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 June 30, 2024
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.)**

Fitzwilliam Court 1st Floor,
Leeson Close,
Dublin 2, Ireland
(Address of principal executive offices)
Not applicable
(Zip Code)

(+353) 1 669-4820

(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 August 9, 2024, the registrant had 22,705,994 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;
- the design, initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to resolve the issues set forth in the Complete Response Letter (CRL) received from the U.S. Food and Drug Administration in July 2021 in connection with our New Drug Application (NDA) for oral sulopenem;
- 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;
- 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, 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 ability to enter into strategic arrangements, collaborations and/or commercial partnerships in the United States and other territories and the potential benefits of such arrangements;
- 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;
- our ability to regain and maintain compliance with listing requirements of the Nasdaq Capital Market;
- the impact of general economic conditions, including inflation; and
- our strategic process to sell, license, or otherwise dispose of our rights to oral sulopenem to maximize value for our stakeholders and the outcome, impact, effects and results of our pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and our ability to complete one at all.

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 (SEC), 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.

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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,976	$ 6,071
Short-term investments	6,741	17,859
Income taxes receivable	178	38
Prepaid expenses and other current assets	1,800	1,628
Total current assets	13,695	25,596
Property and equipment, net	38	51
Restricted cash	34	34
Other assets	407	578
Total assets	$ 14,174	$ 26,259
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 822	$ 4,996
Accrued expenses	2,260	7,761
Exchangeable Notes	12,952	—
Other current liabilities	741	761
Total current liabilities	$ 16,775	$ 13,518
Exchangeable Notes	—	11,453
Royalty-linked notes	8,296	7,503
Other liabilities	16	188
Total liabilities	$ 25,087	$ 32,662
Commitments and contingencies (Note 14)		
Shareholders' deficit		
Undesignated preferred shares, $0.01 par value per share: 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued at June 30, 2024 and December 31, 2023	—	—
Ordinary shares, $0.01 par value per share: 80,000,000 shares authorized at June 30, 2024 and December 31, 2023, 16,584,029 shares issued at June 30, 2024; 13,499,003 shares issued at December 31, 2023	166	135
Additional paid-in capital	462,318	454,759
Accumulated deficit	(473,396)	(461,298)
Accumulated other comprehensive (loss) / income	(1)	1
Total shareholders' deficit	(10,913)	(6,403)
Total liabilities and shareholders' deficit	$ 14,174	$ 26,259

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ (2,075)	$ (8,964)	$ (6,052)	$ (15,396)
General and administrative	(1,901)	(1,858)	(4,087)	(3,956)
Total operating expenses	(3,976)	(10,822)	(10,139)	(19,352)
Operating loss	(3,976)	(10,822)	(10,139)	(19,352)
Interest expense, net	(571)	(324)	(1,058)	(723)
Adjustments to fair value of derivatives	(407)	(960)	(793)	(1,838)
Other (expense) / income, net	(12)	50	(29)	91
Total other expense	(990)	(1,234)	(1,880)	(2,470)
Loss before income taxes	(4,966)	(12,056)	(12,019)	(21,822)
Income tax expense	(31)	(187)	(79)	(310)
Net loss	$ (4,997)	$ (12,243)	$ (12,098)	$ (22,132)
Net loss per share – basic and diluted	$ (0.30)	$ (0.95)	$ (0.76)	$ (1.73)
Weighted average ordinary shares outstanding – basic and diluted	16,552,214	12,942,969	15,992,454	12,812,398
Statements of Comprehensive Loss				
Net loss	$ (4,997)	$ (12,243)	$ (12,098)	$ (22,132)
Other comprehensive (loss) / income:				
Unrealized (loss) / gain on marketable securities	(1)	105	(2)	324
Comprehensive loss	$ (4,998)	$ (12,138)	$ (12,100)	$ (21,808)

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)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (12,098)	$ (22,132)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	15	16
Amortization of intangible asset	—	858
Share-based compensation expense	206	503
Interest on short-term investments	1	54
Amortization of debt discount and deferred financing costs	1,138	1,162
Interest on exchangeable notes - non-cash	361	410
Adjustments to fair value of derivatives	793	1,838
Other	980	946
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,223)	(2,729)
Accounts payable	(4,175)	942
Accrued expenses	(5,501)	812
Income taxes	(140)	302
Other liabilities	(199)	(204)
Net cash used in operating activities	(19,842)	(17,222)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(2)	(16)
Purchases of short-term investments	(12,390)	(26,859)
Proceeds from sale of short-term investments	23,800	36,328
Net cash provided by investing activities	11,408	9,453
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares, net of transaction costs	7,384	435
Net cash provided by financing activities	7,384	435
Effect of exchange rates on cash and cash equivalents	(45)	(24)
Net decrease in cash, cash equivalents and restricted cash	(1,095)	(7,358)
Cash, cash equivalents and restricted cash, at beginning of period	6,105	21,126
Cash, cash equivalents and restricted cash, at end of period	$ 5,010	$ 13,768
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid - U.S.	$ 220	$ 11

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

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

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount				
Balance at March 31, 2024	16,470,414	$ 165	$ 462,084	$ (468,399)	$ —	$ (6,150)
Issuance of ordinary shares, net	84,471	1	108	—	—	109
Exercise of share options	29,144	—	29	—	—	29
Share-based compensation expense	—	—	97	—	—	97
Net loss	—	—	—	(4,997)	—	(4,997)
Unrealized gain on available-for-sale securities	—	—	—	—	(1)	(1)
Balance at June 30, 2024	16,584,029	$ 166	$ 462,318	$ (473,396)	$ (1)	$ (10,913)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (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	3,055,882	31	7,324	—	—	7,355
Exercise of share options	29,144	—	29	—	—	29
Share-based compensation expense	—	—	206	—	—	206
Net loss	—	—	—	(12,098)	—	(12,098)
Unrealized gain on available-for-sale securities	—	—	—	—	(2)	(2)
Balance at June 30, 2024	16,584,029	$ 166	$ 462,318	$ (473,396)	$ (1)	$ (10,913)

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at March 31, 2023	12,805,833	$ 128	$ 451,776	$ (432,816)	$ (131)	$ 18,957
Issuance of ordinary shares, net	222,570	2	198	—	—	200
Share-based compensation expense	—	—	110	—	—	110
Net loss	—	—	—	(12,243)	—	(12,243)
Unrealized gain on available-for-sale securities	—	—	—	—	105	105
Balance at June 30, 2023	13,028,403	$ 130	$ 452,084	$ (445,059)	$ (26)	$ 7,129

	Ordinary Shares		Additional Paid in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at December 31, 2022	12,598,641	$ 126	$ 451,150	$ (422,927)	$ (350)	$ 27,999
Issuance of ordinary shares, net	429,762	4	431	—	—	435
Share-based compensation expense	—	—	503	—	—	503
Net loss	—	—	—	(22,132)	—	(22,132)
Unrealized gain on available-for-sale securities	—	—	—	—	324	324
Balance at June 30, 2023	13,028,403	$ 130	$ 452,084	$ (445,059)	$ (26)	$ 7,129

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 Fitzwilliam Court, 1st Floor, Leeson Close, Dublin 2, 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 a clinical-stage pharmaceutical company dedicated to developing and commercializing sulopenem to be potentially the first oral penem available in the United States and the first and only oral and intravenous (IV) branded penem available globally.

Liquidity and Going Concern

Since inception, the Company has devoted substantially all of its efforts to research and development, recruiting management and technical staff, and raising capital, and 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 (Rights Offering) pursuant to which its wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda) issued and sold approximately $51.8 million aggregate principal amount of 6.500% Exchangeable Senior Subordinated Notes due 2025 (Exchangeable Notes) and $0.1 million aggregate principal amount of Limited Recourse Royalty-Linked Subordinated Notes (the RLNs and, together with the Exchangeable Notes, the Securities). The Company has not generated any product revenue. 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 achieve regulatory approval, 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. Product candidates currently under development will require additional research and development efforts, including regulatory approval prior to commercialization.

Even if the Company's product development efforts are successful, 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 SEC, which was declared effective on October 17, 2022 (File No. 333-267795), and pursuant to which the Company registered for sale up to $100.0 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 the Company may determine. On October 7, 2022, the Company entered into a sales agreement with H.C. Wainwright & Co., LLC (HC Wainwright), as agent, pursuant to which the Company may offer and sell ordinary shares, nominal value $0.01 per share, 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 of 1933, as amended.

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 and proceeds of the Private Placement and Rights Offering. The Company has incurred operating losses since inception, including net losses of $12,098 and $22,132 for the six months ended June 30, 2024 and 2023, respectively, and a net loss of $38,371 for the year ended December 31, 2023. The Company had an accumulated deficit of $473,396 as of June 30, 2024 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 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, cash equivalents and short-term investments, 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 including the repayment of the Exchangeable Notes in January 2025. 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 plans to address this condition by raising funding through the possible sale of the Company's equity or debt through public or private equity financings, which may include sales of the Company's ordinary shares under the Company's sales

agreement with H.C. Wainwright. 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 the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. In addition, the Company's ability to raise additional capital through the issue of new shares for cash is limited to issuing only 1.7 million ordinary shares (or rights to acquire such shares) for cash, based on the amount of authorized ordinary shares unissued or unreserved and free from any statutory rights of pre-emption, and therefore available for issuance as of July 31, 2024. While shareholders approved an increase of an additional 60,000,000 ordinary shares at our annual general meeting in May 2023 (the Additional Shares), we did not receive approval for the disapplication of statutory pre-emption rights over such shares. Absent shareholder approval of the dis-application of statutory pre-emption rights with respect to the Additional Shares, any Additional Shares that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. As a result of this limitation, we are currently severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering. Furthermore, while the statutory pre-emption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time consuming and complex to execute. In addition, in parallel, the Company is evaluating its corporate, strategic, financial and financing alternatives, with the goal of maximizing value for its stakeholders. These alternatives could potentially include the licensing, sale or divestiture of the Company's assets or proprietary technologies or another strategic transaction involving the Company. 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.

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, 2023 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (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, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2024. 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 June 30, 2024, and results of operations for the three and six months ended June 30, 2024 and 2023, and cash flows for the six months ended June 30, 2024 and 2023 have been made. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

2. Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

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

(In thousands, except share and per share data)

not limited to, the valuation of the RLNs and the accrual for research and development expenses. 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 3 – Fair Value of Financial Assets and Liabilities).

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 U.S. 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 $107 (€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 $17 as of June 30, 2024 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), $6 as of June 30, 2024 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 $11 as of June 30, 2024 relating to warrants issued in the underwritten offering in October 2020 (October 2020 Offering). These restricted cash amounts are unchanged from December 31, 2023. On the closing date of each of the registered direct offerings in June 2020 (June 3 Offering) and July 2020 (June 30 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.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company has most of its cash, cash equivalents and short-term investments 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.

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, unvested restricted share units, warrants and the Exchangeable Notes have been excluded from the calculation because they would be anti-dilutive.

	Three and Six Months Ended	
	June 30, 2024	June 30, 2023
Options to purchase ordinary shares	986,488	1,125,991
Unvested restricted share units	—	38,540
Warrants	480,186	480,186
Exchangeable Notes	1,504,767	1,386,255
Total	2,971,441	3,030,972

Segment and Other Information

The Company determines and presents operating segments based on the information that is internally provided to the Chief Executive Officer and Chief Financial Officer, who together are considered the Company's chief operating decision maker, in accordance with ASC 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.

(In thousands, except share and per share data)

The distribution of total operating expenses by geographical area was as follows:

Operating expenses	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Ireland	$ 3,009	$ 9,485	$ 7,530	$ 16,553
U.S.	967	1,336	2,575	2,776
Bermuda	—	1	34	23
Total	$ 3,976	$ 10,822	$ 10,139	$ 19,352

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

Long-lived assets	June 30, 2024	December 31, 2023
Ireland	$ 247	$ 342
U.S.	198	287
Total	$ 445	$ 629

Recent Accounting Pronouncements

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

On November 27, 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which enhances segment disclosures and requires additional disclosures of segment expenses. This ASU is effective for annual periods in fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 is not expected to have a material impact on the consolidated financial statements.

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, or ASU 2023-06, which incorporates into the Codification 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*, or 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 condensed consolidated financial statements.

3. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets that were carried at fair value on a recurring basis on the condensed consolidated balance sheet as of June 30, 2024 and December 31, 2023 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value.

(In thousands, except share and per share data)

June 30, 2024 Assets	Total	Level 1	Level 2	Level 3
Short-term investments:				
Commercial paper	$ 790	$ —	$ 790	$ —
U.S. Treasury bonds	5,951	—	5,951	—
	$ 6,741	$ —	$ 6,741	$ —

December 31, 2023 Assets	Total	Level 1	Level 2	Level 3
Short-term investments:				
Corporate bonds	$ 1,179	$ —	$ 1,179	$ —
Commercial paper	3,287	—	3,287	—
U.S. Treasury bonds	13,393	—	13,393	—
	$ 17,859	$ —	$ 17,859	$ —

See Note 4 for details on the short-term investments. The carrying amounts reported in the condensed consolidated balance sheets for 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.

The following table presents information about the Company's Exchangeable Notes and RLNs and indicates the fair value hierarchy of the valuation inputs utilized to determine the approximate fair value:

June 30, 2024 Short-term Liabilities	Book Value	Approximate Fair Value	Level 1	Level 2	Level 3
Exchangeable Notes					
Exchangeable note	$ 12,952	$ 12,862	$ —	$ 12,862	$ —
Total short-term liabilities	$ 12,952	$ 12,862	$ —	$ 12,862	$ —
Long-term Liabilities					
Revenue Futures					
Royalty-linked notes	8,296	8,296	—	—	8,296
Total long-term liabilities	$ 8,296	$ 8,296	$ —	$ —	$ 8,296

December 31, 2023 Long-term Liabilities	Book Value	Approximate Fair Value	Level 1	Level 2	Level 3
Exchangeable Notes					
Long-term exchangeable note	$ 11,453	$ 11,645	$ —	$ 11,645	$ —
Revenue Futures					
Royalty-linked notes	7,503	7,503	—	—	7,503
Total long-term liabilities	$ 18,956	$ 19,148	$ —	$ 11,645	$ 7,503

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 June 30, 2024 consist of a separate financial instrument, that was issued as part of the Units, the RLNs (see Note 10 – Royalty-Linked Notes).

At any time on or after January 21, 2021, subject to specified limitations, the Exchangeable Notes are exchangeable for the Company's ordinary shares, cash or a combination of ordinary shares and cash, at an exchange rate of 105.0398 shares per $1,000 of principal and interest on the Exchangeable Notes (equivalent to an exchange price of approximately $9.520 per ordinary share) as of June 30, 2024, which was adjusted from an initial exchange rate of 66.666 shares per $1,000 principal and interest on the Exchangeable Notes (equivalent to an initial exchange price of $15.00 per ordinary share) and is subject to further adjustment pursuant to the terms of the Exchangeable Notes Indenture. Beginning on January 21, 2021 to June 30, 2024, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes have exchanged 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. The aggregate principal amount of Exchangeable Notes outstanding as of June 30, 2024 was $11,117. The fair value of the exchange option at June 30, 2024 was $0.

(In thousands, except share and per share data)

The RLN liability is carried at fair value on the condensed consolidated balance sheet (see Note 10 – Royalty-Linked Notes). The total fair value of $8,296 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.

4. Short-term Investments

The Company classifies its short-term investments as available-for-sale. Short-term investments comprise highly liquid investments with minimum "A-" rated securities and as at quarter end consist of corporate bonds, commercial paper and U.S. Treasury bonds with maturities of more than three months at the date of purchase. Short-term investments as of June 30, 2024 have a weighted average maturity of 0.16 years. The investments are reported at fair value with unrealized gains or losses recorded in the condensed consolidated statements of operations and comprehensive loss. Any differences between the amortized cost and fair value of investments are represented by unrealized gains or losses. The fair value of corporate bonds, commercial paper and U.S. Treasury bonds are represented by Level 2 fair value measurements - quoted price for a similar asset, or other observable inputs such as interest rates or yield curves.

The following table represents the Company's available for sale short-term investments by major security type as of June 30, 2024 and December 31, 2023:

June 30, 2024					Maturity by period	
Available-for-sale	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Fair Value Total	Less than 1 Year	1 to 5 Years
Commercial paper	$ 791	$ —	$ (1)	$ 790	$ 790	$ —
U.S. Treasury bonds	5,951	—	—	5,951	5,951	—
Total	$ 6,742	$	$ (1)	$ 6,741	$ 6,741	$ —

December 31, 2023					Maturity by period	
Available-for-sale	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Fair Value Total	Less than 1 Year	1 to 5 Years
Corporate bonds	$ 1,179	$ 1	$ —	$ 1,180	$ 1,180	$ —
Commercial paper	3,288	—	(1)	3,287	3,287	—
U.S. Treasury bonds	13,391	3	(2)	13,392	13,392	—
Total	$ 17,858	$ 4	$ (3)	$ 17,859	$ 17,859	$ —

For the three and six months ended June 30, 2024 and 2023, no allowance was recorded for credit losses. Unrealized gains and losses are reported as a component of accumulated other comprehensive (loss) / income in shareholders' deficit.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2024	December 31, 2023
Prepaid insurance	$ 779	$ 472
Deferred financing expenses	734	—
Other prepaid assets	188	89
Prepaid research and development expenses	82	872
Research and development tax credit receivable	17	195
Total	$ 1,800	$ 1,628

(In thousands, except share and per share data)

6. Property and Equipment, net

Property and equipment and related accumulated depreciation are as follows:

	June 30, 2024	December 31, 2023
Leasehold improvements	$ 148	$ 148
Furniture and fixtures	120	120
Computer equipment	95	98
	363	366
Less: accumulated depreciation	(325)	(315)
	$ 38	$ 51

Depreciation expense for the six months ended June 30, 2024 and 2023 was $15 and $16, respectively. In addition, accumulated depreciation decreased by $5 due to the removal of fully depreciated computer equipment during the six months ended June 30, 2024.

7. Leases

The Company has entered into a number of operating leases, primarily for office space and commercial property. These leases have remaining terms which range from 0.7 years to 1.1 years. The renewal option on one lease was exercised in February 2022 for an additional period of three years, extending this lease term to June 2025. A Deed of Assignment was signed in August 2023 in relation to a commercial property lease and accordingly the related Right of Use asset and lease liability were derecognized. In September 2020, the Company entered into a sublease agreement for a commercial unit. This sublease agreement was assigned with the related lease in August 2023.

In November 2021, the Company entered into a 12-month lease, with a rolling extension, for office space, and in May 2022, the Company entered into a 6-month lease for office space, which was extended to November 2023, and elected not to apply the measurement and recognition requirements of ASC 842 to these short-term leases as any renewal term exercised or considered reasonably certain of exercise by the Company did not extend more than 12 months from the end of the previously determined lease term. In August 2023, the Company extended the lease agreements for a further nine months, with a rolling extension, and twelve months, respectively. While neither of the extended agreements extend more than 12 months from the end of the previously determined lease term, it is considered to be reasonably certain that these lease arrangements will be extended beyond a period of more than 12 months. Accordingly, the Company has applied the measurement and recognition requirements of ASC 842 to these lease arrangements.

Certain leases contain variable lease payments, including payments based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement. Certain agreements contain both lease and non-lease components. The Company has elected to separately account for these components in determining the lease liabilities and right-of-use assets. The Company's lease agreements generally do not provide an implicit borrowing rate; therefore, an internal incremental borrowing rate was determined based on information available at lease commencement date for the purposes of determining the present value of lease payments. The Company used the incremental borrowing rate on January 1, 2019 for all leases that commenced prior to that date.

All operating lease expenses are recognized on a straight-line basis over the lease term. The Company recognized $99 and $198 of operating lease costs for right-of-use assets during the three and six months ended June 30, 2024, respectively, and $108 and $214 of operating lease costs for right-of-use assets during the three and six months ended June 30, 2023, respectively. No rental expense on short-term leases was recognized during the three and six months ended June 30, 2024, and $73 and $145 of rental expense was recognized on short-term leases during the three and six months ended June 30, 2023, respectively. No sublease income was recognized during the three and six months ended June 30, 2024 and $75 and $151 of sublease income was recognized during the three and six months ended June 30, 2023, respectively.

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

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Cash paid for operating lease liabilities	$ 100	$ 102	$ 200	$ 204

(In thousands, except share and per share data)

	June 30, 2024	December 31, 2023
Weighted-average remaining lease term	0.96 years	1.46 years
Weighted-average discount rate	12.9%	12.9%

Right-of-use assets and lease liabilities for the Company's operating leases were recorded in the condensed consolidated balance sheet as follows, representing the Company's right to use the underlying asset for the lease term ("Other assets") and the Company's obligation to make lease payments ("Other current liabilities" and "Other liabilities"):

	June 30, 2024	December 31, 2023
Other assets	$ 378	$ 549
Other current liabilities	$ 356	$ 365
Other liabilities	16	188
Total lease liabilities	$ 372	$ 553

Future lease payments included in the measurement of lease liabilities on the condensed consolidated balance sheet as of June 30, 2024 for the following five fiscal years and thereafter were as follows:

Due in 12 month period ended June 30,	
2025	$ 375
2026	18
2027	—
2028	—
2029	—
Thereafter	—
	$ 393
Less imputed interest	(21)
Total lease liabilities	$ 372

8. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2024	December 31, 2023
Accrued payroll and bonus expenses	$ 1,349	$ 2,742
Accrued other expenses	489	147
Accrued clinical trial costs	179	4,835
Accrued professional fees	243	37
Total	$ 2,260	$ 7,761

9. Debt

Secured Credit Facility

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. $15,000 of the secured credit facility was funded on closing. A second draw of up to $15,000 was available to the Company through October 31, 2019, upon satisfaction of either of the following: (i) the achievement by the Company of both non-inferiority and superiority primary endpoints from its Phase 3 uncomplicated urinary tract infection (uUTI) trial, as well as reporting satisfactory safety data from the trial, or (ii) the achievement of non-inferiority primary endpoints from both its Phase 3 uUTI and complicated urinary tract infection trials, as well as reporting satisfactory safety data from the trials. The Company did not satisfy the conditions for the second draw above before the deadline of October 31, 2019. All outstanding principal, plus a 4.20% final interest payment, were due and paid on March 1, 2022 (the maturity date), effectively terminating the Loan and Security Agreement.

In connection with the initial $15,000 draw, the Company issued SVB and Life Sciences Fund II LLC (LSF) 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 initial public offering (IPO)) at an exercise price of $282.75 per share. These warrants will expire on April 27, 2028.

In connection with the Private Placement, Iterum Bermuda was joined as a party to the Loan and Security Agreement as a borrower and the Loan and Security Agreement was amended on January 16, 2020 to, among other things, modify the definition of subordinated debt to include the RLNs and Exchangeable Notes.

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 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 are exchangeable for the Company's ordinary shares, cash or a combination of ordinary shares and cash, at the Company's election, at an exchange rate of 105.0398 shares per $1,000 principal and interest on the Exchangeable Notes (equivalent to an exchange price of approximately $9.520 per ordinary share) as of June 30, 2024, which exchange rate was adjusted from an initial exchange rate of 66.666 shares per $1,000 principal and interest on the Exchangeable Notes (equivalent to an initial exchange price of $15.00 per ordinary share) and is subject to further adjustment pursuant to the terms of the Exchangeable Notes Indenture. Any accrued and unpaid interest being exchanged will be calculated to include all interest accrued on the Exchangeable Notes being exchanged to, but excluding, the exchange settlement date. Beginning on January 21, 2021 to June 30, 2024, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes have 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. The aggregate principal amount of Exchangeable Notes outstanding as of June 30, 2024 was $11,117.

In addition, the Exchangeable Notes will become due and payable by the Company upon the occurrence of a Fundamental Change as defined in the Exchangeable Notes Indenture. The Company will be required to pay each holder of the Exchangeable Notes the greater of three times the outstanding principal amount of such Exchangeable Note and the consideration that would be received by the holder of such Exchangeable Note in connection with such Fundamental Change if the holder had exchanged its note for ordinary shares immediately prior to the consummation of such Fundamental Change, plus any accrued and unpaid interest.

The Company evaluates its debt and equity issuances to determine if those contracts, or embedded components of those contracts, qualify as derivatives under ASC 815-15, *Derivatives and Hedging*, requiring separate recognition in the Company's financial statements. The Company evaluated the accounting for the issuance of the Exchangeable Notes and concluded that the embedded exchange option and change of control feature are considered a derivative liability under ASC 815-15 requiring bifurcation, from the Exchangeable Notes, as it does not qualify for the scope exceptions for contracts in an entity's own equity given the terms of the Exchangeable Notes. The exchange option and change of control feature are accounted for as a derivative liability, under ASC 815-15, and are required to be separated and recorded as a single liability, which is revalued at each reporting period with the resulting change in fair value reflected in adjustments to fair value of derivatives in the condensed consolidated statements of operations and comprehensive loss.

The fair value of the derivative liability related to the Private Placement on January 21, 2020 was $27,038, and the fair value of the derivative liability related to the Rights Offering on September 8, 2020 was $82, both of which were recorded as a reduction to the book value of the host debt contract. This debt discount is being amortized to interest expense over the term of the debt using the effective interest method. Transaction costs amounting to $2,848 were allocated to the exchange option. These costs were reflected in financing transaction costs in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2020. Transaction costs amounting to $2,814 were allocated to the debt host and capitalized in the host debt book value.

In circumstances where the embedded exchange option in a convertible instrument is required to be bifurcated, and there are other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not settlement of the derivative instrument is expected within twelve months of the balance sheet date.

(In thousands, except share and per share data)

The Company determined that all other features of the Exchangeable Notes were clearly and closely associated with a debt host and did not require bifurcation as a derivative liability. The initial value of the Exchangeable Notes on inception, net of transaction costs, was $9,891.

The Company recognized $180 and $361 of interest expense related to the Exchangeable Notes during the three and six months ended June 30, 2024, respectively, and $205 and $410 of interest expense related to the Exchangeable Notes during the three and six months ended June 30, 2023, respectively. The Company recognized $569 and $1,138 related to the amortization of the debt discounts and deferred financing costs during the three and six months ended June 30, 2024, respectively, and $584 and $1,162 related to the amortization of the debt discounts and deferred financing costs during the three and six months ended June 30, 2023, respectively. These amounts are recorded in interest expense, net in the condensed consolidated statements of operations and comprehensive loss. The balance of the Exchangeable Notes as of June 30, 2024 is as follows:

	June 30, 2024	
	Principal	Accrued Interest
January 2020 $1,000 Exchangeable Notes, 6.5% interest, due January 31, 2025 (2025 Exchangeable Notes)	$ 51,588	$ 6,219
September 2020 $1,000 Exchangeable Notes, 6.5% interest, due January 31, 2025 (2025 Exchangeable Notes)	220	32
Conversion of $1,000 Exchangeable Notes, 6.5% interest, due January 31, 2025 (2025 Exchangeable Notes)	(40,691)	(3,071)
2025 Exchangeable Notes, net	11,117	3,180
Unamortized discount and debt issuance costs	(1,345)	—
2025 Exchangeable Notes, net	$ 9,772	$ 3,180

Scheduled principal payments on outstanding debt, including principal amounts owed to RLN holders (see Note 10 – Royalty-Linked Notes), as of June 30, 2024, for the following five fiscal years and thereafter were as follows:

Year Ending June 30,	
2025	$ 11,117
2026	—
2027	—
2028	—
2029	—
Thereafter	104
Total	$ 11,221

10. 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 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 receives FDA approval for one or more specified sulopenem products prior to December 31, 2025 and the Company earns net revenues on such 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 (or December 31, 2025, in the event that the Company has not yet received FDA approval with respect to one or more specified sulopenem products by such date), 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*, 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 inputs can result

(In thousands, except share and per share data)

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:

		June 30, 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 Rights Offering		51
Amortization of discount and debt issuance costs		3,666
Adjustments to fair value		(6,411)
Total liability related to the sale of future royalties at June 30, 2024	$	8,296
Current Portion		—
Long-term Portion	$	8,296

		December 31, 2023
Total liability related to the sale of future royalties, on inception	$	10,990
Liability related to the sale of future royalties, arising from the Rights Offering		51
Amortization of discount and debt issuance costs		3,666
Adjustments to fair value		(7,204)
Total liability related to the sale of future royalties at December 31, 2023	$	7,503
Current Portion		—
Long-term Portion	$	7,503

11. 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

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 June 30, 2024. The holders of ordinary shares are entitled to one vote for each share held. The holders of ordinary shares currently have preemptive rights over 60,000,000 ordinary shares and no preemptive or other subscription rights over 20,000,000 ordinary shares. There are no redemption or sinking fund provisions with respect to the authorized ordinary shares.

The Company 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), and pursuant to which the Company 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 the Company may determine.

On October 7, 2022, the Company entered into a sales agreement with HC Wainwright, as agent, pursuant to which the Company may offer and sell ordinary shares, nominal value $0.01 per share, 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 of 1933, as amended. During the six months ended June 30, 2024, the Company sold 3,055,882 ordinary shares under the "at the market" agreement at an average price of $2.49 per share for net proceeds of $7.4 million.

Beginning on January 21, 2021 to June 30, 2024, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes have exchanged 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. The aggregate principal amount of Exchangeable Notes outstanding as of June 30, 2024 was $11,117.

Warrants to purchase Ordinary Shares

In connection with the initial drawdown under the Loan and Security Agreement, the Company issued SVB and LSF 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 share. These warrants will expire on April 27, 2028. No warrants had been exercised as of June 30, 2024.

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. 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 and will expire on June 3, 2025. No warrants had been exercised as of June 30, 2024.

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. 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 and will expire on June 30, 2025. As of June 30, 2024, warrants issued in connection with the June 30, 2020 Offering had been exercised for 84,317 ordinary shares, for net proceeds of $1,796.

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 June 30, 2024, 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 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 June 30, 2024, 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 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 June 30, 2024.

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 June 30, 2024.

Undesignated Preferred Shares

The Company has authorized 100,000,000 undesignated preferred shares of $0.01 par value each as of June 30, 2024. 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 in issue as of June 30, 2024 or December 31, 2023.

12. 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.

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 Company does not have sufficient company-specific historical and implied volatility information and it therefore

estimates its expected share volatility based on historical volatility information of reasonably comparable guideline public companies and itself. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. 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. The Company has elected to account for forfeitures as they occur.

The Company did not grant any share options to employees and directors during the six months ended June 30, 2024 and 857,500 share options were granted to employees during the six months ended June 30, 2023. There were 465,795 and 949,235 unvested employee and director share options outstanding as of June 30, 2024 and June 30, 2023, respectively. Total expense recognized related to employee share options was $88 and $211 for the three and six months ended June 30, 2024, respectively, and $44 and $221 for the three and six months ended June 30, 2023, respectively. Total unamortized compensation expense related to employee share options was $432 and $1,248 as of June 30, 2024 and June 30, 2023, respectively, which is expected to be recognized over a remaining weighted average vesting period of 1.70 years and 2.58 years as of June 30, 2024 and June 30, 2023, respectively.

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

	Six Months Ended June 30, 2023
Volatility	100%
Expected term in years	6.00 - 6.25
Dividend rate	0%
Risk-free interest rate	3.55% - 3.67%
Share price	$1.00 - $1.04
Fair value of option on grant date	$0.80 - $0.84

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

	Equity Plans	Inducement Plan	Total
Options outstanding December 31, 2023	984,155	124,833	1,108,988
Granted	—	—	—
Exercised	(29,144)	—	(29,144)
Forfeited	(45,856)	(47,500)	(93,356)
Options outstanding June 30, 2024	909,155	77,333	986,488

The following table summarizes the number of options outstanding and the weighted-average exercise price as of June 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding December 31, 2023	1,108,988	$ 2.73	8.94	$ 832
Granted	—			
Exercised	(29,144)	$ 1.00		
Forfeited	(93,356)	$ 4.19		
Options outstanding June 30, 2024	986,488	$ 2.65	7.94	$ 117
Exercisable at June 30, 2024	520,693	$ 3.99	7.24	$ 49

Restricted Share Units (RSUs)

The Company did not grant any RSUs to employees and directors during the six months ended June 30, 2024 and 2023, respectively.

(In thousands, except share and per share data)

The following table summarizes the number of RSUs granted covering an equal number of the Company's ordinary shares for all of Company plans:

	Equity Plans	Inducement Plan	Total
RSUs outstanding December 31, 2023	—	16,666	16,666
Granted	—	—	—
Shares vested	—	—	—
Forfeited	—	(16,666)	(16,666)
RSUs outstanding June 30, 2024	—	—	—

The table below shows the number of RSUs outstanding covering an equal number of the Company's ordinary shares and the weighted-average grant date fair value of the RSUs outstanding as of June 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSUs outstanding December 31, 2023	16,666	$ 7.26
Granted	—	
Shares vested	—	
Forfeited	(16,666)	$ 7.26
RSUs outstanding June 30, 2024	—	

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 our employees under our 2018 Plan and four years for our employees under our 2021 Inducement Plan. Total benefit recognized related to the RSUs was $20 and $5 for the three and six months ended June 30, 2024, respectively, and total expense recognized related to the RSUs was $66 and $282 for the three and six months ended June 30, 2023, respectively. There was no unamortized compensation expense related to the RSUs as of June 30, 2024 and total unamortized expense related to the RSUs was $149 as of June 30, 2023, which was expected to be recognized over a remaining average vesting period of 2.42 years as of June 30, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	$ 26	$ 95	$ 122	$ 219
General and administrative expense	42	15	84	284

There was a total of $432 and $1,397 unamortized share-based compensation expense for options and RSUs as of June 30, 2024 and June 30, 2023, respectively, which is expected to be recognized over a remaining average vesting period of 1.70 years and 2.57 years as of June 30, 2024 and June 30, 2023, respectively.

13. 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 $31 and $79, for the three and six months ended June 30, 2024, respectively and $187 and $310, for the three and six months ended June 30, 2023, 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 June 30, 2024 and December 31, 2023, the Company has net operating loss carryforwards in Ireland which result in tax benefits of approximately $42,794 and $41,525, 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.

14. Commitments and Contingencies

License Agreement

On November 18, 2015, the Company entered into a license agreement with Pfizer for the worldwide exclusive rights to research, develop, manufacture and commercialize sulopenem (the Pfizer License).

Under the Pfizer License, the Company has agreed to make certain regulatory and sales milestone payments, including a regulatory milestone payment of $20 million upon approval of oral sulopenem by the FDA. The Company intends to defer this payment for a two-year period, at an annual rate of eight percent on a daily compounded basis until paid in full, as permitted pursuant to the terms of the Pfizer License. The Company is obligated to make a potential one-time payment related to sublicensing income that exceeds a certain threshold. The Company is 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.

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 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 receives FDA approval for one or more specified sulopenem products prior to December 31, 2025 and the Company earns net revenues on such 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 (or December 31, 2025, in the event that the Company has not yet received FDA approval with respect to one or more specified sulopenem products by such date), 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 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.

15. 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 June 30, 2024, $11,117 aggregate principal amount of Exchangeable Notes and all RLNs remained outstanding.

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 Exchangeable Notes and RLNs. 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 Exchangeable Notes and 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.

16. Subsequent Events

In July 2024, the Company launched a rights offering (the 2024 Rights Offering), where it distributed, at no charge, subscription rights to shareholders and holders of warrants that had contractual rights to participate in the securities offering, which were not waived (each an eligible warrant holder and collectively, the eligible warrant holders). In connection with the 2024 Rights Offering, the Company distributed an aggregate of 17,007,601 non-transferable subscription rights to purchase an aggregate of 8,503,800 units (Units) at a subscription price of $1.21 per whole 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). Each shareholder and holder of eligible warrants received one subscription right for every ordinary share owned and every ordinary share issuable upon exercise of eligible warrants at 5:00 p.m., Eastern Time, on July 16, 2024. Each subscription right entitled its holder to purchase 0.50 Units, at a subscription price of $0.605 per 0.50 Units, consisting of (i) 0.50 ordinary shares, (ii) a 1-year warrant to purchase 0.25 ordinary shares and (iii) a 5-year warrant to purchase 0.50 ordinary shares. During the 2024 Rights Offering, rights holders validly subscribed for 6,121,965 Units. The 2024 Rights Offering closed on August 9, 2024 and resulted in aggregate net proceeds, after deducting estimated fees and expenses, of approximately $5.8 million (assuming no exercise of any warrants included in the Units sold by the Company in the 2024 Rights Offering).

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 clinical-stage pharmaceutical company dedicated to developing and commercializing sulopenem to be potentially the first oral branded penem available in the United States and 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 also developed sulopenem in an oral tablet formulation, sulopenem etzadroxil-probenecid, which we refer to herein as oral sulopenem. We believe that sulopenem and oral sulopenem 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.

During the third quarter of 2018, we initiated three clinical trials in our Phase 3 development program which included: a Phase 3 uncomplicated urinary tract infection (uUTI) clinical trial, known as Sulopenem for Resistant Enterobacteriaceae (SURE) 1, comparing oral sulopenem to oral ciprofloxacin in women with uUTI, a Phase 3 complicated urinary tract infection (cUTI) clinical trial known as SURE 2, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by oral ciprofloxacin in adults with cUTI and a Phase 3 complicated intra-abdominal infection (cIAI) clinical trial known as SURE 3, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by a combination of oral ciprofloxacin and oral metronidazole in adults with cIAI. We designed one Phase 3 clinical trial in each indication based on our end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and feedback from the European Medicines Agency (EMA). We conducted the Phase 3 clinical trials under Special Protocol Assessment (SPA) agreements from the FDA. In December 2019, we announced that sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy for the cIAI trial. In the second quarter of 2020, we announced the results of our Phase 3 clinical trials in cUTI and uUTI. In the cUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapies with the difference in response rates driven almost entirely by higher rates of asymptomatic bacteriuria on the sulopenem IV to oral sulopenem arm relative to the ertapenem IV to oral ciprofloxacin arm, only evident at the test of cure visit. The rates of patients receiving additional antibiotics or with residual cUTI symptoms were similar between therapies. Similarly, in the uUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin in the population of patients with baseline pathogens susceptible to ciprofloxacin driven to a large degree by a greater amount of asymptomatic bacteriuria in the sulopenem treated patients at the test of cure visit relative to those receiving ciprofloxacin. However, in the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating statistical significance in the overall response rate by treatment arm in the ciprofloxacin resistant population, providing evidence of a treatment effect in patients with uUTI. Based on discussions with the FDA at a pre-New Drug Application (NDA) meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. We received a Complete Response Letter (CRL) from the FDA on July 23, 2021 in respect of our NDA. The CRL provided that the FDA had completed its review of the NDA and had determined that it could not approve the NDA in its present form. The CRL further 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 we commenced enrollment in that clinical trial, known as REnewed ASsessment of Sulopenem in uUTI caused by Resistant Enterobacterales (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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA to the FDA for oral sulopenem for the treatment of uUTIs in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the Prescription Drug User Fee Act ("PDUFA"), which has a six-month review period from the date of resubmission. As a

result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial and/or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

Going Concern

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of oral sulopenem and sulopenem. As of June 30, 2024, we had an accumulated deficit of $473.4 million. We expect to continue to incur significant expenses for the foreseeable future as we seek regulatory approval of oral sulopenem. In addition, if we obtain marketing approval for oral sulopenem, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Additionally, principal and interest on the outstanding Exchangeable Notes become due on January 31, 2025. We may also incur expenses in connection with the further clinical development of IV sulopenem and clinical development of sulopenem in additional indications, the establishment of additional sources for the manufacture of 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 additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

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 obtain marketing approval for oral sulopenem, sulopenem or any future product candidate and generate significant revenue from product sales, if ever, 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. Additionally, in the event we are not able to obtain shareholder approval for the disapplication of pre-emption rights over our ordinary shares at a general meeting of the shareholders, our ability to raise additional capital through the issue of new shares for cash will be severely limited.

Because of the numerous risks and uncertainties associated with product development, 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 if we are able to generate product sales, we may not 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 development and commercialization of our sulopenem program. As of June 30, 2024, we had cash, cash equivalents and short-term investments of $11.7 million. Based on our available cash resources, we do not believe that our existing cash, cash equivalents and short-term investments, including amounts received under our 2024 Rights Offering, 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 including through repayment of the 6.500% Exchangeable Senior Subordinated Notes due in January 2025 (Exchangeable Notes). This condition raises substantial doubt about our ability to continue as a going concern. 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 the Company has successfully raised capital in the past, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. In addition, the Company's ability to raise additional capital through the issue of new shares for cash is limited to issuing only 0.8 million ordinary shares (or rights to acquire such shares) for cash, based on the amount of authorized ordinary shares unissued or unreserved and free from any statutory rights of pre-emption, and therefore available for issuance as of August 9, 2024. While shareholders approved an increase of an additional 60,000,000 ordinary shares at our annual general meeting in May 2023 (the Additional Shares), we did not receive approval for the disapplication of statutory pre-emption rights over such shares. Absent shareholder approval of the disapplication of statutory pre-emption rights with respect to the Additional Shares, any Additional Shares that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. As a result of this limitation, we are currently severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering similar to the rights offering launched in July 2024, where we distributed, at no charge, subscription rights (the 2024 Rights Offering) to our shareholders and holders of warrants that had contractual rights to participate in the securities offering, which were not waived (each an eligible warrant holder and collectively, the eligible warrant holders). In connection with the 2024 Rights Offering, we distributed an aggregate of 17,007,601 non-transferable subscription rights to purchase an aggregate of 8,503,800 units (Units) at a subscription price of $1.21 per whole 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). Each shareholder and holder of eligible warrants received one subscription right for every ordinary share owned and every ordinary share issuable upon exercise of eligible warrants at 5:00 p.m., Eastern Time, on July 16, 2024. Each subscription right entitled its holder to purchase 0.50 Units, at a subscription price of $0.605 per 0.50 Units, consisting of (i) 0.50 ordinary shares, (ii) a 1-year warrant to purchase 0.25 ordinary shares and (iii) a 5-year warrant to purchase 0.50 ordinary shares. During the 2024 Rights Offering, rights holders validly subscribed for 6,121,965 Units. The 2024 Rights Offering closed on August 9, 2024 and resulted in aggregate net proceeds, after deducting estimated fees and expenses, of approximately $5.8 million (assuming no exercise of any warrants included in the units sold by us in the 2024 Rights Offering).

Furthermore, while the statutory pre-emption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time-consuming and complex to execute.

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.

In addition, we are currently focusing on a strategic process to sell, license or otherwise dispose of our rights to sulopenem with the goal of maximizing value for our stakeholders and have engaged a financial advisor to assist management and the board in evaluating strategic alternatives. There can be no assurance that any such process will 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. For more information, refer to “Liquidity and Capital Resources—Liquidity and Going Concern” below and Note 1, “—Liquidity and Going Concern” of the Notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Components of Our Results of Operations

Operating Expenses

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 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.

The successful development and commercialization of oral sulopenem and/or sulopenem is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of our sulopenem program or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- our ability to apply for regulatory approval, and the timing or likelihood of any such filings and approvals;

•the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;

•establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;

•development and timely delivery of commercial drug formulations (i) that can be used in our clinical trials and (ii) that are available for commercial launch;

•obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;

•significant and changing government regulation;

•launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

•general economic conditions, including inflation; and

•maintaining a continued acceptable safety profile of the product candidates following approval.

We may never succeed in achieving regulatory approval for any of our product candidates. For example, in the results of our cIAI clinical trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy for the cIAI trial. In the second quarter of 2020, we announced the results of our Phase 3 clinical trials of sulopenem for the treatment of cUTI and uUTI. In the cUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapies with the difference in response rates driven almost entirely by higher rates of asymptomatic bacteriuria on the sulopenem IV to oral sulopenem arm relative to the ertapenem IV to oral ciprofloxacin arm, only evident at the test of cure visit; the rates of patients receiving additional antibiotics or with residual cUTI symptoms were similar between therapies. Similarly, in the uUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin in the population of patients with baseline pathogens susceptible to ciprofloxacin driven to a large degree by a greater amount of asymptomatic bacteriuria in the sulopenem treated patients at the test of cure visit relative to those receiving ciprofloxacin. However, in the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating statistical significance in the overall response rate by treatment arm in the ciprofloxacin-resistant population, providing evidence of a treatment effect in patients with uUTI. Notwithstanding failure to meet the endpoints described above, in all three Phase 3 clinical trials, at all timepoints measured, the clinical response to sulopenem and/or oral sulopenem was similar to the comparator regimen (non-inferior), except in the instance of the quinolone non-susceptible population in the Phase 3 uUTI trial in which oral sulopenem was statistically superior. Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone nonsusceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. We received a CRL from the FDA on July 23, 2021, for our NDA. 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 nonclinical PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional nonclinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA to the FDA for oral sulopenem for the treatment of uUTIs in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial and/or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

General and Administrative Expenses

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

Payroll and expenses may increase in preparation for commercial operations if regulatory approval for oral sulopenem appears likely.

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 due 2025 (Exchangeable Notes), realized gains and losses on our short-term investments, interest earned on our cash and cash equivalents, which are generally invested in money market accounts and interest earned on our investments in marketable securities. Interest on the Exchangeable Notes is 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 becomes due and payable.

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) / Income, Net

Other (expense) / income, 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 and sub-lease income from a sub-lease agreement for a commercial unit (terminated in August 2023).

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 SEC on March 28, 2024, 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 from those described in our Annual Report on Form 10-K filed with the SEC on March 28, 2024.

Results of Operations

Comparison of the three months ended June 30, 2024 and 2023

The following table summarizes our operating loss and loss before income taxes for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30, 2024	2023	Change
Operating expenses:			
Research and development	$ (2,075)	$ (8,964)	$ 6,889
General and administrative	(1,901)	(1,858)	(43)
Total operating expenses	(3,976)	(10,822)	6,846
Operating loss	(3,976)	(10,822)	6,846
Total other expense, net	(990)	(1,234)	244
Loss before income taxes	$ (4,966)	$ (12,056)	$ 7,090

Research and Development Expenses (in thousands)

	Three Months Ended June 30, 2024	2023	Change
CRO and other preclinical and clinical trial expenses	$ 665	$ 7,067	$ (6,402)
Personnel related (including share-based compensation)	527	928	(401)
Chemistry, manufacturing and control (CMC) related expenses	477	697	(220)
Consulting fees	406	272	134
Total research and development expenses	$ 2,075	$ 8,964	$ (6,889)

The decrease in CRO and other preclinical and clinical trial expenses of $6.4 million was primarily due to higher costs incurred in 2023 to support our REASSURE trial, which began enrollment in October 2022 and completed enrollment in October 2023. Personnel related costs decreased by $0.4 million primarily due to lower headcount and a decrease in share-based compensation expense. Personnel related costs for the three months ended June 30, 2024 and 2023 included share-based compensation expense of $0.0 million and $0.1 million, respectively. CMC related expenses decreased by $0.2 million primarily as a result of a decrease in activities following completion of our REASSURE trial. The increase in consulting fees of $0.1 million was due to an increase in the use of consultants in connection with the preparation of our NDA filing for oral sulopenem for the treatment of uUTIs in adult women..

General and Administrative Expenses (in thousands)

	Three Months Ended June 30, 2024	2023	Change
Personnel related (including share-based compensation)	$ 790	$ 827	$ (37)
Facility related and other	602	665	(63)
Professional and consulting fees	509	366	143
Total general and administrative expenses	$ 1,901	$ 1,858	$ 43

Personnel related costs of $0.8 million were substantially the same as those incurred in the prior year. Personnel related costs for the three months ended June 30, 2024 and 2023 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. Facility related and other costs for the three months ended June 30, 2024 and 2023 included share-based compensation expense of $0.0 million and $0.0 million, respectively, for directors. Professional and consulting fees increased by $0.1 million primarily as a result of an increase in consultants used to support pre-commercial activities.

Total Other Expense, net

The following table summarizes our total other expense, net for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30, 2024	2023	Change
Interest expense, net	$ (571)	$ (324)	$ (247)
Adjustments to fair value of derivatives	(407)	(960)	553
Other (expense) / income, net	(12)	50	(62)
Total other expense, net	$ (990)	$ (1,234)	$ 244

Interest Expense, Net

Interest expense, net increased by $0.2 million for the three months ended June 30, 2024 primarily as a result of decreases in interest income on short-term investments and money market funds.

Adjustments to Fair Value of Derivatives

Adjustments to the fair value of the derivative liability were $0.4 million and $1.0 million for the three months ended June 30, 2024 and 2023, respectively. This non-cash adjustment, for both periods, primarily related to an increase in the fair value of the RLNs due to the passage of time.

Other (Expense) / Income, Net

Other (expense) / income, 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 and sub-lease income from a sub-lease agreement for a commercial unit (which was terminated in August 2023). The decrease of $0.1 million is primarily related to a decrease in sub-lease income.

Comparison of the six months ended June 30, 2024 and 2023

The following table summarizes our operating loss and loss before income taxes for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ (6,052)	$ (15,396)	$ 9,344
General and administrative	(4,087)	(3,956)	(131)
Total operating expenses	(10,139)	(19,352)	9,213
Operating loss	(10,139)	(19,352)	9,213
Total other expense, net	(1,880)	(2,470)	590
Loss before income taxes	$ (12,019)	$ (21,822)	$ 9,803

Research and Development Expenses (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
CRO and other preclinical and clinical trial expenses	$ 2,660	$ 11,583	$ (8,923)
Personnel related (including share-based compensation)	1,528	1,901	(373)
Chemistry, manufacturing and control (CMC) related expenses	1,019	1,357	(338)
Consulting fees	845	555	290
Total research and development expenses	$ 6,052	$ 15,396	$ (9,344)

The decrease in CRO and other preclinical and clinical trial expenses of $8.9 million was primarily due to higher costs incurred in 2023 to support our REASSURE trial, which began enrollment in October 2022 and completed enrollment in October 2023. Personnel related costs decreased by $0.4 million primarily as a result of lower headcount and a decrease in share-based compensation expense. Personnel related costs for the six months ended June 30, 2024 and 2023 included share-based compensation expense of $0.1 million and $0.2 million, respectively. CMC related expenses decreased by $0.3 million primarily as a result of a decrease in activities following completion of our REASSURE trial. Consulting fees of $0.8 million increased by $0.3 million primarily as a result of an increase in the use of consultants in connection with the preparation of our NDA filing for oral sulopenem for the treatment of uUTIs in adult women.

General and Administrative Expenses (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Personnel related (including share-based compensation)	$ 1,660	$ 1,783	$ (123)
Facility related and other	1,153	1,415	(262)
Professional and consulting fees	1,274	758	516
Total general and administrative expenses	$ 4,087	$ 3,956	$ 131

Personnel related costs decreased by $0.1 million primarily as a result of a decrease in share-based compensation expense. Personnel related costs for the six months ended June 30, 2024 and 2023 included share-based compensation expense of $0.1 million and $0.2 million, respectively. Facility related and other costs decreased by $0.3 million primarily as a result of a decrease in directors share-based compensation expense and insurance costs. Facility related and other costs for the six months ended June 30, 2024 and 2023 included share-based compensation expense of $0.0 million and $0.1 million, respectively, for directors. Professional and

consulting fees increased by $0.5 million primarily as a result of an increase in legal fees and an increase in consultants used to support pre-commercial activities.

Total Other Expense, Net

The following table summarizes our total other (expense) / income, net for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Interest expense, net	$ (1,058)	$ (723)	$ (335)
Adjustments to fair value of derivatives	(793)	(1,838)	1,045
Other (expense) / income, net	(29)	91	(120)
Total other expense, net	$ (1,880)	$ (2,470)	$ 590

Interest Expense, Net

Interest expense, net increased by $0.3 million for the six months ended June 30, 2024 primarily as a result of a decrease in interest income on short-term investments and money market funds.

Adjustments to Fair Value of Derivatives

Adjustments to the fair value of the derivative liability were $0.8 million and $1.8 million for the six months ended June 30, 2024 and 2023, respectively. This non-cash adjustment, for both periods, primarily related to an increase in the fair value of the RLNs due to the passage of time.

Other (Expense) / Income, Net

Other expense / income, 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 and sub-lease income from a sub-lease agreement for a commercial unit (which was terminated in August 2023). The decrease of $0.1 million is primarily related to a decrease in sub-lease income.

Liquidity and Capital Resources

Under Irish law, our board of directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital once authorized to do so by our articles of association or by an ordinary resolution 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 special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Our board of directors was initially authorized under our articles of association to issue new shares, and to disapply statutory pre-emption rights. The authorization of our board of directors to issue shares and the disapplication of statutory pre-emption rights must both be renewed by the shareholders at least every five years. We asked our shareholders to renew the authorization of our board of directors to issue shares and the disapplication of statutory pre-emption rights at our 2023 Annual General Meeting of Shareholders (2023 Annual Meeting), and to extend that authorization to the increase in authorized share capital that was approved by our shareholders at the 2023 Annual Meeting. Our shareholders renewed the authorization of our board of directors to issue shares; however, we did not receive approval on the disapplication of statutory pre-emption rights. We asked our shareholders to renew the disapplication of statutory pre-emption rights over the authorized but unissued share capital at an extraordinary general meeting of the Company on August 1, 2023; however, although we received over 62% support of the votes cast on renewing the pre-emption rights opt-out authority at that meeting, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of special resolutions. We asked our shareholders again to approve the disapplication of statutory pre-emption rights over 5,000,000 authorized but unissued ordinary shares at an extraordinary general meeting of the Company on January 30, 2024; however, again, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of special resolutions.

If our shareholders do not approve the disapplication of statutory pre-emption rights at a future general meeting of the Company, our board of director's existing authority to opt out of the statutory pre-emption right up to the amount of our authorized but unissued share capital (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting) will continue to apply only until January 26, 2026. This would limit us to having the ability to issue for cash only 0.8 million ordinary shares, based on the amount of authorized ordinary shares unissued or unreserved and therefore available for issuance as of August 9, 2024 (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting), up to January 26, 2026. Furthermore, absent shareholder approval of the disapplication of statutory pre-emption rights, the additional authorized but unissued shares that were approved at the 2023 Annual Meeting that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis, similar to the 2024 Rights Offering. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. As a result of this limitation, we are currently, and in the event we are not able to obtain shareholder approval of the disapplication of pre-emption rights, we will continue to be, severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares

for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering similar to the 2024 Rights Offering.

Furthermore, while the statutory preemption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time-consuming and complex to execute.

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We have generated limited revenue to date from a funding arrangement with the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program. We have funded our operations to date primarily through the issuance of ordinary and convertible preferred shares, warrants, debt raised under financing arrangements with SVB including the PPP loan, a sub-award from the Trustees of Boston University under the CARB-X program and the proceeds of the private placement which closed in January 2020 (the Private Placement) and the subsequent rights offering (the Rights Offering) pursuant to which our wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda), issued and sold $51.8 million aggregate principal amount of Exchangeable Notes and $0.1 million aggregate principal amount of RLNs. Through June 30, 2024, we had received cash proceeds of $198.3 million from sales of our Series A and Series B preferred shares and ordinary shares, $15.0 million from the first drawdown of our SVB loan, net proceeds of $45.0 million from the Private Placement and the Rights Offering, $0.7 million from the drawdown of our PPP loan, combined net proceeds of $8.6 million from the registered direct offering in June 2020 (June 3, 2020 Offering) and the registered direct offering in June 2020 (June 30, 2020 Offering) and $1.8 million from the exercise of warrants issued in the June 30, 2020 Offering, net proceeds of $15.5 million from the underwritten offering in October 2020 (October 2020 Offering) and $13.9 million from the exercise of warrants issued in the October 2020 Offering, net proceeds of $42.1 million from the underwritten offering in February 2021 (February 2021 Underwritten Offering) and $0.5 million from the exercise of warrants issued in the February 2021 Underwritten Offering and net proceeds of $32.2 million from the registered direct offering in February 2021 (February 2021 Registered Direct Offering).

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), 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 a sales agreement (the Sales Agreement), with H.C. Wainwright & Co., LLC (HC Wainwright), as agent, pursuant to which we may offer and sell ordinary shares, nominal value $0.01 per share, 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 of 1933, as amended. During the six months ended June 30, 2024, we sold 3,055,882 ordinary shares under the Sales Agreement at an average price of $2.49 per share for net proceeds of $7.4 million, after deducting commissions to HC Wainwright of $0.2 million.

As of June 30, 2024, we had cash, cash equivalents and short-term investments of $11.7 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 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 are exchangeable for our ordinary shares, cash or a combination of ordinary shares and cash, at an exchange rate of 105.0398 shares per $1,000 principal and interest on the Exchangeable Notes (equivalent to an exchange price of approximately $9.520 per ordinary share) as of June 30, 2024, which exchange rate was adjusted from an initial exchange rate of 66.666 shares per $1,000 of principal and interest on the Exchangeable Notes (equivalent to an initial exchange price of approximately $15.00 per ordinary share), and is subject to further adjustment pursuant to the terms of the Exchangeable Notes Indenture. The Exchangeable Notes will mature on January 31, 2025. Beginning on January 21, 2021 to June 30, 2024, certain noteholders of $40,691 aggregate principal amount of Exchangeable Notes have exchanged their notes for an aggregate of 3,760,155 of our ordinary shares, which included accrued and unpaid interest relating to such notes. The aggregate principal amount of Exchangeable Notes outstanding as of June 30, 2024 was $11,117. 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 either 15% or 20% of net revenues from U.S. sales of such products, depending on the indication approved by the FDA. 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.

Registered Direct Offerings

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, in the June 3, 2020 Offering, an aggregate of 198,118 ordinary shares, $0.01 nominal value per share, at a purchase price per 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. 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 June 3 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 will expire on June 3, 2025.

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 in the June 30, 2020 Offering an aggregate of 224,845 ordinary shares, $0.01 nominal value per share, at a purchase price per 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. 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 the June 30 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 will expire on June 30, 2025.

On February 9, 2021, we entered into the securities purchase agreement (February SPA) with certain institutional investors pursuant to which we issued and sold in the February 2021 Registered Direct Offering an aggregate of 1,166,666 ordinary shares, $0.01 nominal value per share, at a purchase price of $30.00 per share, for aggregate net proceeds to us of $32.2 million after deducting placement agent fees and other offering expenses payable by us. 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 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.

October 2020 Offering

On October 27, 2020, we completed the October 2020 Offering in which we sold an aggregate of (i) 1,034,102 ordinary shares, $0.01 nominal value per 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 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 22, 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, $0.01 nominal value per share, at a public offering price of $17.25 per share. 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.

Cash Flows

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

	Six Months Ended June 30,	
	2024	**2023**
Net cash used in operating activities	(19,842)	(17,222)
Net cash provided by investing activities	11,408	9,453
Net cash provided by financing activities	7,384	435
Effect of exchange rates on cash and cash equivalents	(45)	(24)
Net decrease in cash, cash equivalents and restricted cash	$ (1,095)	$ (7,358)

Operating Activities

During the six months ended June 30, 2024, operating activities used $19.8 million of cash, resulting from our net loss of $12.1 million and net cash used by changes in our operating assets and liabilities of $11.2 million consisting primarily of a decrease in accounts payable and accrued expenses, partially offset by net non-cash charges of $3.5 million.

During the six months ended June 30, 2023, operating activities used $17.2 million of cash, resulting from our net loss of $22.1 million and net cash used by changes in our operating assets and liabilities of $0.9 million, partially offset by net non-cash charges of $5.8 million.

Investing Activities

During the six months ended June 30, 2024, net cash provided by investing activities of $11.4 million was related to the proceeds from the sale of short-term investments of $23.8 million, partially offset by the purchase of short-term investments of $12.4 million.

During the six months ended June 30, 2023, net cash provided by investing activities of $9.5 million was related to the proceeds from the sale of short-term investments of $36.3 million, partially offset by the purchase of short-term investments of $26.9 million.

Financing Activities

During the six months ended June 30, 2024, net cash provided by financing activities of $7.4 million was primarily related to net proceeds from the sale of ordinary shares pursuant to the Sales Agreement.

During the six months ended June 30, 2023, net cash provided by financing activities of $0.4 million was related to net proceeds from the sale of ordinary shares of $0.4 million pursuant to the Sales Agreement.

Funding Requirements

We expect to continue to incur significant expenses and increasing operating losses as we seek potential marketing approval for oral sulopenem, resume any pre-commercialization activities and pursue the development of our sulopenem program in additional indications through preclinical and clinical development.

As of June 30, 2024, we had cash, cash equivalents and short-term investments of $11.7 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 research and development programs or commercialization efforts. Our future viability is dependent on our ability to raise additional capital to finance our operations. Without additional external funding, we do not believe that our existing cash, cash equivalents and short-term investments, including amounts received under our 2024 Rights Offering will enable us to fund our operating expenses for the next 12 months from the date of this Quarterly Report on Form 10-Q including repayment of the Exchangeable Notes in January 2025. 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 and/or may be conducted in response to the CRL;

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

•establish manufacturing and supply chain capacity sufficient to provide commercial quantities of oral sulopenem and/or sulopenem, 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 timing and costs of our clinical trials of oral sulopenem and sulopenem, 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, including oral sulopenem for the treatment of uUTI;

•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 commercialization activities for oral sulopenem and/or 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 marketing approval and revenue received from any potential commercial sales of oral sulopenem and/or 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. (Pfizer) (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 and the repayment of the Exchangeable Notes, if required;

•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 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

•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.

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, any potential economic slowdown or recession, including trade wars or civil or political unrest (such as the ongoing conflicts between Ukraine and Russia and Israel and Gaza) may increase the cost of capital and limit our ability to access capital. 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. Additionally, in the event we are not able to obtain shareholder approval for the disapplication of pre-emption rights over our ordinary shares at a general meeting of the shareholders, our ability to raise additional capital through the issue of new shares for cash will be severely limited. 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, the Exchangeable Notes and the investor rights agreement we entered into in connection with the Private Placement each impose operating and other restrictions on us. Such restrictions affect, and in many cases limit or prohibit, our ability to dispose of certain assets, pay dividends, incur additional indebtedness, undergo a change of control and enter into certain collaborations, strategic alliances or other similar partnerships, among other things. 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 stakeholders while prudently managing our remaining resources.

Contractual Obligations and Commitments

Under the Pfizer License, we have agreed to make certain regulatory and sales milestone payments, including a regulatory milestone payment of $20 million upon approval of oral sulopenem by the FDA. We intend to defer this payment for a two-year period, at an annual rate of eight percent on a daily compounded basis until paid in full, as permitted pursuant to the terms of the Pfizer License. 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.

Under the RLN Indenture, holders of RLNs will be 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) thve "End Date" occurs, which is December 31, 2045, or (iii) December 31, 2025, in the event that we have not yet received FDA approval with respect to one or more specified sulopenem products by such date. 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), determined based on which of the specified sulopenem products have received FDA approval. The Payment Rate will be based on the maximum aggregate principal amount of RLNs and will equal (i) up to 15% if we or one of our affiliates has received FDA approval for the use of specified sulopenem products for the treatment of uUTIs and (ii) up to 20% if we or one of our affiliates has received FDA approval for the use of specified sulopenem products for the treatment of cUTIs but has not received FDA approval for treatment of uUTIs. There was no payment due for each of the Payment Measuring Periods through the payment measuring period ending June 30, 2024. 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).

Our operating lease obligations primarily consist of payments for office space, which are described further in Note 7 of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Future contractual payments on operating lease obligations due within one year of June 30, 2024 are $0.2 million, and there were no future contractual payments on operating lease obligations due greater than one year from June 30, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2024, we had cash, cash equivalents and short-term investments of $11.7 million, consisting of cash, money market funds, commercial paper and U.S. treasury bills. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. We are exposed to interest rate risk in connection with our investments in marketable securities. As interest rates change, the unrealized gains and losses associated with those securities will fluctuate accordingly. An immediate interest rate increase of 100 basis points would result in a decrease of $0.01 million in the fair market value of our portfolio as of June 30, 2024. Such losses would only be realized if we sold the investments prior to maturity.

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 June 30, 2024 and December 31, 2023, 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 six months ended June 30, 2024 and 2023 or for the year ended December 31, 2023. 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 June 30, 2024. 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, or 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 June 30, 2024, 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

No change 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 June 30, 2024, 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, or 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 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 June 30, 2024, we had $11.7 million of cash, cash equivalents and short-term investments. Based on our available cash resources we do not believe that our existing cash, cash equivalents and short-term investments, including amounts received under our 2024 Rights Offering, 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 including through repayment of the 6.500% Exchangeable Senior Subordinated Notes due in January 2025 (Exchangeable Notes).

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 of the condensed 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 addition, our ability to raise additional capital through the issue of new shares for cash is limited to issuing only 759,854 ordinary shares (or rights to acquire such shares) for cash, based on the amount of authorized ordinary shares unissued or unreserved and free from any statutory rights of pre-emption, and therefore available for issuance as of August 9, 2024. While shareholders approved an increase of an additional 60,000,000 ordinary shares at our annual general meeting in May 2023 (the "Additional Shares"), we did not receive approval for the disapplication of statutory pre-emption rights over such shares. Absent shareholder approval of the disapplication of statutory pre-emption rights with respect to the Additional Shares, any Additional Shares that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. As a result of this limitation, we are currently severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering similar to the rights offering launched in July 2024, where we distributed, at no charge, subscription rights (the "2024 Rights Offering") to our shareholders and holders of warrants that had contractual rights to participate in the securities offering, which were not waived (each an "eligible warrant holder" and collectively the "eligible warrant holders"). In connection with the 2024 Rights Offering, we distributed an aggregate of 17,007,601 non-transferable subscription rights to purchase an aggregate of 8,503,800 units ("Units") at a subscription price of $1.21 per whole 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 warrant) 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"). Each shareholder and holder of eligible warrants received one subscription right for every ordinary share owned and every ordinary share issuable upon exercise of eligible warrants at 5:00 p.m., Eastern Time, on July 16, 2024. Each subscription right entitled its holder to purchase 0.50 Units, at a subscription price of $0.605 per 0.50 Units, consisting of (i) 0.50 ordinary shares, (ii) a 1-year warrant to purchase 0.25 ordinary shares and (iii) a 5-year warrant to purchase 0.50 ordinary shares. During the 2024 Rights Offering, rights holders validly subscribed for 6,121,965 Units. The 2024 Rights Offering closed on August 9, 2024 and resulted in aggregate net proceeds, after deducting estimated fees and expenses, of approximately $5.8 million (assuming no exercise of any warrants included in the units sold by us in the 2024 Rights Offering).

Furthermore, while the statutory pre-emption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time-consuming and complex to execute. 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 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 are a clinical-stage pharmaceutical company with a limited operating history. We have not generated any product revenue and have incurred net losses in each year since our inception in 2015. As of June 30, 2024, we had an accumulated deficit of $473.4 million, cash and cash equivalents of $5.0 million and short-term investments of $6.7 million. Our product candidates, oral sulopenem and sulopenem (together, the sulopenem program), are in clinical development, and have not been approved for sale and we may never have our product candidates approved for commercialization. We submitted a New Drug Application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTIs) in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the U.S. Food and Drug Administration (FDA) accepted the application for review in January 2021. We received a Complete Response Letter (CRL) from the FDA on July 23, 2021, in respect of our NDA. The CRL provided that the FDA had completed its review of the NDA and had determined that it could not approve the NDA in its present form. The CRL further 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 special protocol assessment (SPA) process on the design, endpoints and statistical analysis of a Phase 3 clinical trial for oral sulopenem for the treatment of uUTIs and we commenced enrollment in that clinical trial, known as REnewed ASsessment of Sulopenem in uUTI caused by Resistant Enterobacterales (REASSURE), in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA for oral sulopenem for the treatment of uUTIs to the FDA in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the Prescription Drug User Fee Act (PDUFA), which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem.

We have financed our operations to date primarily with the issuance of 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 Rights Offering) pursuant to which our wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda), sold units (Units) consisting of (i) Exchangeable Notes; and (ii) Limited Recourse Royalty-Linked Subordinated Notes (RLNs and, together with the Exchangeable Notes, the Securities), 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 an "at the market offering" agreement (the Sales Agreement) with H.C. Wainwright & Co., LLC (HC Wainwright), as agent, pursuant to which we may offer and sell ordinary shares, nominal value $0.01 per share 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 of 1933, as amended. During the period ended June 30, 2024, we sold 3,055,882 ordinary shares under the Sales Agreement at an average price of $2.49 per share for net proceeds of $7.4 million. As of June 30, 2024, net proceeds of $16.2 million have been received from the exercise of certain warrants issued as part of the June 30, 2020 Offering, October 2020 Offering and February 2021 Underwritten Offering. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical development, for our sulopenem program.

Following receipt of the CRL, in order to reduce operating expenses and conserve cash resources, we halted any remaining pre-commercial activities for oral sulopenem and limited spending to essential costs required in connection with the resubmission of the NDA.

We expect to continue to incur significant expenses and increasing operating losses as we conduct clinical trials of oral sulopenem and sulopenem, seek marketing approval for oral sulopenem if clinical trials are successful, engage in pre-commercialization activities and pursue the development of our sulopenem program in additional indications, including through preclinical and clinical development. 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 and/or may be conducted in response to the CRL;
- establish sales, marketing and distribution capabilities either directly or through a third-party, to commercialize oral sulopenem and/or sulopenem in the United States if we obtain marketing approval from the FDA;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of oral sulopenem and/or sulopenem, 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.

We will require additional capital to fund our operations. 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 pharmaceutical products is a time-consuming, expensive and uncertain process that takes years to complete. We expect to continue to incur significant expenses and increasing operating losses as we conduct clinical trials of oral sulopenem and sulopenem, seek marketing approval for oral sulopenem if clinical trials are successful, engage in pre-commercialization activities, and pursue the development of our sulopenem program in additional indications, including through preclinical and clinical development. If we obtain marketing approval for oral sulopenem, sulopenem or any future product candidate and undertake commercialization activities, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval, and could be substantial. Additionally, principal and interest on the outstanding Exchangeable Notes become due on January 31, 2025.

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.

Furthermore, under Irish law, our directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital 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. We asked our shareholders to renew the authorization of our board of directors to issue shares and the disapplication of statutory pre-emption rights at the 2023 Annual General Meeting of Shareholders (the 2023 Annual Meeting) and to extend that authorization to the increase in authorized share capital that was approved by our shareholders at the 2023 Annual Meeting. Our shareholders renewed the authorization of our board of directors to issue shares; however, we did not receive approval on the disapplication of statutory pre-emption rights. We asked our shareholders to renew the disapplication of statutory pre-emption rights over the authorized but unissued share capital at an extraordinary general meeting of the Company on August 1, 2023; however, although we received over 62% support of the votes cast on renewing the pre-emption rights opt-out authority at that meeting, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of special resolutions. We asked our shareholders again to approve the disapplication of statutory pre-emption rights over 5,000,000 authorized but unissued ordinary shares at an extraordinary general meeting of the Company on January 30, 2024 (the January EGM) however, again, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of special resolutions.

If our shareholders do not approve the disapplication of statutory pre-emption rights, our board of director's existing authority to opt out of the statutory pre-emption right up to the amount of our authorized but unissued share capital (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting) will continue to apply only until January 26, 2026. This would limit us to having the ability to issue for cash only 759,854 ordinary shares (or rights to acquire such shares) , based on the amount of authorized ordinary shares unissued or unreserved and therefore available for issuance as of August 9, 2024 (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting), up to January 26, 2026. Furthermore, absent shareholder approval of the disapplication of statutory pre-emption rights, the additional authorized but unissued shares that were approved at the 2023 Annual Meeting that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis, similar to the 2024 Rights Offering. As a result of this limitation, we are currently severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering, similar to the 2024 Rights Offering. Furthermore, while the statutory pre-emption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time-consuming and complex to execute. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. In the event we are not able to obtain such shareholder approval of the disapplication of pre-emption rights at a future general meeting of the shareholders, we will continue to be limited in the amount of ordinary shares we may sell for cash in any capital raising transaction without first offering those shares to all of our existing shareholders.

Additional capital will be required in order to repay the Exchangeable Notes when they become due. We may not have enough available cash or be able to obtain financing at that time. Our failure to make repayments when due would constitute a default under the indenture governing the Exchangeable Notes. A default under that indenture could also lead to a default under any agreements governing our future indebtedness.

We expect that additional capital will be required to complete our sulopenem development program and file with regulatory agencies and commercialize oral sulopenem if regulatory approval is received. If we receive regulatory approval for oral sulopenem, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. 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 efforts, which 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 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 timing and costs of our clinical trials of oral sulopenem and sulopenem, 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, including oral sulopenem for the treatment of uUTI;
- 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 commercialization activities for oral sulopenem and/or 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 marketing approval and revenue received from any potential commercial sales of oral sulopenem and/or 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. (Pfizer) (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 and the repayment of the Exchangeable Notes, if required;

•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 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 report 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. Certain of the derivative values are directly correlated to the value of our ordinary shares. Due to the nature of the required calculations and the large number of ordinary shares involved in such calculations, changes in our share price and/or 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.

Provisions in the EN Indenture and RLN Indenture may deter or prevent us from raising additional capital to fund our operations or entering into a strategic transaction to sell, license, or otherwise dispose of our rights to sulopenem.

Provisions in the agreements we entered into in connection with our financings may deter or prevent us from raising additional capital to fund our operations as and when needed. For example, the indenture governing the Exchangeable Notes (the EN Indenture) contains negative covenants prohibiting our wholly owned subsidiary, Iterum Therapeutics Bermuda Limited (Iterum Bermuda), as well as us and our wholly owned subsidiaries and their subsidiaries (the Guarantors), who guaranteed Iterum Bermuda's obligations under the Exchangeable Notes, from, among other things, incurring any indebtedness that is not permitted by the EN Indenture and entering into transactions with significant shareholders (as defined in the EN Indenture). In addition, the indenture governing the RLNs (the RLN Indenture) contains negative covenants prohibiting Iterum Bermuda and the Guarantors from, among other things, selling, transferring or assigning certain assets and taking other actions outside the ordinary course of business that would reasonably be expected to reduce the amount of payments under the RLNs.

These provisions could deter or prevent us from raising additional capital or entering into a strategic transaction to sell, license, or otherwise dispose of our rights to sulopenem. 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. Furthermore, our inability to consummate a strategic transaction to sell, license, or otherwise dispose of our rights to sulopenem could impact our ability to maximize stakeholder value.

We are heavily dependent on the success of our sulopenem program, and our ability to develop, obtain marketing approval for and successfully commercialize oral sulopenem and 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 oral sulopenem and sulopenem, which are currently our two product candidates in development. Our prospects, including our ability to finance our operations and generate revenue from product sales, currently depend entirely on the development and commercialization of our sulopenem program.

We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, oral sulopenem and/or sulopenem. 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:

•resolving the matters set out in the CRL received in July 2021 in connection with our NDA for oral sulopenem;

•successfully navigating the Advisory Committee on September 9, 2024, relating to our NDA for oral sulopenem for the treatment of uUTIs in adult women, or in the event of an unfavorable recommendation(s), convincing the FDA not to accept the Advisory Committee's recommendation(s), which are non-binding on FDA;

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

•applying for and obtaining marketing approval for oral sulopenem and/or sulopenem;

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

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

•establishing sales, marketing and distribution capabilities either directly or through a third-party, to commercialize oral sulopenem and/or sulopenem or entering into collaboration arrangements for the commercialization of oral sulopenem and/or sulopenem where we choose not to commercialize directly ourselves; and

•obtaining market acceptance of oral sulopenem and/or sulopenem as viable treatment options.

Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, 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, including in response to the CRL received in July 2021, or if there are any delays in completing such studies or with the development of our sulopenem program or any future product candidates. Even if oral sulopenem or sulopenem are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of oral sulopenem and/or sulopenem. Where we enter into collaboration arrangements with third-party collaborators for commercialization of 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.

The EN Indenture and the RLN Indenture each contain affirmative and negative covenants which impose operating and other restrictions on us, including, among other things, incurring any indebtedness that is not permitted by the EN Indenture or amending the terms of any subordinated indebtedness, entering into strategic transactions or transferring any material assets and undergoing a change of control transaction (subject to certain exceptions, including in the case of a change of control transaction, a transaction in which each holder of an outstanding Exchangeable Note receives cash consideration of at least 300% of the outstanding principal amount of such Exchangeable Notes). For example, pursuant to the EN Indenture, we are required to obtain the consent of a portion of the holders of the Exchangeable Notes prior to entering into collaboration agreements, exclusive selling arrangements or similar partnerships including a definitive agreement for commercialization services in the United States. Failure to comply with these terms could result in an event of default which could lead, among other things, to an acceleration of amounts due under the EN Indenture and the obligation to pay default interest. Moreover, obtaining a consent to a waiver of these terms is subject to a veto right of the holders of 30% of the outstanding Exchangeable Notes, in the case of the EN Indenture, and 30% of the outstanding RLNs, in the case of 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 rate at which the Exchangeable Notes are exchangeable for our ordinary shares is subject to adjustment, including pursuant to anti-dilution protections. For example, following the closing of the 2024 Rights Offering on August 9, 2024, the exchange rate of the Exchangeable Notes increased and, effective as of August 15, 2024, the exchange price of the Exchangeable Notes will $5.7071 per ordinary share (at an adjusted exchange rate of 175.2191 shares per $1,000 of principal and interest on the Exchangeable Notes). As of August 9, 2024, $11.1 million aggregate principal amount of Exchangeable Notes remained outstanding.

Depending on the public offering prices, the number of shares that we sell pursuant to our Sales Agreement with HC Wainwright as agent and any potential increase to the exchange rate of the Exchangeable Notes, we may not have sufficient authorized share capital or share issuance authorities to convert all of the Exchangeable Notes into ordinary shares following any sales of shares pursuant to the Sales Agreement and could be required to settle any exchanges with cash to the extent we do not have available authorized shares. If we elect to settle any exchanges in cash, or we do not have authorized and available ordinary shares needed to satisfy physical exchange of the Exchangeable Notes, our liquidity could be adversely affected and/or we may not have sufficient cash available at that time to satisfy such cash settlement. In addition, in the event we elect to settle exchanges of Exchangeable Notes with ordinary shares, we would be limited in our ability to issue equity for other purposes which could adversely affect our shareholders and our ability to raise additional capital. During the six months ended June 30, 2024, the Company sold 3,055,882 ordinary shares under the “at the market” agreement at an average price of $2.49 per share for net proceeds of $7.4 million.

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.

Servicing our indebtedness will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our indebtedness.

Our ability to make payments of the principal of, to pay interest and special interest on the Exchangeable Notes, or to make cash payments, if we so elect, in connection with any exchange of Exchangeable Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow sufficient to service the Exchangeable Notes or other indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Additionally, in the event we are not able to obtain shareholder approval for the disapplication of pre-emption rights over our ordinary shares at a general meeting of the shareholders, we may not be able to efficiently and cost effectively engage in equity-capital raising prior to January 31, 2025, when principal and interest on the outstanding Exchangeable Notes become due.

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. While the EN Indenture restricts our ability to incur additional indebtedness, it allows for certain additional indebtedness and any such restrictions may be waived. If new debt is added to our current debt levels, the related risks that we now face could intensify.

We may not have the ability to raise the funds necessary to settle exchanges of the Exchangeable Notes in cash or to repurchase the Exchangeable Notes upon a fundamental change, and our future debt may limit our ability to pay cash upon exchange or repurchase of the Exchangeable Notes.

Holders of the Exchangeable Notes will have the right to require us to repurchase all or a portion of their Exchangeable Notes upon the occurrence of a fundamental change at specified repurchase prices. In addition, upon exchange of the Exchangeable Notes, unless we elect to deliver solely ordinary shares to settle such exchange (other than paying cash in lieu of delivering any fractional share), we would be required to make specified cash payments in respect of the Exchangeable Notes being exchanged. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Exchangeable Notes surrendered therefor or to pay cash with respect to Exchangeable Notes being exchanged. Additionally, in the event we are not able to obtain shareholder approval for the disapplication of pre-emption rights over our ordinary shares at the extraordinary general meeting of the shareholders, we may not be able to efficiently and cost effectively engage in equity-capital raising prior to January 31, 2025, when principal and interest on the outstanding Exchangeable Notes become due. Our ability to repurchase or to pay cash upon exchange of the Exchangeable Notes may also be limited by law, regulatory authority, and future indebtedness.

Our failure to repurchase Exchangeable Notes at a time when the repurchase is required by the EN Indenture or to pay cash upon exchange of the Exchangeable Notes as required by the EN Indenture would constitute a default under the EN Indenture. A default under the EN Indenture or a fundamental change itself could also lead to a default under agreements governing our future

indebtedness. If the payment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and any accrued and unpaid interest and repurchase the Exchangeable Notes or to pay cash upon exchange of the Exchangeable Notes. As of June 30, 2024, $11.1 million aggregate principal amount of Exchangeable Notes remained outstanding.

The exchange feature of the Exchangeable Notes may adversely affect our financial condition and operating results.

Beginning January 21, 2021 and prior to the earlier of (i) the close of business on the scheduled trading day immediately preceding a mandatory exchange notice for the Exchangeable Notes, which would be triggered by the occurrence of any of certain mandatory exchange trigger events specified in the EN Indenture, and (ii) the close of business on the second scheduled trading day immediately preceding the interest record date, holders of Exchangeable Notes are entitled to exchange the Exchangeable Notes at any time at their option. If holders continue to elect to exchange their Exchangeable Notes, unless we elect to satisfy our exchange obligation by delivering solely ordinary shares (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our exchange obligation in cash, which could adversely affect our liquidity. The relevant accounting rules require that we recognize liabilities which appropriately reflect our obligations specified in the EN Indenture. Therefore, even if holders do not elect to exchange their Exchangeable Notes, our liabilities and statement of operations could be significantly impacted.

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 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), and pursuant to which we registered for sale up to $100.0 million of any combination of our 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 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, nominal value $0.01 per share for aggregate gross sales proceeds of up to $16.0 million (not to exceed 4,478,180), 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.

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.

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. Similarly, while we believe that sulopenem has the potential to treat uUTIs in humans based on the results of prior preclinical studies and clinical trials, oral sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin in the population of patients with baseline pathogens susceptible to ciprofloxacin in our prior Phase 3 uUTI clinical trial. However, in the uUTI clinical trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating statistical significance in the overall response rate by treatment arm in the ciprofloxacin-resistant population, providing evidence of a treatment effect in patients with uUTI. Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. We received a CRL from the FDA on July 23, 2021 for our NDA. The CRL provided that the FDA had completed its review of the NDA and had determined that it could not approve the NDA in its present form. The CRL further 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA to the FDA for oral sulopenem for the treatment of uUTIs in April of 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

Further, 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 for uUTI or any other indication or for any other product or to successfully commercialize sulopenem.

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, Silicon Valley Bank (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.

Risks Related to Our Evaluation of Strategic Options

Our exploration and pursuit of strategic alternatives may not be successful.

Our board of directors, after receiving positive data from our REASSURE trial determined that we should focus on a strategic process to sell, license, or otherwise dispose of our rights to sulopenem with the goal of maximizing shareholder value. In connection with this strategic process, we have engaged a financial advisor to assist management and the board in evaluating strategic alternatives.

Despite our plan to devote significant efforts to identify and evaluate potential strategic options, the process may not result in any definitive offer to consummate such a transaction, or, if we receive such a definitive offer, the terms may not be as favorable as anticipated or may not result in the execution or approval of a definitive agreement. Even if we enter into a definitive agreement, we may not be successful in completing a transaction or, if we complete such a transaction, it may not enhance shareholder value or deliver expected benefits. In the event that we are unable to raise sufficient capital to fund our operations while we evaluate our strategic options, and, if able, consummate a transaction, or identify a viable strategic option at all, our board of directors may determine that a liquidation and dissolution of our business approved by shareholders is the best method to maximize shareholder value.

Risks Related to Clinical Development and Commercialization

We are heavily dependent on the success of our sulopenem program, and our ability to develop, obtain marketing approval for and successfully commercialize oral sulopenem and/or sulopenem. If we are unable to obtain marketing approvals for oral sulopenem or sulopenem, or if thereafter we fail to commercialize oral sulopenem or sulopenem or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for sale and have invested substantially all of our efforts and financial resources in the development of our sulopenem program. Our near-term prospects are substantially dependent on our ability to develop, apply for and obtain marketing approval for and successfully commercialize oral sulopenem and/or sulopenem. The success of our sulopenem program will depend on several factors, including the following:

- resolving the issues set out in the CRL received in July 2021 in connection with our NDA for oral sulopenem;
- successful enrollment in, and completion of, clinical trials, including any clinical trials that may be required for regulatory approval of our product candidates;
- clinical trial results with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- timely completion of any additional clinical trials and non-clinical studies conducted to support the filing for regulatory approvals of our sulopenem program, if required by the FDA or any comparable foreign regulatory authority;
- receipt of marketing approvals from applicable regulatory authorities;

•establishment and maintenance of arrangements with third-party manufacturers to obtain commercial supply at a scale sufficient to meet anticipated demand and at a cost appropriate for our commercialization;

•acquisition and maintenance of patent, trade secret and other intellectual property protection and regulatory exclusivity, both in the United States and internationally, including our ability to maintain the Pfizer License;

•protection of our rights in our intellectual property portfolio;

•launch of commercial sales of oral sulopenem and/or sulopenem, if approved, whether alone or in collaboration with others;

•the effectiveness of our own or any future collaborators' marketing, sales and distribution strategy and operations;

•acceptance of oral sulopenem and/or sulopenem, if approved, by patients, physicians and the medical community at large;

•our ability to obtain and sustain coverage and an adequate level of reimbursement by third-party payors;

•the prevalence, frequency and severity of adverse side effects of oral sulopenem and/or sulopenem;

•the availability, perceived advantages, relative cost and relative efficacy of alternative and competing therapies; and

•an acceptable safety profile of oral sulopenem and/or sulopenem following approval.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights, manufacturing and the impact of competition.

Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. We received a CRL from the FDA on July 23, 2021 in respect of our NDA. 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA for oral sulopenem for the treatment of uUTIs to the FDA in the second quarter of 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

If we are unable to develop, receive marketing approval for, or successfully commercialize oral sulopenem and/or sulopenem, or if we experience delays as a result of any of these factors or otherwise, our business could be materially harmed.

Our company has no experience in obtaining regulatory approval for a drug.

Our company has never obtained regulatory approval for, or commercialized, a drug. We must complete extensive preclinical and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals. To gain approval to market a product candidate, we must provide the FDA and foreign regulatory authorities with non-clinical, clinical and chemistry, manufacturing, and controls (CMC) data that adequately demonstrates the safety and efficacy of the product for the intended indication(s) applied for in the NDA(s) or other respective regulatory filing.

We may never succeed in achieving regulatory approval for any of our product candidates. For example, in the results of our cIAI clinical trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy for the cIAI trial. In the second quarter of 2020, we announced the results of our Phase 3 clinical trials of sulopenem for the treatment of cUTI and uUTI. In the cUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapies with the difference in response rates driven almost entirely by higher rates of asymptomatic bacteriuria on the sulopenem IV to oral sulopenem arm relative to the ertapenem IV to oral ciprofloxacin arm, only evident at the test of cure visit; the rates of patients receiving additional antibiotics or with residual cUTI symptoms were similar between therapies. Similarly, in the uUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin in the population of patients with baseline pathogens susceptible to ciprofloxacin driven to a large degree by a greater amount of asymptomatic bacteriuria in the sulopenem treated patients at the test of cure visit relative to those receiving ciprofloxacin. However, in the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating statistical significance in the overall response rate by treatment arm in the ciprofloxacin-resistant population, providing evidence of a treatment effect in patients with uUTI. Notwithstanding failure to meet the endpoints described above, in all three Phase 3 clinical trials, at all timepoints measured, the clinical response to sulopenem and/or oral sulopenem was similar to the comparator regimen (non-inferior), except in the instance of the quinolone non-susceptible population in the prior Phase 3 uUTI trial in which oral sulopenem was statistically superior. Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. We received a CRL from the FDA on July 23, 2021 for our NDA. 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA for oral sulopenem for the treatment of uUTIs to the FDA in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates.

Additionally, any failure or delay in obtaining regulatory approvals would prevent us from commercializing oral sulopenem and/or sulopenem, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA(s) or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in other countries.

If clinical trials of oral sulopenem, 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 oral sulopenem, sulopenem or any other product candidate.

We may not commercialize, market, promote, or sell any 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 submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020, for which we received a CRL from the FDA on July 23, 2021, we had not previously submitted an NDA to the FDA or similar applications to comparable foreign regulatory authorities for any of our product candidates.

Our business currently heavily depends on the successful development, regulatory approval and commercialization of our sulopenem program. The 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, 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA to the FDA in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

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, sulopenem or any of our other product candidates, including:

- although we conducted our prior Phase 3 clinical trials pursuant to SPA agreements, the FDA or other comparable foreign regulatory authorities may ultimately disagree as to the design or implementation of such clinical trials or other clinical trials, or may request additional data to support approval, such as that requested in the CRL from July 2021;
- although we conducted the REASSURE clinical trial comparing oral sulopenem and Augmentin® (amoxicillin/clavulanate) pursuant to an SPA agreement, there is no guarantee that the FDA, or any other regulatory authorities, will approve any application that is supported by a clinical trial conducted in accordance with such agreement;
- 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 oral sulopenem, sulopenem or any other 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 oral sulopenem, sulopenem or any other 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 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 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 of oral sulopenem, sulopenem or 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;
- 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 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 and/or sulopenem, or slow down or halt our product development for oral sulopenem 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.

The FDA Advisory Committee may render an opinion on our NDA for oral sulopenem for the treatment of uUTIs in adult women which is negative or may delay approval or limit oral sulopenem's marketability.

In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. The FDA is not bound by the recommendation of an Advisory Committee, which is composed of clinicians, statisticians and other experts, but it generally follows such recommendations. The Advisory Committee may recommend against approval of our NDA for oral sulopenem for the treatment of uUTIs or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions. This may delay and increase the cost of the review process. Any delay in obtaining, or an inability to obtain, marketing approval could prevent the commercialization of oral sulopenem and generation of revenue and profit.

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 indication.

Although we believe that oral sulopenem and sulopenem have the potential to treat uUTI, cUTI and cIAI in humans based on the results of prior preclinical studies and clinical trials, 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. 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 cIAI or cUTI. Similarly, while we believe that sulopenem has the potential to treat uUTI in humans based on the results of prior preclinical studies and clinical trials, and based on our prior Phase 3 uUTI clinical trial, in the population of patients with baseline pathogens resistant to quinolones, in which sulopenem met the related primary endpoint by demonstrating statistical significance in the overall response rate by treatment arm in the ciprofloxacin-resistant population, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin in the population of patients with baseline pathogens susceptible to ciprofloxacin in our prior Phase 3 uUTI clinical trial. Based on discussions with the FDA at a pre-NDA meeting and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTI in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021. On July 23, 2021, we received a CRL from the FDA in respect of the NDA. 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA for oral sulopenem for the treatment of uUTIs to the FDA in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the

matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

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 oral sulopenem, 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 oral sulopenem, sulopenem or any of our other product candidates 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 (1.3% 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 recently completed uUTI trial, REASSURE, patients received either oral sulopenem or Augmentin®. Among 2,214 treated patients, treatment related adverse events were observed in 18.9% and 12.3% of patients on sulopenem 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 sulopenem 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 sulopenem and 0.4% of patients on Augmentin®. Serious adverse events were seen in 0.0% of patients on sulopenem 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 in the CRL received from the FDA in July 2021, in future trials there may be unforeseen serious adverse events or side effects that differ from those seen in our prior Phase 3 program, in Phase 1 normal healthy volunteers with oral sulopenem or the prior post-marketing experience with probenecid. There may also be unexpected adverse events associated with probenecid that have not been seen to date.

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 oral sulopenem, sulopenem or any of our other future product candidates could arise or become known either during clinical development or, if approved, 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, oral sulopenem, 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.

Even if a product candidate does obtain regulatory approval, it 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 if we obtain FDA or other regulatory approvals and are able to launch oral sulopenem, sulopenem or any other product candidate commercially, the product candidate 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 our product candidates may require significant resources and may not be successful. If oral sulopenem, 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 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 oral sulopenem and sulopenem 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 oral sulopenem and/or sulopenem could be smaller than our estimates of the potential market opportunity. If the actual market for oral sulopenem and/or sulopenem 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 no 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 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 has limited experience and has not yet demonstrated an ability to successfully obtain marketing approval, 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. Assuming we obtain marketing approval for oral sulopenem or sulopenem, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities whether we choose to commercialize product candidates directly ourselves or seek to commercialize them through third-party collaboration arrangements. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We currently have no 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, oral sulopenem may not be successfully commercialized, if it is approved.

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, oral sulopenem may not be successfully commercialized, if it is approved.

We are currently evaluating our commercialization strategy in the United States and other territories. 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 currently do not have a sales, marketing or distribution infrastructure and we have no experience in the sales, marketing

or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either build our marketing, sales, distribution, managerial and other non-technical capabilities, make arrangements to outsource those functions to third parties or enter a strategic transaction with a partner that has established commercial capabilities in the U.S. If oral sulopenem receives regulatory approval, we may build a commercial organization and recruit a targeted sales force with technical expertise, an internal marketing and health resource group, as well as a managed markets group focused on reimbursement activities with third-party payors and a specialty distribution team to ensure pharmacy-level stocking and, where we choose not to commercialize directly ourselves, we will seek to commercialize oral sulopenem collaboration arrangements. We are not currently party to any such arrangements but engaged a potential commercial partner to provide pre-commercial activities and we commenced negotiations on a definitive agreement for commercialization services. Following receipt of the CRL in July 2021, in order to reduce operating expenses and conserve cash resources, we halted any remaining pre-commercial activities and paused negotiations on the definitive agreement for commercialization services. There is no assurance that we will seek or be able to reach a definitive agreement for commercialization services in the future. Furthermore, while we are currently undergoing a strategic process to sell, license or otherwise dispose of our rights to sulopenem with the goal of maximizing stakeholder value and with the intention of completing such a strategic transaction with a partner that has established commercial capabilities in the U.S., there can be no certainty as to the timing and outcome of our efforts or our ability to consummate such a transaction at all.

The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we, recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire 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 establish a 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.

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, like COVID-19;

•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 oral sulopenem. 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, our 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 would expect would compete with oral sulopenem and sulopenem, such as levofloxacin, ciprofloxacin, nitrofurantoin, fosfomycin, amoxicillin-clavulanate, cephalexin, trimethoprim-sulfamethoxazole and pivmecillinam. 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. If oral sulopenem or sulopenem is approved, the pricing may be at a significant premium over other competitive products that are generic. This may make it difficult for oral sulopenem or sulopenem to compete with these products.

There is one oral product candidate, gepotidacin from GlaxoSmithKline, in late-stage clinical development that is intended to treat uUTIs. If our competitor obtains marketing approval from the FDA or comparable foreign regulatory authorities for their product candidate more rapidly than us, it could result in our competitor establishing a strong market position before we are able to enter the market.

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 Melinta Therapeutics, Inc., Zerbaxa from Merck & Co., Zemdri from Cipla, Xerava from Innovia, 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 regulatory 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 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 commercialize oral sulopenem, sulopenem 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 oral sulopenem 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 our 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 IV, if approved, will be administered in a hospital setting, and oral sulopenem, if approved, 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 our product candidates, if approved, 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 any 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 oral sulopenem or sulopenem, which could affect their revenue potential.

We are developing oral sulopenem and sulopenem to treat 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 oral sulopenem 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 oral sulopenem 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 oral sulopenem and sulopenem if they are concerned about contributing to the rise of antibiotic resistance. If resistance to oral sulopenem or sulopenem becomes prevalent, or concerns about such resistance are strong, our ability to generate revenue from oral sulopenem and sulopenem could suffer.

We may be subject to costly product liability claims related to our clinical trials and product candidates 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.

Because we conduct clinical trials with human patients, we face the risk that the use of our product candidates may result in adverse side effects to patients in our clinical trials. We face even greater risks upon any commercialization of our product candidates. Although we have product liability insurance, which covers our clinical trials for up to $10.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will need to increase our insurance coverage if and when we receive marketing approval for and begin selling oral sulopenem, sulopenem or any other product candidate. We do not know whether we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, on acceptable terms, if at all.

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:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- 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 cyber attack 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.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates if approved.

We do not have sales, marketing or distribution infrastructure and have limited experience as an organization in the sales, marketing, and distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. The development of sales, marketing and distribution capabilities will require substantial resources, will be time consuming and, if not initiated sufficiently in advance of marketing approval, could delay any product launch. Conversely, if the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could incur substantial costs and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. 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 to perform sales, marketing and distribution services, our product revenues or the profitability of these products may be substantially lower than if we were to directly market and sell products in those markets. 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 our products effectively.

We may seek to enter into collaborations that we believe may contribute to our ability to advance development and ultimately commercialize our 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 sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

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, as well as 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 (IPO)) 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 candidate that is covered by the Pfizer License, including sulopenem etzadroxil 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 expect to depend on collaborations with third parties for the development and commercialization of oral sulopenem and/or sulopenem in certain territories. Our prospects with respect to those product candidates will depend in part on the success of those collaborations.

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 currently do not have a sales, marketing or distribution infrastructure and we have no experience in the sales, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either build our marketing, sales, distribution, managerial and other non-technical capabilities, or make arrangements to outsource those functions to third parties. For those countries in which we choose not to commercialize directly ourselves, we intend to seek to commercialize oral sulopenem and/or sulopenem through 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 include service providers to the pharmaceutical industry, large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangements but engaged a potential commercial partner to provide pre-commercial activities and we commenced negotiations on a definitive agreement for commercialization services. Following receipt of the CRL in July 2021, in order to reduce operating expenses and conserve cash resources, we halted any remaining pre-commercial activities and paused negotiations on a definitive agreement for commercialization services. There is no assurance that we will seek or be able to reach a definitive agreement for commercialization services in the future.

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 a product candidate that we license to a third party.

We face significant competition in seeking and obtaining appropriate collaborators. Collaborations involving our 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 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 product candidates, might lead to additional responsibilities for us with respect to 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 product candidates.

Collaboration agreements may not lead to development or commercialization of 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 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 its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we will need to obtain additional expertise and 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, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

We may rely on third parties to perform many essential services for any products that we commercialize, 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 our product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of our product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management, and cash collection. If we retain a service provider, we would 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 may engage 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 our product candidates 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 may contract 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 or commercialize any of our 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 for the manufacture of preclinical and clinical supplies of oral sulopenem and sulopenem and expect to continue to do so in connection with any future clinical trials and future commercialization of our product candidates and potential product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our 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 oral sulopenem and sulopenem for use in the conduct of our preclinical research or clinical trials or for commercialization. We rely on third-party contract manufacturers to manufacture supplies of oral sulopenem and sulopenem, and we expect to rely on third-party contract manufacturers to manufacture commercial quantities of 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 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. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. If any of our existing manufacturers should become unavailable to us for any reason, we may incur delays in identifying or qualifying replacements.

We will enter into agreements with third-party contract manufacturers for the commercial production of oral sulopenem and/or sulopenem. 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, or cGMPs, that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

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. 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 oral sulopenem 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 in the CRL received from the FDA in July 2021, 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 product candidates.

Our current and anticipated future dependence upon others for the manufacture of oral sulopenem and sulopenem and any future product candidates may adversely affect our future profit margins and our ability to commercialize 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 to develop and commercialize oral sulopenem 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 sulopenem. We do not own or license any patent rights that cover the IV formulation of sulopenem. In addition, all patents directed to the compound 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 oral sulopenem or 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 oral sulopenem 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 develop or commercialize oral sulopenem or 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 oral sulopenem 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. We own two U.S. patents, one Japanese patent, one Korean patent and one Australian patent, with one US patent, the Japanese patent, the Korean patent and the Australian patent directed to the composition of the bilayer tablet of oral sulopenem and its related preparations and/or uses, and the other U.S. patent directed to the method of use of oral sulopenem in treating multiple

diseases, including uUTIs. We also own three pending U.S. patent applications, and 24 pending foreign patent applications, which collectively cover uses of sulopenem and probenecid and bilayer tablets of sulopenem etzadroxil and probenecid. Two pending U.S. patent applications and one pending Canadian patent application were recently allowed, with one allowed U.S. patent application directed to the method of use of oral sulopenem in treating uUTI, with the other allowed U.S. patent application directed to the method of use of sulopenem etzadroxil, probenecid, and valproic acid in treating multiple diseases, and with the allowed Canadian patent application directed to the bilayer tablet of oral sulopenem and its related preparations and/or uses. The patent prosecution process is expensive and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. 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 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 product candidates that we may develop. Furthermore, even if they are unchallenged, our patents rights may not adequately protect our product candidates and technology, provide exclusivity for our 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 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 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 commercialization of our 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 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 product candidates or the use of our 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 product candidates. We may incorrectly determine that our 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 product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

The patent protection for our 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 our product candidates 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 (referred to as the Hatch-Waxman Act) and our newly granted 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. However, that does not guarantee that we will receive any regulatory exclusivity 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 the compound 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 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 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 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 oral sulopenem, 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 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 oral sulopenem, 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 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 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 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 further develop and commercialize one or more of our 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 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 oral sulopenem, 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 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 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 our 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 potential product candidates in various jurisdictions including the United States, 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 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 oral sulopenem or any other product candidate 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. While we have submitted our proposed proprietary name for oral sulopenem in connection with our NDA for oral sulopenem and have received conditional acceptance from the FDA, if there are any changes to proposed product characteristics prior to approval of the marketing application, the proprietary name would need to be resubmitted. Additionally, if our NDA receives a complete response, a new request for name review for the proposed name would need to be submitted with our response to the application deficiencies. In both cases, there is no guarantee that the FDA would conclude that the proprietary name continues to be acceptable when resubmitted. If the FDA objects to our proposed proprietary product name, 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 oral sulopenem, sulopenem or other future product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates, oral sulopenem and sulopenem, 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. We currently do not have any products approved for sale in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

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. We have not obtained regulatory approval for any product candidate and it is possible that we will not be able to obtain regulatory approval for sulopenem or any 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. Although we conducted our prior Phase 3 clinical trials pursuant to SPA agreements, met with the FDA at a pre-NDA meeting and had our NDA application accepted for review by the FDA in January 2021, we received a CRL from the FDA on July 23, 2021 in respect of our NDA. The CRL provided that the FDA had completed its review of the NDA and had determined that it could not approve the NDA in its present form. The CRL further 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 we commenced enrollment in that clinical trial, known as REASSURE, in October 2022. The study is 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 sulopenem 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 PK/PD studies to support dose selection for the proposed treatment indication(s). We have also completed the additional non-clinical PK/PD investigations, as recommended by the FDA, which we believe support the dosing regimen selected for oral sulopenem. We resubmitted our NDA for oral sulopenem for the treatment of uUTIs to the FDA in April 2024. In May 2024, we received a notice from the FDA acknowledging receipt of the resubmission of the NDA and indicating that the FDA deemed our NDA resubmission to be a Class II complete response under the PDUFA, which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to our resubmitted NDA of October 25, 2024. In June 2024, the FDA notified us that it had determined that our NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee, with September 9, 2024 as the date for the Advisory Committee meeting. In its communication advising us of the Advisory Committee, the FDA highlighted that the purpose of the meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. There can be no assurance that we will be in a position to resolve the matters set forth in the CRL or that the data generated by the REASSURE clinical trial or the additional PK/PD data will be adequate to support approval of our resubmitted NDA for oral sulopenem for the treatment of uUTIs in adult women.

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;
- 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.

Further, under the Pediatric Research Equity Act, or PREA, a Biologics License Application, or 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 European Medicines Agency, or 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.

Even if we eventually receive approval of an NDA or foreign marketing application for our 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. For example, the FDA may approve our NDA or oral sulopenem for a more limited indication than the treatment of uUTIs. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Although we conducted the Phase 3 clinical trial comparing oral sulopenem and Augmentin® (amoxicillin/clavulanate) under an SPA agreement with the FDA, an SPA agreement does not guarantee marketing approval of, or any other particular outcome from, regulatory review.

We conducted the Phase 3 clinical trial comparing oral sulopenem and Augmentin® (amoxicillin/clavulanate) under an SPA agreement with the FDA. Under the SPA process, the FDA provides a clinical trial sponsor with an official evaluation and written guidance on the design of a proposed protocol intended to form the basis for an NDA. An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of the overall protocol design for a clinical trial intended to support a future marketing application, but it does not indicate FDA concurrence on every protocol detail. An SPA agreement also does not ensure the receipt of marketing approval or that the approval process will be faster than conventional procedures. A determination regarding marketing approval is addressed during the review of a submitted NDA and depends on efficacy and safety results and an evaluation of the overall benefits and risks of treatment after review of the data from the development program in its totality.

Even after the FDA agrees to the design, execution, and analysis proposed in a protocol reviewed under the SPA process, the FDA may revoke or alter its agreement if a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun. An SPA agreement may also be changed through written agreement between the sponsor and the FDA. A revocation or alteration in an existing SPA agreement could delay or prevent approval of an NDA. In addition, any significant change to the protocol for a clinical trial subject to an SPA agreement would require prior FDA approval, which could delay implementation of such a change and the conduct of the related clinical trial. The FDA retains significant discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

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 and 2019, 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.

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

In order to market and sell oral sulopenem, 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. 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. For example, although we have obtained agreement on an SPA with the FDA for the additional Phase 3 clinical trial for oral sulopenem, the EMA or other regulatory authorities may not agree with the overall protocol design for this additional clinical trial. 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.

We are currently evaluating our commercialization strategy in the United States and other territories. 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 UK as a result of the withdrawal of the UK from the EU, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, or GB, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland is currently subject to EU rules. The UK and EU have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK Once implemented, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the UK market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in

obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the UK 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.

If we receive regulatory approval for any product candidate, we will be subject to ongoing obligations and continuing regulatory review, which may result in significant additional expense. Our product candidates, including oral sulopenem and 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 our product candidates, when and if approved.

Any product candidate, including oral sulopenem and 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.

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.

Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the U.S. Among other determinations, the district court held that plaintiffs were likely to prevail in their claim that FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that FDA's drug approval decision effectively compelled the plaintiffs to provide care for patients suffering adverse events caused by a given drug.

On April 12, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay of the district court's decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to or the Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case on May 17, 2023 and, on August 16, 2023, issued its decision. The court declined to order the removal of mifepristone from the market, finding that a challenge to the FDA's initial approval in 2000 is barred by the statute of limitations. But the Appeals Court did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. On September 8, 2023, the Justice Department and a manufacturer of mifepristone filed petitions for a writ of certiorari, requesting that asked the U.S. Supreme Court to review the Appeals Court decision. On December 13, 2023, the Supreme Court granted these petitions for writ of certiorari for the appeals court decision.

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 products and assuming we, or our collaborators, receive marketing approval for one or more of our 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 October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft 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, or the 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.

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, or 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, or the 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.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this executive order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" while adding a definition of "price concession" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or 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.

In addition, several significant administrative law cases were decided by the U.S. Supreme Court in 2024, most notably *Loper Bright Enterprises v. Raimondo*, which overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*. Since 1984, Chevron had required that courts defer to reasonable agency interpretations of statutes and agency action. In Loper Bright, the Supreme Court held that the U.S. Administrative Procedure Act requires courts to exercise their independent judgment when deciding whether an agency has acted within its statutory authority, and that courts may not defer to an agency interpretation solely because a statute is ambiguous. These decisions may result in additional legal challenges to regulations and guidance issued by federal regulatory agencies, including the FDA and CMS, that we have relied on and intend to rely on in the future. Any such challenges, if successful, could have an impact on our business, and any such impact could be material. In addition to potential changes to

regulations and agency guidance as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays in and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations.

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, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or 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. Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2023, the FDA approved Florida's plan for Canadian drug importation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until January 1, 2032 by the Inflation Reduction Act, or IRA.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. To address these costs, the executive order directs HHS to create a plan within 45 days to combat "excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such drugs, and to address the recurrent problem of price gouging." Thereafter, on September 9, 2021, HHS released its plan to reduce drug prices. The key features of that plan are to: (a) make drug prices more affordable and equitable for all consumers and throughout the health care system by supporting drug price negotiations with manufacturers; (b) improve and promote competition throughout the prescription drug industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, 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 does not apply to drugs and biologics that have been approved for a single rare disease or condition. 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.

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. 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.

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 European Economic Area (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 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. 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 all are 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.

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.

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 or in the event we are successful in obtaining regulatory approval 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 Securities in accordance with the terms and conditions of the EN Indenture and 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 Securities. 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, 2024; 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, or "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.

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 $2.30 on November 24, 2023, and a low price of $0.65 on October 25, 2023, in the twelve-month period ending on August 9, 2024. During this time, the price per ordinary share has ranged from an intra-day low of $0.622 per share to an intra-day high of 2.50 per 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:

- 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;
- announcements with respect to the outcome, impact, effects or 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 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;
- delays in the commercialization of oral sulopenem, sulopenem or any future product candidates;
- manufacturing and supply issues related to our development programs and commercialization of oral sulopenem, 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 oral sulopenem, 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. For example, we asked our shareholders to approve the disapplication of statutory pre-emption rights over the increased authorized share capital that was approved by our shareholders at our annual general meeting of shareholders in May 2023 (the 2023 Annual Meeting). However, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of such resolutions at the 2023 Annual Meeting or at subsequent extraordinary general meetings of shareholders held in August 2023 and January 2024. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. As a result, our ability to raise additional capital to finance our business through the issue of new shares for cash is severely limited. Additionally, where we find it necessary to delay or adjourn meetings or to seek approval again, it will be time consuming and we will incur additional costs.

If we fail to comply or regain compliance 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 April 3, 2024, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC, (Nasdaq) indicating that were not in compliance with Nasdaq Listing Rule 5550(a)(2) to maintain a minimum bid price of $1.00 per share (the Bid Price Rule). Under Nasdaq Listing Rule 5550(b)(1), because (i) the stockholders' equity (deficit) of the Company of ($6,403,000) as of December 31, 2023, as reported in our Annual Report on Form 10-K for the year ended December 31, 2023, was below the

minimum stockholders' equity requirement of $2,500,000 and (ii) we did not, as of April 3, 2024, meet the alternative standards of market value of listed securities or net income from continuing operations for compliance with Nasdaq Listing Rule 5550(b)(1).

Nasdaq's letter has no immediate impact on the listing of our ordinary shares, which will continue to be listed and traded on the Nasdaq Capital Market, subject to our compliance with the other continued listing requirements. The letter indicated that we had a period of 45 calendar days from the date of the letter to submit a plan to regain compliance. We submitted our plan to regain compliance to Nasdaq on May 20, 2024.

On May 29, 2024, we received a letter from Nasdaq notifying us that Nasdaq had reviewed our plan for regaining compliance with Nasdaq Listing Rule 5550(b)(1) and granted us a 180-calendar day extension from April 3, 2024 (or until September 30, 2024) to evidence compliance with Nasdaq Listing Rule 5550(b)(1).

If we fail to evidence compliance with Nasdaq Listing Rule 5550(b)(1) on or before September 30, 2024, we may be subject to delisting. Were this to occur, Nasdaq will provide us 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 do appeal any delisting determination by Nasdaq to the panel, that such appeal would be successful.

We intend to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq. However, there can be no assurance that we will be able to regain compliance with Nasdaq Listing Rule 5550(b)(1), 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 regain compliance with respect to the current deficiency or 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. The delisting of our ordinary shares from The Nasdaq Stock Market could also negatively impact our financial condition as it would constitute a fundamental change under the EN Indenture, which could trigger an obligation for us to repurchase the Exchangeable Notes at a repurchase price of 300% of the principal amount of the outstanding Exchangeable Notes.

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 a private placement which closed in January 2020 (the Private Placement) and subsequent rights offering (the 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), or (iii) December 31, 2025, in the event that we have not yet received FDA approval with respect to one or more specified sulopenem products by such date. 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 (Payment Rate), determined based on which of the specified sulopenem products have received FDA approval. The Payment Rate will be based on the maximum aggregate principal amount of RLNs and will equal (i) up to 15% if we or one of our affiliates has received FDA approval for the use of specified sulopenem products for the treatment of uUTIs and (ii) up to 20% if we or one of our affiliates has received FDA approval for the use of specified sulopenem products for the treatment of cUTIs but has not received FDA approval for treatment of uUTIs.

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. In the

event that a change of control occurs before we receive FDA approval with respect to one or more specified sulopenem products, the redemption price per RLN will be reduced to 50% of the Maximum Return for each RLN, less payments made through and including the redemption date, plus certain accrued but unpaid default interest (if any).

The payment obligations under the RLNs may reduce the revenue we are able to derive from commercial sales of sulopenem 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.

In addition, the Exchangeable Notes are exchangeable for ordinary shares, cash or a combination of ordinary shares and cash, at our election, upon the terms and conditions specified therein. If we elect for physical settlement, the issuance of ordinary shares for the Exchangeable Notes may dilute the ownership percentage or voting power of our shareholders. As of June 30, 2024, $11.1 million aggregate principal amount of Exchangeable Notes remained outstanding. The outstanding warrants that we issued the purchasers and/or the designees of the placement agent and underwriter, as applicable, in connection with the June 3, 2020 Offering, the June 30, 2020 Offering, the October 2020 Offering, 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, the Exchangeable Notes are exchangeable for our ordinary shares upon the terms and conditions specified therein and a substantial portion have been exchanged for our ordinary shares. Pursuant to the investor rights agreement we entered into in connection with the Private Placement, we have filed a registration statement covering the resale of the ordinary shares issuable in connection with the exchange of the Exchangeable Notes issued as part of the Private Placement, among other securities, and the resale of the ordinary shares issuable in connection with the exchange of the Exchangeable Notes issued in connection with the Rights Offering are also covered by a registration statement.

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, nominal value $0.01 per share for aggregate gross sales proceeds of up to $16.0 million, 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. 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 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 EN Indenture and RLN Indenture may deter or prevent a business combination that may be favorable to the holders of our ordinary shares.

If a fundamental change occurs prior to the interest record date of the Exchangeable Notes, holders of the Exchangeable Notes will have the right, at their option, to require us to repurchase for cash all or a portion of their Exchangeable Notes for the greater of (i) 300% of the principal amount thereof, and (ii) the consideration that would be received by the holder of such note in connection with a transaction if the holder had exchanged the note for Ordinary Shares immediately prior to the consummation of such transaction. The negative covenants in the EN Indenture also prohibit us from undergoing a change of control transaction, other than a transaction in which each Exchangeable Note holder receives cash consideration of at least 300% of the outstanding principal amount of its notes. Furthermore, the EN Indenture prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the Exchangeable Notes, the EN Indenture and the guarantees. In addition, 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 EN Indenture and 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. The EN Indenture provides that if a holder of Exchangeable Notes notifies us that they would be subject to this mandatory offer requirement, we will only issue to such holder such number of ordinary shares that can be issued without triggering a mandatory cash offer on an exchange with the remaining ordinary shares to be delivered as promptly as practicable after the holder notifies us that they would no longer be subject to a mandatory cash offer request.

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 and the other holders of the Exchangeable Notes to acquire more of our securities, including under the terms of the Exchangeable Notes and 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 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. We asked our shareholders to renew the authorization of our board of directors to issue shares and the disapplication of statutory pre-emption rights at our 2023 Annual Meeting and to extend that authorization to the increase in authorized share capital that was approved by our shareholders at the 2023 Annual Meeting. Our shareholders renewed the authorization of our board of directors to issue shares; however, we did not receive approval on the disapplication of statutory pre-emption rights. We asked our shareholders to renew the disapplication of statutory pre-emption rights over the authorized but unissued share capital at an extraordinary general meeting of the Company on August 1, 2023; however, although we received over 62% support of the votes cast on renewing the pre-emption rights opt-out authority at that meeting, we did not receive the affirmative vote of at least 75% of the votes cast as required

under Irish law for the passing of special resolutions. We asked our shareholders again to approve the disapplication of statutory pre-emption rights over 5,000,000 authorized but unissued ordinary shares at an extraordinary general meeting of the Company on January 30, 2024; however, again, we did not receive the affirmative vote of at least 75% of the votes cast as required under Irish law for the passing of special resolutions.

If our shareholders do not approve the disapplication of statutory pre-emption rights, our board of director's existing authority to opt out of the statutory pre-emption right up to the amount of our authorized but unissued share capital (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting) will continue to apply only until January 26, 2026. This would limit us to having the ability to issue for cash only 759,854 ordinary shares (or rights to acquire such shares), based on the amount of authorized ordinary shares unissued or unreserved and therefore available for issuance as of August 9, 2024 (excluding the increase in authorized share capital that was approved at the 2023 Annual Meeting), up to January 26, 2026. Furthermore, absent shareholder approval of the disapplication of statutory pre-emption rights, the additional authorized but unissued shares that were approved at the 2023 Annual Meeting that we propose to issue for cash will first have to be offered to all of our existing shareholders on the same or more favorable terms on a pro-rata basis, similar to the 2024 Rights Offering. As a result of this limitation, we are currently severely limited in the amount of ordinary shares we may sell for cash in any capital raising transaction, and where we propose to issue shares for cash consideration, we may be required to first offer those shares to all of our existing shareholders in a time-consuming pro-rata rights offering, similar to the 2024 Rights Offering. Furthermore, while the statutory pre-emption right applies only to share issuances for cash consideration and it does not apply where we issue shares for non-cash consideration (such as in a share exchange transaction or in any transaction in which property other than cash is received by us in payment for shares), any such transaction would likely be time-consuming and complex to execute. While we are once again seeking approval of our shareholders to disapply the statutory pre-emption rights generally at an extraordinary general meeting of the shareholders, there is no guarantee that such approval will be forthcoming. In the event we are not able to obtain such shareholder approval of the disapplication of pre-emption rights at a future general meeting of the shareholders, we will continue to be limited in the amount of ordinary shares we may sell for cash in any capital raising transaction without first offering those shares to all of our existing shareholders similar to the 2024 Rights Offering.

Since our inception, we have primarily funded our research and development activities, the commercialization of our products and our operations from the sale of equity securities. We will need to obtain substantial additional funding to achieve our business objectives. If we are unable to raise additional funds when needed, including through the sale of our ordinary shares for cash, we may be unable to pursue our business plans and strategy, and we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Therefore, we believe obtaining shareholder approval of the pre-emption rights disapplication proposal at a future general meeting of the shareholders is critical to our ability to continue to fund our operations and achieve our business objectives.

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 Securities and Exchange Commission. 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 June 30, 2024, 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	Consulting Agreement dated May 29, 2024 between Iterum Therapeutics International Limited and Dr. Sailaja Puttagunta	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			

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: August 14, 2024	By:	/s/ Corey Fishman **Corey Fishman** President and Chief Executive Officer
Date: August 14, 2024	By:	/s/ Judith Matthews **Judith Matthews** Chief Financial Officer

EXHIBIT 10.1

Dated May 29, 2024

ITERUM THERAPEUTICS INTERNATIONAL LIMITED

-and-

DR. SAILAJA PUTTAGUNTA

CONTRACT FOR SERVICES

THIS AGREEMENT is dated May 29, 2024 and made between:

(1) **Iterum Therapeutics International Limited** whose registered office is at Fitzwilliam Court, 1st Floor, Leeson Close, Dublin 2, D02 YW24, Ireland (the **Company**) and

(2) **Dr. Sailaja Puttagunta** with an address at 39 Buell Hill Road, Killingworth, CT 06419 (the **Contractor**)

ereinafter referred to as the **Agreement**.

RECITAL

The Contractor has agreed to provide the Services to the Company and any Associated Company upon and subject to the terms and conditions hereinafter contained.

IT IS HEREBY AGREED as follows:

1.DEFINITIONS AND INTERPRETATION

1.1.In this Agreement, unless the context otherwise requires:

Associated Company means any holding company or any subsidiary of the Company (as such terms are defined by section 7 and section 8 of the Companies Act, 2014) or any subsidiary of such holding company;

Business of the Company means development and commercialization of therapies focused on patients with infectious diseases and other acute illnesses. Our lead product candidate, sulopenem, is in development for the treatment of patients with uncomplicated urinary tract infections (uUTI) associated primarily with resistant gram-negative bacteria;

Business Day means any day on which banks are generally open for business in Dublin;

Business Opportunities means any opportunities which the Contractor becomes aware of during the course of the Agreement which relates to the Business of the Company**;**

Capacity means as agent, contractor, director, employee, owner, partner, and shareholder or in any other capacity;

Commencement Date means June 1, 2024;

Companies mean the Company and any Associated Company or any of them;

Company Property means all documents, books, records, correspondence, papers and information (on whatever media and wherever located) relating to the Business of the Company or its customers and business contacts including any equipment, keys, hardware or software provided to the Contractor during the term of the Agreement and any data or documents (including copies) produced, maintained or stored by the Contractor for the Company on the Contractor's computer systems or other electronic equipment during the Agreement;

Confidential Information means any and all information received or obtained as a result of entering into or performing, or supplied by or on behalf of a party in the negotiations leading to, this Agreement and which relates to:-

(a) the Companies;

(b) any aspect of any Business of the Companies;

(c) the provisions of this Agreement;

(d) the negotiations relating to this Agreement; or

(e) the subject matter of this Agreement.

Fees mean the remuneration payable by the Company to the Contractor for the provision of the Services in accordance with clause 4;

Force Majeure means, in relation to either party, any circumstances beyond the reasonable control of that party (including, without limitation, any strike, lock-out or other form of industrial action);

Intellectual Property Rights means patents, rights to invention, copyright and related rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

Inventions means any invention, idea, discovery, development, improvement or innovation made by the Contractor in connection with the provision of the Services, whether or not patentable or capable of registration, and whether or not recorded in any medium;

Month means calendar month; and

Services means the Services specified in Schedule 1 to this Agreement.

Works means all records, reports, documents, papers, drawings, designs, transparencies, photos, graphics, logos, software programmes, inventions, ideas, discoveries, developments, improvements or innovations and all materials embodying them in whatever form prepared by the Contractor or Individual in connection with the provision of the Service.

1.2.The Schedules referred to in this Agreement form an integral part of this Agreement, and references to this Agreement include reference to the Schedules.

1.3.All references in this Agreement to costs, charges or expenses include any value added tax or similar tax charged or chargeable on them.

1.4.Unless the context otherwise requires, in this Agreement:

1.4.1.words denoting the singular include the plural and vice versa and words importing the masculine include the feminine;

1.4.2.references to Acts, statutory instruments and other legislation are to legislation operative in Ireland and to such legislation, modified, consolidated, amended or re-enacted (whether before or after the date of this Agreement) and any subordinate legislation made under that legislation;

1.4.3.reference to any Irish legal term, concept, legislation or regulation (including, without limitation, those for any action, remedy, method of judicial proceeding, document, statute, court official, governmental authority or agency) or any accounting term or concept, in respect of any jurisdiction other than Ireland is construed as a reference to the term or concept which most nearly corresponds to it in that jurisdiction; and

1.4.4.reference to any document includes that document as amended or supplemented whether before or after the date of this Agreement.

2.APPOINTMENT OF CONTRACTOR

2.1.The Company hereby appoints the Contractor to provide the Services to the Companies during the term of this Agreement, and the Contractor shall act in that capacity subject to the terms and conditions of

this Agreement.

3.TERM

3.1.This Agreement on the Commencement Date and continues until terminated in accordance with clause 3.2 or clause 14.

3.2.Subject to clause 14, either party may terminate this Agreement on not less than two weeks' notice in writing to the other party and the termination date shall be the expiry of the notice period.

4.FEES

4.1.The Company shall pay to the Contractor the Fees, being US$400 per hour**,** payable within 30 days of receipt of the Contractor's invoice therefor to such bank account as the Contractor may from time to time notify in writing to the Company. Invoices shall be furnished by the Contractor monthly in arrears on the last day of each month and will be payable by the Company 30 days from the date of the invoice.

4.2.The Fees shall be fixed for a period of twelve months and thereafter the Fees may be reviewed from time to time by the Contractor and the Company.

5.DUTIES AND OBLIGATIONS OF CONTRACTOR

5.1.The Contractor shall provide the Services on such days as are required and agreed in writing by the Company from time to time and in consideration of the Contractor working such days will be remunerated in accordance with Clause 4.1 above.

5.2.The Contractor shall:

5.2.1. provide the Services with all due care, skill and ability and use his best endeavours to promote the interests of the Company;

5.2.2. promptly give to the Company all such information and reports as it may reasonably require in connection with matters relating to the provision of the Services or the Business of the Company

5.3.If the Contractor is unable to provide the Services due to illness or injury, the Contractor shall advise the Company of that fact as soon as reasonably practicable. For the avoidance of doubt, no fee shall be payable in accordance with clause 4 in respect of any period during which the Services are not provided.

5.4.Unless specifically authorised to do so by the Company:

5.4.1.The Contractor shall not have any authority to incur any expenditure in the name of or for the account of the Company; and

5.4.2.The Contractor shall not hold himself out as having authority to bind the Company

5.5.The Contractor undertakes to comply with all reasonable standards of safety and comply with the health and safety procedures of the Company from time to time in force at the premises where the Services are provided and report to the Company any unsafe working conditions or practices.

5.6.The Contractor undertakes during the appointment to take all reasonable steps to offer (or cause to be offered) to the Company any Business Opportunities as soon as practicable after the same shall have come to its or his knowledge and in any event before the same shall have been offered by the Contractor (or caused to be offered) to any other party.

5.7.The Contractor may use a third party to perform any administrative, clerical or secretarial functions which are reasonably incidental to the provision of the Services provided that the Company will not be

liable to bear the cost of such functions.

5.8.The Contractor shall:

5.8.1.comply with all applicable laws, regulations, codes and sanctions relating to anti-bribery and anti-corruption in Ireland or in any other jurisdiction in relation to which work is undertaken;

5.8.2.comply with any Ethics and Anti-bribery and Anti-corruption Policies of the Company and any relevant industry code in force from time to time (Relevant Policies);

5.8.3.promptly report to the Company any request or demand for any undue financial or other advantage of any kind received by the Contractor in connection with the performance of this Agreement; and

5.8.4.ensure that all persons associated with the Contractor who are performing services in connection with this Agreement comply with this clause 5.8.

5.9.Breach of clause 5.8 shall be deemed a material breach of this Agreement.

5.10.The Contractor shall be responsible for all property of the Companies in his possession.

5.11.The Contractor shall obtain all necessary licences, certificates, permits, consents and authorisations from all relevant government departments, agencies or regulatory authorities to enable it to perform and carry out is obligations under or pursuant to this Agreement.

5.12.The Contractor shall comply with all relevant environmental and safety legislation and shall comply with all legal requirements from time to time in force relating to the Services.

5.13.The Contractor shall from time to time consult with representatives of the Companies for the purpose of assessing the quality of the Services and obtaining feedback.

5.14.The Contractor will provide the Company with copies of all necessary documentation, including all and any delivery dockets, route sheets, cash receipts, settlement sheets, cash summaries and other documentation required by the Company for the orderly completion of the Contractor’s duties relating to the Services provided by the Contractor under this Agreement.

6.EXPENSES

6.1.The Company shall reimburse all reasonable expenses properly and necessarily incurred by the Contractor in the course of the appointment, subject to the Contractor seeking prior consent from the Company to incur such expenditure and the production of receipts or other appropriate evidence of payment.

6.2.If the Contractor is required to travel abroad in the course of the appointment the Contractor shall be responsible for any necessary insurances, inoculations and immigration requirements. For the avoidance of doubt, the Company shall discharge the flight and accommodation costs excluding subsistence costs associated with the Contractor's requirement to travel under this agreement.

7.OTHER ACTIVITIES

7.1.Nothing in this Agreement shall prevent the Contractor from being engaged, concerned or having any financial interest in any Capacity in any other business, trade, profession or occupation during the appointment provided that:

7.1.1.such activity does not cause a breach of any of the Contractor's obligations under this Agreement; and

7.1.2.the Contractor shall not engage in any such activity if it relates to a business which is similar to

or in any way competitive with the Business of the Company or Companies, without the prior written consent of the Company and the Contractor agrees to give priority to the provision of the Services to the Company over any other business activities undertaken by it during the course of the appointment.

8.CONFIDENTIAL INFORMATION & COMPANY PROPERTY

8.1.The parties agree that the terms of this Agreement are confidential to the parties and their professional advisors.

8.2.The Contractor acknowledges that prior to, and in the course of, the appointment he will have access to Confidential Information. The Contractor has therefore agreed to accept the restrictions in this clause 8 which will continue to apply after the termination or expiry of the Agreement.

8.3.The Contractor shall not (except in the proper course of his duties), between signing this Agreement and the date of its commencement, during the appointment or at any time after the termination date, use or disclose to any third party (and shall use his reasonable endeavours to prevent the publication or disclosure of) any Confidential Information. This restriction does not apply to:

8.3.1.any use or disclosure authorised by the Company or required by law; or

8.3.2.any information which is already in, or comes into, the public domain otherwise than through the unauthorised disclosure of the Contractor;

8.4.At any stage during the appointment, the Contractor will promptly on request return all and any Company Property in his possession.

9.INTELLECTUAL PROPERTY

9.1.The Contractor shall give the Company full written details of all Inventions and of all works embodying Intellectual Property Rights made wholly or partially by the Contractor, or any appointed substitute (as the case may be) at any time during the course of this Agreement which relate to, or are reasonably capable of being used in the Business of the Company.

9.2.The Contractor acknowledges that all Intellectual Property Rights subsisting in any work or Invention made, originated or developed by the Contractor or any appointed substitute (as the case may be) at any time in relation to the Services shall automatically on creation, vest in and be the absolute sole and unencumbered property of the Company. To the extent that the Intellectual Property Rights do not vest automatically with the Company the Contractor holds them on trust for the Company. The Contractor hereby agrees to execute or to procure the execution of all such documents to make such applications and give such assistance as may in the opinion of the Company be necessary to give effect to this clause.

9.3.The Contractor hereby irrevocably waives all moral rights under the Copyright and Related Rights Act 2000 to 2007, as amended, (and all similar rights in other jurisdictions) which the Contractor has or will have in any existing or future works referred to in this clause.

9.4.The Contractor irrevocably appoints the Company or its nominee to be its attorney to execute in its name and on its behalf any document or instrument for the purpose of giving the Company or its nominee the benefit of this clause. The Contractor acknowledges in favour of any third party that a certificate in writing signed by the Company that any instrument or act falls within the authority conferred by this clause shall be conclusive evidence that such is the case.

9.5.The Contractor acknowledges that no further remuneration or compensation other than that provided for in this Agreement is or may become due to the Contractor in respect of the performance of its obligations under this clause 9.

10.DATA PROTECTION

10.1.All personal information which the Company holds about the Contractor is protected by data protection laws. The Company will collect and process personal data relating to employees in accordance with the privacy notice which is attached at Schedule 2.

10.2 The Contractor shall comply and shall procure that the Individual shall comply with the Company data protection policy and relevant obligations under the General Data Protection Regulation ((EU) 2016/679) and the Data Protection Acts 1988 and 2018 and/or such amending legislation and associated codes of practice and/or analogous legislation and associated codes of practice when processing personal data relating to any employee, worker, customer, company, supplier or agent of the Company.

11.WARRANTIES AND REPRESENTATIONS

11.1.The Contractor warrants and represents that it has full capacity and authority to enter into and perform this Agreement.

11.2.The Contractor warrants and represents that the Contractor will carry out the Services in a good and workmanlike manner and:

11.2.1.that the Contractor has the necessary skill to render the Services;

11.2.2.that the Contractor will supply the Services with due skill, care and diligence;

11.2.3.that, where materials are used, they will be sound and reasonably fit for the purpose for which they are required; and

11.2.4.that, where goods are supplied under this Agreement, they will be of merchantable quality within the meaning of section 4(3) of the Sale of Goods Act 1893.

11.3.The Contractor warrants and represents that, in connection with the provision of the Services under this Agreement, it will at all times:

11.3.1.maintain all necessary licences, certificates, permits, consents and authorisations from all relevant government departments, agencies or regulatory authorities;

11.3.2.comply in all material respects with all relevant environmental and safety legislation; and

11.3.3.comply with all legal requirements from time to time in force relating to the Services and the provision of them.

11.4.The Contractor warrants and represents that it will at all times conduct its business in a manner that shall reflect favourably on the Companies, the Services and the good name and reputation of the Companies.

12.INDEMNITY

12.1.The Contractor shall indemnify and keep indemnified the Companies their respective officers, directors and employees from and against any and all loss, damage or liability (whether criminal or civil) suffered and legal fees and costs incurred, resulting from:

12.1.1. any breach of this Agreement by the Contractor, its employees or agents;

12.1.2.any act, neglect or default of the Contractor, its employees or agents; and

12.1.3.breaches in respect of matters arising from the provision of the Services resulting in any successful claim by any third party.

13.LIMITATION OF LIABILITY

13.1.Notwithstanding anything to the contrary in this Agreement, the Company will not (except in respect of death or personal injury caused by any negligent act or omission of the Company) be liable to the Contractor by reason of any representation or implied warranty, condition or other term or any duty at common law, or under the express terms of this Agreement for any consequential loss or damage (whether occasioned by the negligence of the Company, its employees or agents) or otherwise arising out of or in connection with this Agreement.

14.TERMINATION

14.1.Either party may terminate this Agreement in accordance with clause 3.

14.2.The Company will be entitled to terminate this Agreement by giving not less than two weeks' written notice to the Contractor if the Contractor at any time challenges the validity of any intellectual property rights of the Companies.

14.3.The Company will be entitled forthwith to terminate this Agreement by written notice to the Contractor if:

14.3.1.the Contractor commits any breach of any of the provisions of this Agreement and, in the case of a breach capable of remedy, fails to remedy the same within 30 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied;

14.3.2.an encumbrancer takes possession of or a receiver is appointed over any of the property or assets of the Contractor;

14.3.3.the Contractor makes any voluntary arrangement with its creditors or becomes subject to an administration order;

14.3.4.the Contractor is declared bankrupt;

14.3.5.anything analogous to any of the foregoing under the law of any jurisdiction occurs in relation to the Contractor;

14.3.6.the Contractor is incapacitated from carrying on the Service for an aggregate period of 150 days in any 52 week period;

14.3.7.the Contractor is convicted of any criminal offence (other than an offence under the road traffic legislation) in Ireland or elsewhere for which a non-custodial penalty is imposed;

14.3.8.the Contractor is, in the reasonable opinion of the Board of the Company, negligent or incompetent in the performance of the Services; or

14.3.9.the Contractor, ceases or threatens to cease, to carry on business.

14.4.For the purposes of clause 14.3.1, a breach will be considered capable of remedy if the party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).

14.5.Subject as otherwise provided herein and to any rights or obligations which have accrued prior to termination, neither party will have any further obligation to the other under this Agreement.

15.CONSEQUENCES OF TERMINATION

15.1.Upon the termination or expiry of this Agreement for any reason:

15.1.1.the Contractor shall cease to provide the Services;

15.1.2.the Contractor shall immediately return to the Company all the Companies' property held by the Contractor or under his control;

15.1.3.the provisions of clauses 8,9 &17 and this clause 15 will continue in force in accordance with their respective terms;

15.1.4.the Contractor shall cease to refer to himself as being in any way affiliated or associated with the Company;

15.1.5.the Contractor will have no claim against the Company for loss or profits, loss of goodwill or any other loss;

15.1.6.insofar as is reasonably possible the Contractor shall irretrievably delete any information relating to the Business of the Company or any Companies stored on any magnetic or optical disk or memory and all matter derived from such sources which is in his possession or under his control outside the premises of the Company. For the avoidance of doubt, the contact details of business contacts made during the appointment are regarded as Confidential Information, and as such, must be deleted from personal, social or professional networking accounts; and

15.1.7.provide a signed statement that it/he has complied fully with his obligations under this clause 15.

16.STATUS

16.1.The relationship of the Contractor to the Company will be that of independent contractor and nothing in this agreement shall render the Contractor an employee, worker, agent or partner of the Company.

16.2.This Agreement constitutes a contract for the provision of services and is not a contract of employment and accordingly the Contractor shall be fully responsible for any income tax, PRSI and USC contributions and any other liability, deduction, contribution, assessment or claim arising from or made in connection with either the performance of the Services whether in Ireland or elsewhere.

17.MISCELLANEOUS PROVISIONS

17.1.**Announcements:**

17.1.1.Subject to clause 17.1.2, neither party shall make any announcement to shareholders, employees, customers or suppliers, or to securities markets or other authorities or to the media or otherwise, regarding the subject-matter of this Agreement or any term or provision of it without the prior written approval of the other party to this Agreement.

17.1.2.Clause 17.1.1 will not apply if and to the extent that such announcement is required by any law or by:

(1)contractual arrangements in existence at the date of this Agreement; or

(2)any securities exchange, regulatory or governmental authority or Court having jurisdiction over the party making the announcement,

whether or not the requirement has the force of law provided that any such announcement may only be made after consultation with the other party to this Agreement.

17.1.3.The provisions and restrictions in this clause 17 will continue to apply after the termination or expiry of this Agreement.

17.1.4.If either party makes an announcement pursuant to this clause 17 it shall provide a copy of that announcement to the other party to this Agreement before the announcement is made unless

this is not reasonably practicable, in which case, a copy of the announcement shall be so provided to the other party as soon as reasonably practicable.

17.1.5.Each party shall provide all such information known to it or, which on reasonable enquiry ought to be known to it as may reasonably be required by the other party in relation to the Services for the purposes of complying with the requirements of the law or any securities exchange or regulatory or governmental authority having jurisdiction over the Company or the Contractor as the case may be.

18.ASSIGNMENT

18.1.Neither party to this Agreement may assign any of its rights under this Agreement without the prior written consent of the other party except that the Company may assign the benefit of any provision of this Agreement to any Associated Company without the consent of the Contractor and such assignee shall be entitled to enforce the same rights against the Contractor as if it were named as the Company under this Agreement.

18.2.Subject to clause 18.1, this Agreement will be binding on and ensure for the benefit of the permitted assigns and successors in title to each of the parties and references to the parties will be construed accordingly.

19.COSTS AND EXPENSES

19.1.Each party to this Agreement shall pay its own costs of and incidental to this Agreement and its implementation.

20.SEVERABILITY

20.1.All the terms and provisions of this Agreement are distinct and severable, and if any term or provision is held or declared to be unenforceable, illegal or void in whole or in part by any court, regulatory authority or other competent authority, it will to that extent only, be deemed not to form part of this Agreement, and the enforceability, legality and validity of the remainder of this Agreement will not in any event be affected. However, if as a result of the operation of this clause the rights or obligations of a party are materially altered to the detriment of that party, that party may terminate this Agreement within 30 days from the date of the relevant decision of the relevant court, regulatory authority or other competent authority.

21.WHOLE AGREEMENT

21.1.This Agreement (together with any documents to be executed pursuant to the terms of this Agreement) supersede all prior representations, arrangements, understandings and agreements, including, but not limited to, the Contract for Services between the parties dated February 26, 2021, and sets out the entire, complete and exclusive agreement and understanding between the parties. The rights of the Company under this Agreement are independent, cumulative and without prejudice to all other rights available to it whether as a matter of common law, statute, custom or otherwise.

22.FORBEARANCE AND WAIVER

22.1.No waiver by the Company in respect of any breach of this Agreement by the Contractor will operate as a waiver in respect of any subsequent breach. No failure or delay by the Company in exercising any right or remedy will operate as a waiver thereof, nor will any single or partial exercise or waiver of any right or remedy prejudice its further exercise or the exercise of any other right or remedy.

23.FORCE MAJEURE

23.1.If either party is affected by Force Majeure it shall forthwith notify the other party of the nature and extent thereof.

23.2.Neither party shall be deemed to be in breach of this Agreement, or otherwise be liable to the other, by reason of any delay in performance, or non-performance of its obligations hereunder to the extent that such delay or non-performance is due to any Force Majeure of which it has notified the other party, and the time for performance of that obligation shall be extended accordingly.

23.3.If the Force Majeure in question prevails for a continuous period in excess of six months the parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable.

24.NOTICES

24.1.Any notice given under this agreement shall be in writing and signed by or on behalf of the party giving it and shall be served by delivering it personally, or sending it registered post to the Company's registered office for the time being and / or address given in this agreement in the case of the Contractor or by sending it by email to the email address notified by the relevant party to the other party. Any such notice shall be deemed to have been received:

24.1.1.if delivered personally, at the time of delivery;

24.1.2.in the case of registered post, 48 hours from the date of posting; and

24.1.3.in the case of email, at the time of transmission.

24.2.In proving such service it shall be sufficient to prove that the envelope containing the notice was addressed to the address of the relevant party and delivered either to that address or into the custody of the postal authorities as registered post or that the notice was transmitted by email (with delivery confirmation and read receipt) to the email address of the relevant party.

25.VARIATION

25.1.No variation of this agreement or of any document referred to in it shall be valid unless it is in writing and signed by or on behalf the parties.

26.THIRD PARTY RIGHTS

26.1.A person/entity who is not a party to this agreement shall not have any rights under or in connection with it.

27.COUNTERPARTS

27.1.This Agreement may be executed in any number of counterparts, and by the several parties to it on separate counterparts, each of which when so executed will constitute an original but all of which together will evidence the same agreement.

28.GOVERNING LAW

28.1.This Agreement and all relationships created by it will in all respects be governed by and construed in accordance with Irish law.

29.JURISDICTION

29.1.1.The Irish courts will have exclusive jurisdiction to settle any dispute (**Dispute**) which may arise out of or in connection with this Agreement or its performance.

29.1.2.The parties agree that the Irish courts are the most appropriate and convenient courts to settle any Dispute and therefore that they will not argue to the contrary.

29.1.3.This clause is for the exclusive benefit of the Company and it will not prevent the Company

from initiating proceedings in relation to a Dispute (**Proceedings**) in any other court of competent jurisdiction. To the extent permitted by law, the Company may take concurrent Proceedings in any number of jurisdictions.

IN WITNESS whereof this Agreement has been entered into on the date first herein written.

SIGNED on behalf of the Company:

….....

Signature

….....

Title

SIGNED by Contractor:

….....

Signature

SCHEDULE 1

SERVICES

The Contractor will provide general support to the Company in connection with its new drug application (**NDA**) for oral sulopenem including the following:

- support with responses to the U.S. Food and Drug Administration (**FDA**) queries received in connection with the NDA;
- activities related to manuscript preparation;
- guidance on FDA inspection readiness;
- advice and support in connection with any FDA Advisory Committee including;
    - o preparation of briefing document
    - o review/input on any slides to be presented
    - o Assistance with mock Advisory Committee
    - o Assistance with Advisory Committee rehearsal/feedback, and

- any other services as may be agreed between the Company and the Contractor.

SCHEDULE 2

DATA PRIVACY NOTICE

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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: August 14, 2024

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: August 14, 2024

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 June 30, 2024, 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: August 14, 2024

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 June 30, 2024 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: August 14, 2024

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.