthews, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to her knowledge on the date hereof:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2025

By: /s/ Judith Matthews
Judith Matthews
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Iterum Therapeutics plc under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.