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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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 March 31, 2022

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 001-37558

**Nabriva Therapeutics plc**

(Exact name of registrant as specified in its charter)

**Ireland**

(State or other jurisdiction of incorporation or organization)

**Not applicable**

(I.R.S. Employer Identification No.)

**25-28 North Wall Quay**

**IFSC, Dublin 1, Ireland**

(Address of principal executive offices)

**Not applicable**

(Zip Code)

**+353 1 649 2000**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol (s)</u>	<u>Name of each exchange on which registered</u>
Ordinary Shares, nominal value \$0.01 per share	NBRV	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 April 30, 2022, the registrant had 63,204,829 ordinary shares outstanding.

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**NABRIVA THERAPEUTICS plc**  
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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Quarterly Report, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, and objectives of management, are forward-looking statements. The words “anticipate,” “around,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, among other things, statements about:

- our ability to successfully commercialize SIVEXTRO and realize value from our agreement with Merck & Co., Inc.;
- our ability to successfully commercialize XENLETA (lefamulin) for the treatment of community-acquired bacterial pneumonia, or CABP, including the availability of and ease of access to XENLETA through hospital formularies, managed care plans and major U.S. specialty distributors;
- our expectations regarding how far into the future our cash on hand and anticipated revenues from product sales will fund our ongoing operations and the continued availability and cost of capital to sustain our operations on a longer term basis;
- our ability to adequately secure additional financing;
- our ability to meet the minimum listing requirements for continued listing on The Nasdaq Global Select Market;
- our sales, marketing and distribution capabilities and strategy;
- the potential extent of revenues from future sales of SIVEXTRO, XENLETA and/or CONTEPO, if approved;
- our ability to build, manage and maintain a sales force for the commercialization of SIVEXTRO, XENLETA and CONTEPO, if approved;
- our ability to resolve the matters set forth in the Complete Response Letter we received from the U.S. Food and Drug Administration, or FDA, in connection with our New Drug Application, or NDA, for CONTEPO for the treatment of complicated urinary tract infections, or cUTIs, including acute pyelonephritis;
- the timing of the resubmission of the NDA for CONTEPO for the treatment of cUTIs and potential marketing approval of CONTEPO and other product candidates, including the completion of any post marketing requirements with respect to XENLETA for CABP and any other product candidates we may develop or obtain;
- our plans to pursue development of other product candidates including XENLETA for the treatment of infections in patients with cystic fibrosis;
- our expectations regarding our strategy to expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products, including additional community products;
- our ability to comply with the restrictive covenants under our debt facility with Hercules Capital, Inc., or Hercules, including but not limited to the ability to maintain minimum cash balance requirements;

- our ability to satisfy interest and principal payments under our debt facility with Hercules;
- our ability to successfully maintain inventory levels to satisfy product demand, as well as limit the unrealizable value of inventory based on historical usage, known trends, inventory age and market conditions;
- our ability to satisfy payments and comply with the terms of the Hovione Supply Agreement for the long-term commercial supply of the active pharmaceutical ingredient for XENLETA;
- our expectations about the impact of the COVID-19 pandemic on our business operations, ongoing clinical trials and regulatory matters, including the ability of regulatory authorities to operate;
- the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, and whether results of early clinical trials or preclinical studies in different disease indications will be indicative of the results of ongoing or future trials;
- our plans and the related cost expectations to pursue development of XENLETA for additional indications other than CABP, and of CONTEPO for additional indications other than cUTI;
- the future development and commercialization of XENLETA in the greater China region and Canada;
- our expectations with respect to milestone payments pursuant to the Agreement and Plan of Merger, dated July 23, 2018, and expectations with respect to potential advantages of CONTEPO or any other product candidate that we acquired in connection with the acquisition of Zavante Therapeutics, Inc., or the Acquisition;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- the potential advantages of SIVEXTRO, XENLETA, CONTEPO, and our other product candidates;
- our estimates regarding the market opportunities for SIVEXTRO, XENLETA, CONTEPO, and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of SIVEXTRO for acute bacterial skin and skin structure infections, XENLETA for CABP, CONTEPO for cUTI and our other product candidates, if approved;
- our ability to establish and maintain collaborations including additional licensing agreements for XENLETA outside the United States, Canada and the greater China region;
- the potential benefits under our license agreements with Sumitomo Pharmaceuticals (Suzhou), or the China Region License Agreement, and with Sunovion Pharmaceuticals Canada Inc., or the Sunovion License Agreement;
- our future intellectual property position;
- our ability to maintain the level of our expenses consistent with our internal budgets and forecasts;
- the demand for securities of pharmaceutical and biotechnology companies in general and our ordinary shares in particular;
- competitive factors;

- risks of relying on external parties such as contract manufacturing and sales organizations;
- compliance with current or prospective governmental regulation;
- general economic and market conditions;
- our ability to attract and retain qualified employees and key personnel;
- our business and business relationships, including with employees and suppliers;
- our ability to satisfy milestone, royalty and transaction revenue payments pursuant to the Stock Purchase Agreement between our wholly owned subsidiary Zavante Therapeutics, Inc. and SG Pharmaceuticals, Inc.; and
- other risks and uncertainties, including those described in the “Risk Factors” section of this Form 10-Q.

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

You should refer to the “Risk Factor Summary” and “Risk Factors” sections of this Form 10-Q for a discussion of important factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, except as required by applicable law.

Throughout this Form 10-Q, unless the context requires otherwise, all references to “Nabriva,” “the Company,” “we,” “our,” “us” or similar terms refer to Nabriva Therapeutics plc, together with its consolidated subsidiaries.

## RISK FACTOR SUMMARY

Our business is subject to a number of risks of which you should be aware before making an investment decision. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the “Risk Factors” in Part II, Item 1A, together with the other information in this Quarterly Report.

- We depend heavily on the success of SIVEXTRO, XENLETA and CONTEPO. The U.S. Food and Drug Administration, or FDA, has approved SIVEXTRO for oral and intravenous use by adults and adolescents for the treatment of acute bacterial skin and skin structure infections, or ABSSSI, and XENLETA for oral and intravenous use for the treatment of community-acquired bacterial pneumonia, or CABP. CONTEPO is being developed for complicated urinary tract infections, or cUTI. If we are unable to obtain marketing approval for CONTEPO, or if we fail in our commercialization efforts for SIVEXTRO and/or XENLETA, or experience significant delays in doing so, our business will be materially harmed.
- We have incurred significant losses since our inception and anticipate that we will incur losses for at least the next several years and may never generate profits from operations or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- If we fail to meet the requirements for continued listing on The Nasdaq Global Select Market, our ordinary shares could be delisted from trading, which would decrease the liquidity of our ordinary shares and our ability to raise additional capital.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations. We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due or to comply with minimum cash balance requirements.
- The number of ordinary shares underlying our outstanding warrants is significant in relation to our currently outstanding ordinary shares, which could have a negative effect on the market price of our ordinary shares and make it more difficult for us to raise funds through future equity offerings.
- SIVEXTRO, XENLETA and any other product candidate that receives marketing approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for such products and product candidates, if approved, may be smaller than we estimate.
- We have entered into a Sales Promotion and Distribution Agreement with Merck & Co. related to the promotion, distribution and sale of SIVEXTRO. If our collaboration with Merck is not successful, we may incur significant expenses related to the distribution of SIVEXTRO without realizing adequate value from the agreement.
- We have entered into and may enter into additional collaborations with third parties for the development or commercialization of XENLETA, CONTEPO and our other product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products and product candidates.
- If we are unable to obtain and maintain patent protection for our technology, products and product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop

and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology, products and product candidates may be adversely affected.

- Business interruptions resulting from the SARS-CoV-2 infection causing COVID-19 outbreak or similar public health crises have caused and could continue to cause a disruption of the commercialization of our products and the development of our product candidates and adversely impact our business.
- If clinical trials of XENLETA, CONTEPO or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, regulatory authorities in the European Union, or other 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 XENLETA, CONTEPO or any other product candidate.
- If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.
- If serious adverse or undesirable side effects are identified in SIVEXTRO, XENLETA, or CONTEPO or any other product candidate that we develop or following their approval and commercialization, we may need to modify, abandon or limit our development or marketing of that product or product candidate.
- We are a “smaller reporting company”, and the reduced disclosure requirements applicable to smaller reporting companies may make our ordinary shares less attractive to investors.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation. We are incorporated as a public limited company under Irish law.
- The intended efficiency of our corporate structure depends on the application of the tax laws and regulations in the countries where we operate, and we may have exposure to additional tax liabilities or our effective tax rate could change, which could have a material impact on our results of operations and financial position.
- U.S. persons who own 10 percent or more of our shares may be subject to U.S. federal income taxation on certain of our foreign subsidiaries’ income even if such income is not distributed to such U.S. persons.
- A transfer of our ordinary shares, other than a transfer effected by means of the transfer of book-entry interests in the Depository Trust Company, may be subject to Irish stamp duty.
- We may be classified as a passive foreign investment company for one or more of our taxable years, which may result in adverse U.S. federal income tax consequence to U.S. holders.

PART I

ITEM 1. FINANCIAL STATEMENTS

NABRIVA THERAPEUTICS plc  
Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	As of March 31, 2022	As of December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,784	\$ 47,659
Restricted cash	174	175
Short-term investments	—	16
Accounts receivable, net and other receivables	11,007	12,751
Inventory	15,632	14,509
Prepaid expenses	4,602	5,155
Total current assets	65,199	80,265
Property and equipment, net	181	233
Intangible assets, net	21	31
Other non-current assets	379	380
<b>Total assets</b>	<b>\$ 65,780</b>	<b>\$ 80,909</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Current portion of long-term debt	\$ 4,196	\$ 3,765
Accounts payable	1,578	4,372
Accrued expense and other current liabilities	10,496	13,829
Deferred revenue	—	374
Total current liabilities	16,270	22,340
Non-current liabilities:		
Long-term debt	3,917	4,265
Other non-current liabilities	968	954
Total non-current liabilities	4,885	5,219
<b>Total liabilities</b>	<b>21,155</b>	<b>27,559</b>
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Ordinary shares, nominal value \$0.01, 300,000,000 ordinary shares authorized at March 31, 2022; 61,725,236 and 56,715,306 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	617	567
Preferred shares, nominal value \$0.01, 100,000,000 shares authorized at March 31, 2022; None issued and outstanding	—	—
Additional paid in capital	651,476	648,432
Accumulated other comprehensive income	27	27
Accumulated deficit	(607,495)	(595,676)
<b>Total stockholders' equity</b>	<b>44,625</b>	<b>53,350</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 65,780</b>	<b>\$ 80,909</b>

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



**NABRIVA THERAPEUTICS plc**  
**Consolidated Statements of Operations (unaudited)**

<i>(in thousands, except share and per share data)</i>	Three Months Ended	
	March 31,	
	2022	2021
<b>Revenues:</b>		
Product revenue, net	\$ 7,040	\$ 130
Collaboration revenue	629	2,002
Research premium and grant revenue	351	397
<b>Total revenues</b>	<b>8,020</b>	<b>2,529</b>
<b>Operating expenses:</b>		
Cost of revenues	(3,361)	(62)
Research and development expenses	(3,517)	(3,868)
Selling, general and administrative expenses	(12,700)	(12,047)
Total operating expenses	(19,578)	(15,977)
<b>Loss from operations</b>	<b>(11,558)</b>	<b>(13,448)</b>
<b>Other income (expense):</b>		
Other income (expense), net	308	(122)
Interest expense, net	(215)	(221)
<b>Loss before income taxes</b>	<b>(11,465)</b>	<b>(13,791)</b>
Income tax expense	(354)	(190)
<b>Net loss</b>	<b>\$ (11,819)</b>	<b>\$ (13,981)</b>
<b>Loss per share</b>		
Basic and diluted loss per share	\$ (0.20)	\$ (0.53)
<b>Weighted average number of shares:</b>		
Basic and diluted	58,794,142	26,413,590

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

**NABRIVA THERAPEUTICS plc**  
**Consolidated Statements of Changes in Stockholders' Equity (unaudited)**

(in thousands)	Ordinary shares		Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Number of shares	Amount				
<b>January 1, 2021</b>	21,079	\$ 211	\$ 579,123	\$ 27	\$ (546,226)	\$ 33,135
Issuance of ordinary shares	14,294	143	37,097	—	—	37,240
Shares issued in connection with the vesting of restricted share units	40	—	1	—	—	1
Equity transaction costs	—	—	(2,325)	—	—	(2,325)
Stock-based compensation expense	—	—	921	—	—	921
Net loss	—	—	—	—	(13,981)	(13,981)
<b>March 31, 2021</b>	<b>35,413</b>	<b>\$ 354</b>	<b>\$ 614,817</b>	<b>\$ 27</b>	<b>\$ (560,207)</b>	<b>\$ 54,991</b>

(in thousands)	Ordinary shares		Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Number of shares	Amount				
<b>January 1, 2022</b>	56,715	\$ 567	\$ 648,432	\$ 27	\$ (595,676)	\$ 53,350
Issuance of ordinary shares	4,938	49	2,172	—	—	2,221
Shares issued in connection with the vesting of restricted share units	72	1	(1)	—	—	—
Equity transaction costs	—	—	(127)	—	—	(127)
Stock-based compensation expense	—	—	1,000	—	—	1,000
Net loss	—	—	—	—	(11,819)	(11,819)
<b>March 31, 2022</b>	<b>61,725</b>	<b>\$ 617</b>	<b>\$ 651,476</b>	<b>\$ 27</b>	<b>\$ (607,495)</b>	<b>\$ 44,625</b>

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

**NABRIVA THERAPEUTICS plc**  
**Consolidated Statements of Cash Flows (unaudited)**

<b>(in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (11,819)	\$ (13,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other income (expense), net	164	(2)
Non-cash interest income	(1)	—
Non-cash interest expense	93	(76)
Depreciation and amortization expense	78	99
Amortization of right-of-use assets	—	169
Stock-based compensation	1,000	921
Other, net	10	20
Changes in operating assets and liabilities:		
(Increase) decrease in other non-current assets	1	(13)
(Increase) decrease in accounts receivable, net and other receivables and prepaid expenses	2,297	(4,642)
Increase in inventory	(1,123)	(3,151)
Increase (decrease) in accounts payable	(2,781)	734
Decrease in accrued expenses and other liabilities	(3,616)	(1,482)
Decrease in deferred revenue	(374)	—
Increase (decrease) in other non-current liabilities	14	(202)
Increase (decrease) in income tax liabilities	187	(20)
Net cash used in operating activities	(15,870)	(21,626)
<b>Cash flows from investing activities</b>		
Purchases of equipment and intangible assets	(35)	(119)
Changes in restricted cash	(1)	(1)
Net cash used in investing activities	(36)	(120)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock and warrants	1,643	25,462
Proceeds from at-the-market facility	595	11,830
Equity transaction costs	(44)	(2,362)
Net cash provided by financing activities	2,194	34,930
Effects of exchange rate changes on the balance of cash held in foreign currencies	(164)	244
Net increase/(decrease) in cash, cash equivalents and restricted cash	(13,876)	13,428
Cash, cash equivalents, and restricted cash at beginning of period	47,834	41,590
Cash, cash equivalents and restricted cash at end of period	\$ 33,958	55,018
Supplemental disclosure of cash flow information:		
Interest paid	123	122
Taxes paid	1	—
Equity transaction costs included in accounts payable and accrued expenses	795	728

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

**NABRIVA THERAPEUTICS plc**  
**Notes to the Unaudited Consolidated Financial Statements**

**1. Organization and Business Activities**

Nabriva Therapeutics plc, or Nabriva Ireland, together with its wholly owned and consolidated subsidiaries, Nabriva Therapeutics GmbH, or Nabriva Austria, Nabriva Therapeutics US, Inc., Zavante Therapeutics, Inc., or Zavante, and Nabriva Therapeutics Ireland DAC, collectively, Nabriva, or the Company, is a biopharmaceutical company engaged in the commercialization and development of novel anti-infective agents to treat serious infections. The Company's headquarters are located at 25-28 North Wall Quay, Dublin, Ireland.

In September 2021, Sumitomo Pharmaceuticals (Suzhou) and the Company announced the approval received by Sumitomo Pharmaceuticals (Suzhou) to market oral and intravenous formulations of XENLETA for the treatment of community-acquired pneumonia in adults in Taiwan.

In September 2020, the Centers for Medicare & Medicaid Services, or CMS, granted a new technology add-on payment, or NTAP, for XENLETA® (lefamulin) for injection, when administered in the hospital inpatient setting. Both the intravenous, or IV and oral formulations of XENLETA were granted Qualified Infectious Disease Product, or QIDP, and Fast Track designation by the U.S. Food and Drug Administration, or FDA. NTAP was also granted for CONTEPO™ (fosfomycin for injection, previously referred to as ZTI-01 and ZOLYD), making it the first QIDP antibiotic to be granted conditional NTAP approval prior to receiving FDA approval. CONTEPO was granted QIDP and Fast Track Designation by the FDA for the treatment of complicated urinary tract infections, or cUTIs, including acute pyelonephritis.

In July 2020, the Company announced that the European Commission, or EC, issued a legally binding decision for approval of the marketing authorization application for XENLETA™ (lefamulin) for the treatment of community-acquired pneumonia, or CAP, in adults following a review by the European Medicines Agency, or EMA. The EMA approval of XENLETA in CAP patients when it is considered inappropriate to use antibacterial agents that are commonly recommended for initial treatment or when these agents have failed paves the way for the launch of XENLETA across the European Economic Area, or EEA, and United Kingdom, or U.K. The EC approved XENLETA for all countries of the European Economic Area, or EEA, and United Kingdom, or U.K. Nabriva intends to work with a commercial partner to make XENLETA available to patients in the European Economic Area, or EEA, and United Kingdom, or U.K.

In July 2020, the Company announced that Sunovion Pharmaceuticals Canada Inc., or Sunovion, received approval from Health Canada to market oral and IV formulations of XENLETA® (lefamulin) for the treatment of CAP in adults, with the Notice of Compliance from Health Canada dated July 10, 2020. Nabriva entered into a license and commercialization agreement in March 2019 with Sunovion Pharmaceuticals Canada Inc. for XENLETA in Canada.

In July 2020, the Company announced that it entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with MSD International GmbH, or MSD, and Merck Sharp & Dohme Corp., or Supplier, each a subsidiary of Merck & Co. Under the Distribution Agreement, MSD appointed the Company as its sole and exclusive distributor of certain products containing tedizolid phosphate as the active ingredient previously marketed and sold by Supplier and MSD under the trademark SIVEXTRO® for injection, intravenous use and oral use in the United States and its territories. SIVEXTRO is an oxazolidinone-class antibacterial indicated in adults and patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections caused by certain susceptible Gram-positive microorganisms. Nabriva has also engaged Amplity Health, a leading pharmaceutical contract commercial organization, to provide community-based commercial and sales services for SIVEXTRO and XENLETA® in the United States.

In June 2020 the Company announced that WE Pharma Ltd., or WEP Clinical, a specialist pharmaceutical services company, had signed an exclusive agreement with the Company to supply XENLETA® (lefamulin) on a named patient or expanded access basis in certain countries outside of the US, China and Canada. The Named Patient Program, or NPP, is designed to ensure that physicians, contingent on meeting the necessary eligibility criteria and receiving

approval, can request IV or oral XENLETA on behalf of patients who live in certain countries where it is not yet available and have an unmet medical need.

In September 2019, the Company announced that the oral and IV formulations of XENLETA (lefamulin) are available in the United States for the treatment of community-acquired bacterial pneumonia, or CABP, through major specialty distributors. This followed the approval by the FDA of the Company's New Drug Application, or NDA, for XENLETA on August 19, 2019 for the treatment of adults with CABP. XENLETA is the first oral and IV treatment in the pleuromutilin class of antibiotics available for the systematic administration in humans.

### *Liquidity*

Since its inception, the Company has incurred net losses and generated negative cash flows from its operations which has resulted in a significant accumulated deficit to date. The Company has financed its operations through the sale of equity securities, convertible and term debt financings and research and development support from governmental grants and proceeds from its licensing agreements and XENLETA and SEVEXTRO product sales. As of March 31, 2022, the Company had cash and cash equivalents, restricted cash and short-term investments of \$34.0 million.

The Company expects to seek additional funding in future periods to fund its operations. While the Company has raised capital in the past, its ability to raise capital in future periods is not considered probable, as defined under the accounting standards. As such, under the requirements of Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements — Going Concern*, or ASC 205-40, management may not consider the potential for future capital raises in their assessment of the Company's ability to meet its obligations for the next twelve months. It is also uncertain when, if ever, the Company will generate sufficient revenues from product sales to achieve profitability.

The Company follows the provisions of Financial Accounting Standards Board, or FASB, ASC 205-40, which requires management to assess the Company's ability to continue as a going concern for one year after the date the consolidated financial statements are issued. As a result, based on the Company's available cash and cash equivalents, restricted cash and short-term investments, resources, the minimum cash required under the Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc., and in accordance with the requirements of ASC 205-40, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these consolidated financial statements are issued. A failure to raise additional funding or to effectively implement cost reductions could harm the Company's business, results of operations and future prospects. If the Company is not able to secure adequate additional funding in future periods, the Company would be forced to make additional reductions in certain expenditures. This may include liquidating assets and suspending or curtailing planned programs. The Company may also have to delay, reduce the scope of, suspend or eliminate one or more research and development programs or its commercialization efforts.

In May 2021, the Company entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sale Agreement, with Jefferies, as agent, pursuant to which the Company may offer and sell ordinary shares from time to time through Jefferies, by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of March 31, 2022, the Company has issued and sold an aggregate of 19,570,971 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$31.0 million and net proceeds of \$29.8 million, after deducting commissions to Jefferies and other offering expenses. From April 1, 2022 and through the date of this filing, the Company has issued and sold an aggregate of 276,150 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$118 thousand and net proceeds of \$115 thousand, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, the Company may issue and sell ordinary shares for gross proceeds of up to \$10.5 million under the Sale Agreement.

In September 2021, the Company entered into a purchase agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which, subject to the terms and conditions, provides that the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$23.0 million of its ordinary shares. In addition, under the Purchase Agreement, the Company agreed to issue a commitment fee of 632,474 ordinary shares, or the Commitment Shares, as consideration for Lincoln Park entering into the Purchase Agreement and for the payment of \$0.01 per Commitment Share. Under the Purchase Agreement, the Company may from time to time, at its discretion,

direct Lincoln Park to purchase on any single business day, or a Regular Purchase, up to (i) 400,000 ordinary shares if the closing sale price of its ordinary shares is not below \$0.25 per share on Nasdaq, (ii) 600,000 ordinary shares if the closing sale price of its ordinary shares is not below \$2.00 per share on Nasdaq or (iii) 800,000 ordinary shares if the closing sale price of its ordinary shares is not below \$3.00 per share on Nasdaq. In addition to Regular Purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases on the terms and subject to the conditions set forth in the Purchase Agreement. In any case, Lincoln Park's commitment in any single Regular Purchase may not exceed \$2.5 million absent a mutual agreement to increase such amount. As of March 31, 2022, the Company has issued and sold an aggregate of 6,000,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$4.1 million. From April 1, 2022 and through the date of this filing, the Company has issued and sold an aggregate of 1,200,000 ordinary shares pursuant to the Purchase Agreement and received gross proceeds of \$0.4 million. As of the date of this filing, the Company may issue and sell ordinary shares for gross proceeds of up to \$18.6 million under the Purchase Agreement, subject to the Nasdaq rules which may limit the Company's ability to make sales of its ordinary shares to Lincoln Park in excess of a specified amount without prior shareholder approval.

Based on its current operating plans, the Company expects that its existing cash, cash equivalents, restricted cash and short-term investments as of the date of this Quarterly Report on Form 10-Q together with its anticipated SIVEXTRO and XENLETA commercial sales receipts will be sufficient to enable the Company to fund its operating expenses, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than expected. This estimate assumes, among other things, that the Company does not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings. This estimate also assumes that the Company remains in compliance with the covenants and no event of default occurs under the Loan Agreement. The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

## **2. Summary of Significant Accounting Policies**

### **Basis of Preparation**

The unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or US GAAP, for interim financial information, and US Securities and Exchange Commission, or SEC, regulations for quarterly reporting. The unaudited consolidated financial statements include the accounts of Nabriva Therapeutics plc and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying consolidated financial information as of March 31, 2022 and for the three months ended March 31, 2022 and 2021 are unaudited. The December 31, 2021 balance sheet was derived from audited consolidated financial statements but does not include all disclosures required by US GAAP. The interim unaudited consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2022 and results of operations for the three months ended March 31, 2022 and 2021. The financial data and other information disclosed in these notes related to the three months ended March 31, 2022 and 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, any other interim periods or any future year or period. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2021 contained in the Company's Annual Report on Form 10-K, as filed with the SEC on March 29, 2022.

The Company's significant accounting policies are described in Note 2 of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

### Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company has not adopted any new accounting pronouncements for the three months ended March 31, 2022.

### 3. Inventory

Inventory is stated at the lower of cost or net realizable value. Inventory is valued on a first-in, first-out basis and consists primarily of material costs, third-party manufacturing costs, and related transportation costs along the Company's supply chain. The Company capitalizes inventory upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are recorded as research and development expense. Costs of drug product to be consumed in any current or future clinical trials will continue to be recognized as research and development expense and costs of sample inventory is recorded as selling, general and administrative expense. The Company reviews inventories for realization on a quarterly basis and records provisions for estimated excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of net realizable value when necessary. As of March 31, 2022, the Company had a \$1.0 million non-cash reserve for excess and obsolete finished goods inventory due to the uncertainty of commercial activities underlying XENLETA product sales. Inventory reported at March 31, 2022 and December 31, 2021 consisted of the following:

(in thousands)	As of March 31, 2022	As of December 31, 2021
XENLETA raw materials	\$ 1,235	\$ 1,528
XENLETA work in process	9,415	9,142
XENLETA finished goods	402	18
Total XENLETA	11,052	10,688
SIVEXTRO finished goods	4,580	3,821
<b>Total inventory</b>	<b>\$ 15,632</b>	<b>\$ 14,509</b>

### 4. Fair Value Measurement

US GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (as exchange rates).
- Level 3: Valuation techniques that include inputs for the asset or liability that are not based on observable market data (those are unobservable inputs) and significant to the overall fair value measurement.

The following table presents the financial instruments measured at fair value and classified by level according to the fair value measurement hierarchy:

(in thousands)	Level 1	Level 2	Level 3	Total
<b>March 31, 2022</b>				
<b>Assets:</b>				
Cash equivalent:				
Money market fund	\$ 8,066	\$ —	\$ —	\$ 8,066
<b>Total assets</b>	<b>\$ 8,066</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 8,066</b>

(in thousands)	Level 1	Level 2	Level 3	Total
<b>December 31, 2021</b>				
<b>Assets:</b>				
Cash equivalent:				
Money market fund	\$ 8,050	\$ —	\$ —	\$ 8,050
Short-term investments:				
Term deposits	16	—	—	16
<b>Total assets</b>	<b>\$ 8,066</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 8,066</b>

There were no transfers between levels in the three months ended March 31, 2022 or the year ended December 31, 2021. There were no changes in valuation techniques during the three months ended March 31, 2022.

As of March 31, 2022, and December 31, 2021, the Company did not hold any financial instruments as liabilities that were held at fair value. Receivables and accounts payable are carried at their historical cost which approximates fair value due to their short-term nature.

## 5. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities include the following:

(in thousands)	As of March 31, 2022	As of December 31, 2021
Research and development related costs	\$ 821	\$ 789
Payroll and related costs	2,507	5,085
Accounting, tax and audit services	852	736
Manufacturing and inventory	791	592
Product returns	1,310	2,282
Government rebates	1,668	1,751
Other accrued gross to net	1,244	1,090
Other	1,303	1,504
<b>Total other current liabilities</b>	<b>\$ 10,496</b>	<b>\$ 13,829</b>

## 6. Debt

In December 2018, the Company entered into the Loan Agreement by and among the Company, Nabriva Therapeutics Ireland DAC, and certain other subsidiaries of the Company and Hercules Capital, Inc., or Hercules, pursuant to which a term loan of up to an aggregate principal amount of \$75.0 million was available to the Company. The Loan Agreement initially provided for an initial term loan advance of \$25.0 million, which was funded in December 2018, and, at the Company's option and subject to the occurrence of certain funding conditions, several additional tranches of which \$10.0 million became available upon the approval by the FDA of the NDA for XENLETA, which was drawn down. The other tranches are no longer available as their contingencies were not achieved.

The term loan bears interest at an annual rate equal to the greater of 9.80% or 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provided for interest-only payments through July 1, 2021 and repayment of the outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023, or the Maturity Date. In addition, the Company is required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at the Maturity Date, or the End of Term Fee. At the Company's option, the Company may elect to prepay any portion of the outstanding term loan that is greater than or equal to \$5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid, or the Prepayment Fee: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but



before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the Maturity Date.

On March 11, 2020, the Company entered into an amendment, or the Third Amendment, to its Loan Agreement with Hercules. Pursuant to the Third Amendment, the Company repaid \$30.0 million of the \$35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, or the Prepayment. The Company determined to enter into the Third Amendment following the effectiveness of a performance covenant in February 2020 under which it became obligated to either (1) achieve 80% of its net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or \$40.0 million, or the Liquidity Requirement. Under the Third Amendment, the Company and Hercules agreed to defer the end of term loan charge payment of \$2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the Prepayment Fee with respect to the Prepayment from \$600,000 to \$300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Third Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered the minimum liquidity requirement to \$3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the FDA and the Company achieves at least 70% of its revised net product revenue targets under the Loan Agreement.

On June 2, 2021, the Company entered into a further amendment, or the Fourth Amendment, to its Loan and Security Agreement with Hercules. Pursuant to the Fourth Amendment, the date on which the Company must commence repaying principal under the Loan Agreement was extended to April 1, 2022. The Company began making interest and principal payments in April 2022. In addition, pursuant to the Fourth Amendment, the minimum liquidity requirement of \$3.0 million in cash and cash equivalents will be waived at any time the Company has recognized \$15.0 million of net product revenue during the applicable trailing three months.

The Company's obligations under the Loan Agreement are guaranteed by all current and future subsidiaries of the Company, and each of the Company and its subsidiaries has granted Hercules a security interest in all of their respective personal property, intellectual property and other assets owned or later acquired. The Loan Agreement also contains certain events of default, representations, warranties and covenants of the Company and its subsidiaries. For example, the Loan Agreement contains representations and covenants that, subject to certain exceptions, restrict the Company's and its subsidiaries' ability to do the following, among other things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions and asset sales; certain transactions with affiliates; undergo a change in control; and add or change business locations or settle in cash potential milestone payment obligations that may become payable by the Company in the future to former security holders of Zavante. The Company was in compliance with all of its Loan Agreement covenants at March 31, 2022.

The Loan Agreement also grants Hercules or its nominee an option to purchase up to an aggregate of \$2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in any private financing upon the same terms and conditions afforded to such other investors for as long as there are amounts outstanding under the Loan Agreement.

The Company incurred \$1.3 million of costs in connection with the Loan Agreement which along with the initial fee of \$0.7 million paid to Hercules were recorded as debt issuance cost and are being amortized as interest expense using the effective interest method over the term of the loan. The carrying value of the term loan payable at March 31, 2022 includes the present value of the End of Term Fee and the Prepayment Fee. The End of Term Fee on the remaining \$5.0 million principal balance is being accrued as additional interest expense using the effective interest method over the term of the loan.

Long-term debt as of March 31, 2022 and December 31, 2021 consisted of the following:

(in thousands)	As of March 31, 2022	As of December 31, 2021
Term loan payable	\$ 5,000	\$ 5,000
End of term fee	2,401	2,331
Unamortized debt issuance costs	(120)	(145)
Carrying value of term loan	7,281	7,186
Other long-term debt	832	844
Less: Amounts due within one year	(4,196)	(3,765)
<b>Total long-term debt</b>	<b>\$ 3,917</b>	<b>\$ 4,265</b>

Maturities of long-term debt, including the end of term fee as of March 31, 2022 were as follows:

(in thousands)		
2022	\$	3,129
2023	\$	5,020
2024	\$	208
2025	\$	208

## 7. Revenues

(in thousands)	Three Months Ended March 31,	
	2022	2021
Product revenue, net	\$ 7,040	\$ 130
Collaboration revenues	629	2,002
Research premium and grant revenue	351	397
<b>Total revenues</b>	<b>\$ 8,020</b>	<b>\$ 2,529</b>

Collaboration revenues for the three months ended March 31, 2022 included \$0.6 million related to the restructured China Region License Agreement, a portion of which is recognized over the estimated period the manufacturing collaboration and regulatory support will be provided to Sumitomo Pharmaceuticals (Suzhou) (see Note 11). Collaboration revenues for the three months ended March 31, 2021 included \$0.7 million related to the restructured license agreement with Sinovant Sciences, Ltd., or Sinovant, which is recognized over the estimated period the manufacturing collaboration and regulatory support will be provided to Sinovant, as well as \$1.0 million of the Company's share of revenues associated with the SIVEXTRO distribution agreement with Merck & Co., Inc.

The Company sells its products to pharmaceutical wholesalers/distributors (i.e., the Company's customers). The Company's wholesalers/distributors in turn sell the Company's products directly to clinics, hospitals, and private practices. Revenue from the Company's product sales is recognized as physical delivery of product occurs (when the Company's customer obtains control of the product), in return for agreed-upon consideration.

For the three months ended March 31, 2022, SIVEXTRO product revenues, net of gross-to-net accruals and adjustments for returns were \$7.2 million. For the three months ended March 31, 2022 and 2021 XENLETA product revenues, net of gross-to-net accruals and adjustments for returns, were negative \$0.2 million and \$130 thousand, respectively. The Company's gross-to-net, or GTN, estimates are based upon information received from external sources (such as written or oral information obtained from the Company's customers with respect to their period-end inventory levels and sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred may be materially above or below the amount initially estimated when product revenues are originally recorded, then requiring prospective adjustments to the Company's reported product revenues, net.

For the three months ended March 31, 2022, the Company recorded a \$0.3 million returns reserve adjustment for shelf life expiration of certain XENLETA products. For the three months ended March 31, 2021, the Company did not record any adjustments to the return reserve.

## **8. Share-Based Payments**

### **Stock Plan Activity**

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015, or the SOP 2015, as amended. Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining 75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation. With the approval of the 2017 Share Incentive Plan, there were no further shares available for issuance under the SOP 2015. However, all outstanding awards under SOP 2015 will remain in effect and continue to be governed by the terms of the SOP 2015.

On July 26, 2017, the Company's board of directors adopted the 2017 Share Incentive Plan, or the 2017 Plan, and the shareholders approved the 2017 Plan at the Company's Extraordinary General Meeting of Shareholders on September 15, 2017. The 2017 Plan permitted the award of share options (both incentive and nonstatutory options), share appreciation rights, or SARs, restricted shares, restricted share units, or RSUs, and other share-based awards to the Company's employees, officers, directors, consultants and advisers. The 2017 Plan is administered by the Company's board of directors. Under the 2017 Plan, the Company granted RSUs which vest over a period of four years with 25% vesting upon the first anniversary of the grant date and on a monthly pro rata basis thereafter over the remaining three years. Lastly, the Company granted RSUs in 2018 to certain employees where vesting of the RSUs is subject to FDA approval of an NDA for CONTEPO. Fifty percent (50%) of each RSU award will vest upon FDA approval, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval. With the approval of the 2020 Share Incentive Plan, there were no further shares available for issuance under the 2017 Plan.

On March 12, 2019, the Company's board of directors adopted the 2019 Inducement Share Incentive Plan, or the 2019 Inducement Plan and, subject to the adjustment provisions of the 2019 Inducement Plan, reserved 200,000 ordinary shares for issuance pursuant to equity awards granted under the 2019 Inducement Plan. In accordance with Nasdaq Listing Rule 5635(c)(4), awards under the 2019 Inducement Plan may only be made to individuals who were not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company. On April 28, 2020, the board of directors resolved not to make any further awards under the 2019 Inducement Plan.

In July 2018, the Company granted a non-statutory option to purchase 85,000 of its ordinary shares to the Company's newly appointed Chief Executive Officer, or the CEO. These equity awards were granted outside of the 2017 Plan and the 2019 Inducement Plan, were approved by the Company's compensation committee and board of directors and were made as an inducement material to the CEO entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The exercise price per share for the share option is \$35.30 per share, and the option award has a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. The Company also issues non-statutory options to new employees upon the commencement of their employment.

On March 4, 2020, the Company's board of directors adopted the 2020 Share Incentive Plan, or the 2020 Plan, which was approved by the Company's shareholders at the 2020 Annual General Meeting of Shareholders in July 2020, or the 2020 AGM. As of the date of the 2020 AGM, the total number of ordinary shares reserved for issuance under the 2020 Plan was for the sum of 930,000 ordinary shares, plus the number of the Company's ordinary shares that remained

available for grant under the 2017 Plan as of immediately prior to the 2020 AGM and the number of ordinary shares subject to awards granted under the 2017 Plan and the 2015 SOP, that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right. The 2020 Plan provides for the grant of incentive share options, non-statutory share options, share appreciation rights, restricted share awards, restricted share units, other share-based and cash-based awards and performance awards. Under the 2020 Plan the Company granted RSUs to certain employees that vest in three six-month increments beginning in January 2021 and ending in January 2022. The Company also granted RSUs to certain employees, where vesting of the RSUs was subject to individual performance goals. The Company granted RSUs to certain employees which vest as to 25% of the shares underlying the RSUs in four annual increments. Additionally, the Company granted 7,000 RSUs to its former Chief Medical Officer and to its former Chief Financial Officer, which vest as to 50% of the shares underlying the RSUs each year over the term of their respective consulting agreements. During the three months ended March 31, 2022, option awards to purchase 592,000 ordinary shares with an exercise price of \$0.45 per share and 295,900 RSUs were granted under the 2020 Plan, subject to shareholder approval, which, in the case of the options, will automatically convert to cash-settled share appreciation rights and, in the case of the RSUs, will represent the right to receive the economic equivalent of one ordinary share of the Company in cash on the applicable vesting date, in each case, if our shareholders do not approve the increase to our 2020 Plan at our 2022 Annual General Meeting of Shareholders. As a result, such grants awarded under the 2020 Plan are liability classified until such shareholder approval is obtained. Stock-based compensation expense for liability classified option awards and RSUs under the 2020 Plan was \$16 thousand for the three months ended March 31, 2022.

At March 31, 2022, 99,220 ordinary shares excluding the liability classified awards were available for future issuance under the 2020 Plan.

On December 9, 2020, the Company's board of directors adopted without stockholder approval the 2021 Inducement Share Incentive Plan, or the 2021 Inducement Plan and, subject to the adjustment provisions of the 2021 Inducement Plan, reserved 200,000 ordinary shares for issuance pursuant to equity awards granted under the 2021 Inducement Plan. In accordance with Nasdaq Listing Rule 5635(c)(4), awards under the 2021 Inducement Plan may only be made to individuals who were not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the company), as an inducement material to the individuals' entry into employment with the Company. In September 2021, the Company's board of directors adopted an amendment to the 2021 Inducement Plan that increased the amount of shares reserved for issuance under the plan from 200,000 shares to 500,000 shares. Options and SARs granted will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option agreement; provided, however, that no option or SAR will be granted with a term in excess of ten years. The board will also determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

### Stock Options

The following table summarizes information regarding the Company's stock option awards for the three months ended March 31, 2022:

	Options	Weighted average exercise price in \$ per share	Weighted Average Remaining Contractual Term (in years)	Aggregate intrinsic value (in thousands)
<b>Outstanding as of January 1, 2022</b>	<b>1,348,477</b>	<b>20.46</b>	<b>8.0</b>	<b>—</b>
Granted	604,000	0.45	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(422)	24.79	—	—
<b>Outstanding as of March 31, 2022</b>	<b>1,952,055</b>	<b>14.26</b>	<b>8.4</b>	<b>\$ —</b>
<b>Vested and exercisable as of March 31, 2022</b>	<b>587,726</b>	<b>41.94</b>	<b>6.8</b>	<b>\$ —</b>

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The Company has 1,952,055 option grants outstanding at March 31, 2022 with exercise prices ranging from \$0.45 per share to \$110.00 per share. As of March 31, 2022, there was \$1.6 million of total unrecognized compensation expense related to unvested stock options, which will be recognized over the weighted-average remaining vesting period of 1.1 years.

The stock options granted in the three months ended March 31, 2022 had a weighted average grant date fair value of \$0.44 per share based on a Black Scholes option pricing model. The significant inputs into the model were as follows

Expected volatility	76.4% - 76.9%
Expected term of options (in years)	6.1
Range of risk-free interest rate	1.68% - 1.76%
Dividend yield	—

The expected price volatility is based on historical trading volatility of our ordinary shares under consideration of the remaining life of the options. The risk-free interest rate is based on the average of five and seven-year market yield on U.S. treasury securities in effect at the time of grant.

### Restricted Share Units (“RSUs”)

The following table summarizes information regarding the Company’s restricted share unit awards for the three months ended March 31, 2022:

	RSUs	Weighted average fair value in \$ per share
<b>Outstanding as of January 1, 2022</b>	<b>789,738</b>	<b>2.92</b>
Granted	461,700	0.45
Vested and issued	(87,552)	4.13
Forfeited	—	—
<b>Outstanding as of March 31, 2022</b>	<b>1,163,886</b>	<b>1.88</b>

The Company has total unrecognized compensation costs of \$0.9 million associated with RSUs which are expected to be recognized over the awards average remaining vesting period of 1.5 years. The intrinsic value of RSU’s that vested during the three months ended March 31, 2022 was \$41 thousand.

### Stock-based Compensation

The following table presents stock-based compensation expense included in the Company’s consolidated statements of operations:

(in thousands)	Three Months Ended March 31,	
	2022	2021
Research and development expense	\$ 94	\$ 216
Selling, general and administrative expense	906	705
<b>Total stock-based compensation expense</b>	<b>\$ 1,000</b>	<b>\$ 921</b>

### Employee Stock Purchase Plan

The Company’s board of directors adopted, and in August 2018 Company’s stockholders approved, the 2018 employee stock purchase plan, or the 2018 ESPP. The maximum aggregate number of shares of ordinary shares that may

be purchased under the 2018 ESPP is 50,000 shares, or the ESPP Share Pool, subject to adjustment as provided for in the 2018 ESPP. The 2018 ESPP allows eligible employees to purchase shares at a 15% discount to the lower of the closing share price at the beginning and end of the six-month offering periods commencing November 1 and ending April 30 and commencing May 1 and ending October 31 of each year. The Company suspended the 2018 ESPP in April 2020.

## 9. Income Tax Expense

For the three months ended March 31, 2022, the Company recorded a tax expense of \$0.4 million. For the three months ended March 31, 2021, the Company recorded a tax expense of \$0.2 million.

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 concluded that it is more likely than not that the Company will not recognize the benefits of its deferred tax assets. On the basis of this evaluation the Company has recorded a valuation allowance against all of its deferred tax assets at March 31, 2022 and December 31, 2021.

## 10. Earnings (Loss) per Share

### Basic and Diluted Loss per Share

For the three months ended March 31, 2022 and 2021, basic and diluted net loss per share was determined by dividing net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share is the same as basic net loss per share during the periods presented as the effects of the Company's potential ordinary share equivalents are antidilutive since the Company had net losses for each period presented below.

(in thousands, except per share data)	Three Months Ended March 31,	
	2022	2021
Net loss for the period	\$ (11,819)	\$ (13,981)
Weighted average number of shares outstanding	58,794,142	26,413,590
<b>Basic and diluted loss per share</b>	<b>\$ (0.20)</b>	<b>\$ (0.53)</b>

The following ordinary share equivalents were excluded from the calculations of diluted loss per share as their effect would be anti-dilutive since the Company had net losses for each period presented below:

	Three Months Ended March 31,	
	2022	2021
Stock option awards	1,952,055	1,021,698
Restricted share units	1,163,886	502,680
Warrants	10,619,347	10,619,347

## 11. Significant Arrangements and License Agreements

### Sales Promotion and Distribution Agreement with Merck & Co.

On July 15, 2020, the Company entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with MSD International GmbH, or MSD, and Merck Sharp & Dohme Corp., or Supplier, each a subsidiary of Merck & Co., Inc. Under the Distribution Agreement and subject to the satisfaction of certain conditions, MSD appointed the Company as its sole and exclusive distributor of certain products containing tedizolid phosphate as the active ingredient previously marketed and sold by Supplier and MSD under the trademark SIVEXTRO® for injection, intravenous use and oral use, or the Products, in the United States and its territories, or the SIVEXTRO Territory. SIVEXTRO is an oxazolidinone-class antibacterial indicated in adults and pediatric patients 12 years of age and older

for the treatment of acute bacterial skin and skin structure infections caused by certain susceptible Gram-positive microorganisms. On April 12, 2021, in accordance with the terms of the Distribution Agreement, the Company began exclusive distribution of SIVEXTRO under its own National Drug Code, or NDC, and the Company recognizes 100% of net product sales of SIVEXTRO in its results of operations.

Under the Distribution Agreement and subject to the fulfillment of certain conditions, including the Company having engaged sufficient sales representatives, restrictions relating to travel and physician office access in the SIVEXTRO Territory due to COVID-19 having continued to decrease in a sufficient portion of the SIVEXTRO Territory so as not to hinder the successful detailing of SIVEXTRO, the Company has been granted the right by MSD initially to promote the Products in the SIVEXTRO Territory and, upon satisfaction of additional conditions, including an increase in sales representatives, the right to exclusively distribute the Products in the SIVEXTRO Territory, including the sole right and responsibility to fill orders with respect to the Products in the SIVEXTRO Territory. The Company successfully satisfied those conditions, including the increase in the number of sales representatives, and began filling orders of SIVEXTRO with its own Nabriva NDC beginning April 12, 2021. Subject to applicable law, the Company is entitled to determine the final selling prices of the Products charged by the Company to its customers at its sole discretion, subject to an overall annual limit on price increases, and will be solely responsible for sales contracting and all market access activities, including bidding, hospital listing and reimbursement. The Company is responsible for all costs related to the promotion, sale and distribution of the Products by the Company, as well as all costs required to meet its staffing obligations under the Distribution Agreement. The Company is obligated to use commercially reasonable efforts to promote and distribute the Products and to maximize the sales of the Products throughout the SIVEXTRO Territory. The Company has agreed to employ a sales force or retain the services of a contract sales organization to fulfill its obligations under the Distribution Agreement. The Company continues to operate a virtual and in-person sales effort with community-based expertise with Amplitude Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. The Company expanded this effort to 60 sales representatives and may expand it further. The Company also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022. On April 22, 2022, the Company agreed to an extension of the Sales Promotion and Distribution Agreement with MSD International GmbH and Merck Sharp & Dohme Corp. for exclusive distribution of SIVEXTRO® for injection, intravenous use and oral use, in the SIVEXTRO Territory through December 31, 2026. SIVEXTRO is an oxazolidinone-class antibacterial indicated in adults and pediatric patients 12 years of age and older for the treatment of ABSSSI caused by certain susceptible Gram-positive microorganisms.

Furthermore, a subsidiary of Merck will sell, and the Company has agreed to purchase, SIVEXTRO at specified prices in such quantities as the Company may specify. Although the Company is entitled, subject to applicable law, to determine the final selling prices of SIVEXTRO in its sole discretion, subject to an overall annual limit on price increases, the Company may not be able to sell SIVEXTRO at prices high enough to recoup its investment in a sales force and other commercialization activities.

### **China Region License Agreement**

In March 2018, the Company entered into the China Region License Agreement, with Sinovant Sciences, Ltd., or Sinovant, an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the China Region License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, the Company's wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin, or the China Region Licensed Products, in the People's Republic of China, Hong Kong, Macau, and Taiwan, together the Extended China Territory. In May 2021, the Company entered into an assignment, assumption and novation agreement, or the Assignment Agreement, pursuant to which the Company consented to the assignment by Sinovant, an affiliate of Roivant Sciences, Ltd., of the China Region License Agreement to develop and commercialize lefamulin in the greater China region to Sumitomo Pharmaceuticals (Suzhou), a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo. Pursuant to the Assignment Agreement, the Company agreed to release Sinovant and its affiliates from their obligations under the China Region License Agreement and consented to Sumitomo Pharmaceuticals (Suzhou)'s assumption of such obligations. In addition, Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo, has agreed to guarantee all of the obligations of Sumitomo Pharmaceuticals (Suzhou) under the China Region License Agreement.

Under the China Region License Agreement, Sumitomo Pharmaceuticals (Suzhou) and the Company's subsidiaries have established a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Extended China Territory. The China Region License Agreement includes milestone events consisting of a non-refundable \$5.0 million upfront payment, an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any China Region Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The Company has received the \$5.0 million upfront payment, a \$1.5 million payment for the submission of a clinical trial application, or CTA, by Sinovant to the Chinese Food and Drug Administration, which was received in the first quarter of 2019 and a \$5.0 million milestone payment in the third quarter of 2019 in connection with the FDA approval for lefamulin. The Company will also be eligible to receive low double-digit royalties on sales, if any, of China Region Licensed Products in the Extended China Territory. In December 2020, the Company announced the restructuring of its China Region License Agreement. The restructured agreement provided for additional manufacturing collaboration and regulatory support to be provided to the contract counterparty by the Company that is expected to help expedite the delivery of XENLETA to patients in greater China. The restructured agreement also accelerated \$3.0 million of the \$5.0 million milestone payment to the Company that was previously payable upon regulatory approval of XENLETA in China, including a non-refundable upfront payment of \$1.0 million which was received in the fourth quarter of 2020 and a \$1.0 million milestone achieved during the first quarter of 2021. During 2021, management determined that the remaining \$1.0 million milestone payment was probable of achievement and therefore the Company is recognizing the \$3.0 million of accelerated payments under the restructured agreement as collaboration revenue in the consolidated statements of operations over the estimated period the manufacturing collaboration and regulatory support will be provided to the contract counterparty, which was \$0.6 million for the three months ended March 31, 2022, based on the proportional performance of the underlying performance obligation. The remaining milestones of \$86.0 million are tied to additional regulatory approvals and annual sales targets. The future regulatory and commercial milestone payments under the China Region License Agreement will be recorded during the period the milestones become probable of achievement.

Except for the manufacturing collaboration and regulatory support discussed above, Sumitomo Pharmaceuticals (Suzhou) will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing China Region Licensed Products in the Extended China Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize China Region Licensed Products in the Extended China Territory. The Company is obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sumitomo Pharmaceuticals (Suzhou) a sufficient supply of lefamulin for Sumitomo Pharmaceuticals (Suzhou) to manufacture finished drug products for development and commercialization of the China Region Licensed Products in the Extended China Territory.

Unless earlier terminated, the China Region License Agreement will expire upon the expiration of the last royalty term for the last China Region Licensed Product in the Extended China Territory, which the Company expects will occur in 2033. Following the expiration of the last royalty term, the license granted to Sumitomo Pharmaceuticals (Suzhou) will become non-exclusive, fully-paid, royalty-free and irrevocable. The China Region License Agreement may be terminated in its entirety by Sumitomo Pharmaceuticals (Suzhou) upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the China Region License Agreement in the event of the other party's uncured material breach. Either party may also terminate the China Region License Agreement under specified circumstances relating to the other party's insolvency. The Company has the right to terminate the China Region License Agreement immediately if Sumitomo Pharmaceuticals (Suzhou) does not reach certain development milestones by certain specified dates (subject to specified cure periods). The China Region License Agreement contemplates that the Company will enter into ancillary agreements with Sumitomo Pharmaceuticals (Suzhou), including clinical and commercial supply agreements and a pharmacovigilance agreement.

### **Sunovion License Agreement**

In March 2019, the Company entered into the Sunovion License Agreement with Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, the Company's wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize certain products containing XENLETA in the forms clinically developed by us or any of our affiliates, or the Sunovion Licensed



Products, in Canada in all uses in humans in CABP and in any other indication for which the Sunovion Licensed Products have received regulatory approval in Canada. Under the Sunovion License Agreement, Sunovion and DAC established a joint development committee, or the Sunovion JDC, to review and oversee regulatory approval and commercialization plans in Canada. Sunovion will be solely responsible for all costs related to obtaining regulatory approval of and commercializing Sunovion Licensed Products in the Canada and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Canada.

On November 7, 2019, the Company, through Sunovion, submitted a New Drug Submission, or NDS. Health Canada determined there was a screening deficiency in December 2019 and a response from the Company/Sunovion was provided on December 18, 2019 and acknowledged by Health Canada on January 13, 2020. The NDS approval occurred on July 10, 2020.

The Company identified two performance obligations at inception: (1) the delivery of the exclusive license to Sunovion, which the Company has determined is a distinct license of functional intellectual property that Sunovion has obtained control of; and, (2) the participation in the Sunovion JDC. The \$1.0 million non-refundable upfront payment was allocated entirely to the delivery of the license as the Sunovion JDC deliverable was deemed to be de minimis. With the NDS approval that occurred on July 10, 2020, the Company received a regulatory milestone payment of \$0.5 million. Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestones become probable of achievement.

#### **Named Patient Program Agreement with WE Pharma Ltd.**

On June 30, 2020 the Company announced that WE Pharma Ltd., or WEP Clinical, a specialist pharmaceutical services company, had signed an exclusive agreement with the Company to supply XENLETA on a named patient or expanded access basis in certain countries outside of the US, China and Canada. The Named Patient Program, or NPP, is designed to ensure that physicians, contingent on meeting the necessary eligibility criteria and receiving approval, can request IV or oral XENLETA on behalf of patients who live in certain countries where it is not yet available and have an unmet medical need.

## **12. Commitments and Contingencies**

The Company has contractual commitments related primarily to contracts entered into with contract manufacturing organizations and contract research organizations in connection with the commercial manufacturing of XENLETA, the purchase of SIVEXTRO finished product and other research and development activities. The payments to the service providers are based on the achievement of milestones included within the agreements. Also, some of these contracts are subject to early termination clauses exercisable at the discretion of the Company.

#### **XENLETA API Supply**

On August 4, 2021, our wholly-owned subsidiary, Nabriva Therapeutics Ireland DAC, entered into an amendment, or the First Amendment, to its API Supply Agreement, or the Hovione Supply Agreement, with Hovione Limited, or Hovione, which provides for the long-term commercial supply of the active pharmaceutical ingredients, or API, for XENLETA. Under the First Amendment, Hovione agreed to cancel our May 2021 purchase order for XENLETA API, which represented our minimum purchase requirement under the Hovione Supply Agreement. In addition, pursuant to the First Amendment, Hovione agreed to reduce our annual minimum purchase requirements for XENLETA API to no minimum purchase requirement in 2021, by 50% from 2022 to 2024 and by 25% in 2025, in consideration for cash payments from us totaling €3.2 million and the right to a low single-digit royalty on total net sales of XENLETA in the United States for a period commencing on August 4, 2021 and ending on November 22, 2030, or the Royalty Term, which royalty payments shall be no greater than an aggregate of €10.0 million. If the aggregate amount of royalties payments received by Hovione under the First Amendment is less than an aggregate of €4.0 million, we are obligated to pay Hovione the difference in a lump sum payment at the end of the Royalty Term. In addition, pursuant to the First Amendment, Hovione agreed to extend the duration of the Hovione Supply Agreement from November 22, 2025 to November 22, 2030 with annual minimum purchase requirements for 2026 to 2030 at the newly agreed annual minimum purchase amount for 2025. Pursuant to the First Amendment, upon the occurrence of certain

events of insolvency for us, any unpaid minimum annual commitment amounts and royalty amounts under the agreement will become immediately due and payable.

### **Zavante Obligations**

In connection with the acquisition of Zavante in July 2018, the Company is obligated to pay up to \$97.5 million in contingent consideration to the former Zavante shareholders, of which \$25.0 million would become payable upon the first approval of a NDA from the FDA for CONTEPO for any indication, or the Approval Milestone Payment, and an aggregate of up to \$72.5 million would become payable upon the achievement of specified sales milestones, or the Net Sales Milestone Payments. The Company's shareholders have approved the issuance of the Company's ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in Company ordinary shares. The Company also has the right to settle the Net Sales Milestone Payments in Company ordinary shares, except as otherwise provided in the Merger Agreement.

The Company is obligated to pay \$3.0 million in cash upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments of up to \$26.0 million that may be settled in ordinary shares in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments of a mid-single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. Zavante will also pay a mid-single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the 21st Century Cures Act) related to a Zavante Product.

### **Litigation**

As of the date of filing this Quarterly Report on Form 10-Q, there are no material outstanding legal proceedings against the Company or its current officers or directors.

### **13. Subsequent Events**

The Company has evaluated all subsequent events through the filing date of this Form 10-Q with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of March 31, 2022, and events which occurred subsequently but were not recognized in the financial statements. There were no subsequent events which required recognition, adjustment to, or disclosure in the financial statements.

## 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 consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our historical consolidated financial statements and the related notes thereto appearing in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 29, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factor Summary" and "Risk Factors" sections of this Quarterly Report, 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 biopharmaceutical company engaged in the commercialization and research and development of novel anti-infective agents to treat serious infections. We have the commercial rights to two approved products, SIVEXTRO and XENLETA, as well as one development product candidate, CONTEPO. In August 2019, our first product was approved by the U.S. Food and Drug Administration, or FDA, and we made it available in the United States in September 2019 under the brand name XENLETA. XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic for systematic administration in humans discovered and developed by our team. XENLETA is designed to inhibit the synthesis of bacterial protein, that is required for bacteria to grow, by binding with high affinity, high specificity and at molecular targets that are different than other antibiotic classes. Based on results from two global, Phase 3 clinical trials, we believe that XENLETA is well-positioned for use as a first-line monotherapy for the treatment of community-acquired bacterial pneumonia, or CABP, due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, availability of oral and intravenous, or IV, formulations and a generally well-tolerated safety profile. We believe XENLETA represents a potentially important treatment option for the five million adults in the United States diagnosed with CABP each year.

Since inception, we have incurred significant operating losses. As of March 31, 2022 we had an accumulated deficit of \$607.5 million. To date, we have financed our operations primarily through equity offerings, convertible and term debt financings and research and development support from governmental grants and proceeds from our licensing agreements and SIVEXTRO and XENLETA product sales. We have devoted substantially all of our efforts to research and development, including clinical trials, as well as commercializing SIVEXTRO and XENLETA. Our ability to generate profits from operations and become and remain profitable depends on our ability to successfully develop and commercialize drugs that generate significant revenue.

We expect to continue to incur significant expenses and have negative cash flows for at least the next several years. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. In light of the COVID-19 pandemic, a substantial decrease of non-COVID-19 respiratory infections, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, the timing and amount of sales of SIVEXTRO, XENLETA or any product candidates are uncertain. Based on our current forecasts and plans, we will need to obtain substantial additional capital in connection with our continuing operations. Adequate additional capital may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

### Business Update Regarding COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic. The outbreak had an impact on the global economy, resulting in rapidly changing market and economic conditions. National

and local governments around the world instituted certain measures, including travel bans, prohibitions on group events and gatherings, shutdowns of certain non-essential businesses, curfews, shelter-in-place orders and recommendations to practice social distancing. The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, communities and business operations, as well as the U.S. economy and financial markets.

The extent of the impact of COVID-19 on our business will depend on the length and severity of the pandemic, including the extent there is any resurgence of the COVID-19 virus or any variant strains of the virus, the availability and effectiveness of vaccines and the impact of the foregoing on our business. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted. The full impact of COVID-19 is unknown. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, and the adoption of hybrid-remote-working policies, all of which have had, and we believe will continue to have, an impact on our consolidated results of operations, financial position and cash flows.

In response to the COVID-19 pandemic, we closed our administrative offices and shifted to a remote working business model. We have implemented a hybrid-remote-working policy for all of our employees, and we may take further actions that alter our operations as may be required by federal, state, or local authorities, or which we determine are in our best interests. The commercial and medical organizations suspended in-person interactions with physicians and customers and were restricted to conducting educational and promotional activities virtually. The impact of the COVID-19 pandemic could continue to have a material adverse effect on our business, results of operations, financial condition, liquidity and prospects in the near-term and beyond 2022. While we have used currently available information in our forecasts, the ultimate impact of the COVID-19 pandemic and our product sales for SIVEXTRO and XENLETA, on our results of operations, financial condition and cash flows is highly uncertain, and cannot currently be accurately predicted. Influenza-like illness cases are largely responsible for the seasonality observed with community-acquired bacterial pneumonia and we believe the decrease in bacterial respiratory tract infection rates, indicated by the decrease in the number of physician office visits, hospitalizations and antibiotic prescriptions, are a consequence of the public health measures that have been taken in response to the COVID-19 pandemic. Data from clinical laboratories in the United States indicated a 61% decrease in the number of specimens submitted and a 98% decrease in influenza activity as measured by percentage of submitted specimens testing positive. Our results of operations, financial condition and cash flows are dependent on future developments, including the duration of the pandemic and the related length of its impact on the global economy or any other negative trend in the U.S. or global economy and any new information that may emerge concerning the COVID-19 pandemic and the actions to contain it or treat its impact, which at the present time are highly uncertain and cannot be predicted with any accuracy.

SIVEXTRO is approved for the treatment of ABSSSIs caused by certain susceptible Gram-positive microorganisms. Before we were permitted to sell SIVEXTRO under the Distribution Agreement, we were required to secure a sales force of a certain size and the restrictions related to COVID-19 needed to be eased in a sufficient manner to permit us to promote and distribute SIVEXTRO. Re-securing a sales force of a certain size for the promotion and distribution of SIVEXTRO resulted in significant additional expense and our efforts to maintain a sales force may not be successful. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplitry Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and have engaged in-house district managers in April 2022.

XENLETA is approved for the treatment of CABP in adults in the United States. The National Institute for Allergy and Infectious Diseases, or NIAID, has identified that secondary bacterial pneumonia caused by common upper respiratory tract bacteria plays a predominant role in the cause of death in pandemic influenza. NIAID recommends that the prevention, diagnosis, prophylaxis, and treatment of secondary bacterial pneumonia, as well as the stockpiling of antibiotics and bacterial vaccines, be high priorities for pandemic planning. We believe there is a potential for XENLETA to be considered for U.S. government stockpiling for pandemic preparedness.

Two ongoing pediatric Phase 1 clinical trials for lefamulin and IV fosfomycin were temporarily closed for enrollment as hospitals suspended access and non-essential clinical research to focus on health care delivery to COVID-19 patients. As of July 2020, both trials started to re-open, where allowed by the institution, and initiated screening of potential subjects at sites.

## **Financial Operations Overview**

### ***Revenue***

In September 2019, we had our commercial launch of XENLETA and, in April 2021 we began exclusive distribution of SIVEXTRO in the United States and certain of its territories. For the three months ended March 31, 2022, we recorded \$7.2 million of SIVEXTRO product revenue, net of gross-to-net accruals and adjustments for returns, and negative \$0.2 million of XENLETA product revenue, net of gross-to-net accruals and adjustments for returns. Our distribution partners for XENLETA continue to hold inventory, with a 36 month shelf life, from the initial launch. With a near term shelf life expiration, we recorded a \$0.3 million returns reserve adjustment in the first quarter of 2022. We launched a new 10-count blister pack of XENLETA in the fourth quarter of 2021, which has a four year shelf life. Future product revenues will be generated by the amount and frequency of reorders from our wholesale customers based on the ultimate consumption patterns from the end users of SIVEXTRO and XENLETA.

Collaboration revenues for the three months ended March 31, 2022 included \$0.6 million related to the restructured China Region License Agreement, a portion of which is recognized over the estimated period the manufacturing collaboration and regulatory support will be provided to Sumitomo Pharmaceuticals (Suzhou).

Our revenues for the three months ended March 31, 2022 included governmental research premiums, collaboration revenues and the benefit of government loans at below-market interest rates.

### ***Cost of Revenues***

Cost of revenues represented 17.2% and 0.4% of our total operating expenses for the three months ended March 31, 2022 and 2021, respectively. Cost of revenues primarily represent the cost of the product itself, labor and overhead, and any reserve for excess or obsolete inventory. Other cost of revenues include costs associated with the manufacturing collaboration and regulatory support under our licensing agreements. The increase in cost of revenue for the three months ended March 31, 2022 was primarily due to the launch of SIVEXTRO under our own National Drug Code, or NDC, on April 12, 2021.

### ***Research and Development Expenses***

Research and development expenses represented 18.0% and 24.2% of our total operating expenses for the three months ended March 31, 2022 and 2021, respectively.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third-party expenses related to these programs such as expenses for manufacturing services (prior to our products receiving FDA approval, after which time these costs are capitalized in inventory until product is sold), non-clinical and clinical studies and other third party development services. Indirect expenses include salaries and related costs, including stock-based compensation, for personnel in research and development functions, infrastructure costs allocated to research and development operations, costs associated with obtaining and maintaining intellectual property associated with our research and development operations, laboratory consumables, consulting fees related to research and development activities and other overhead costs. We utilize our research and development staff and infrastructure resources across multiple programs, and many of our indirect costs historically have not been specifically attributable to a single program. Accordingly, we cannot state precisely our total indirect costs incurred on a program-by-program basis.

The following table summarizes our direct research and development expenses by program and our indirect costs.

(in thousands)	Three Months Ended March 31,	
	2022	2021
<b>Direct Costs</b>		
XENLETA	\$ 531	\$ 513
CONTEPO	95	129
Other programs and initiatives	422	358
<b>Indirect Costs</b>	2,469	2,868
<b>Total research and development expenses</b>	<b>\$ 3,517</b>	<b>\$ 3,868</b>

We expect to continue to incur research and development expenses in connection with required regulatory activities, our activities related to our ongoing pediatric studies of lefamulin for the treatment of CABP and of CONTEPO for the treatment of cUTI, and may incur costs related to the pursuit of the clinical development of lefamulin and CONTEPO for additional indications including the treatment of resistant bacterial infections in patients with cystic fibrosis and engagement in earlier stage research and development activities. It is difficult to estimate the duration and completion costs of our research and development programs.

We initiated screening of our Phase 1 clinical trial to assess the safety and pharmacokinetics of oral and intravenous XENLETA for the treatment of resistant bacterial infections in adult patients with CF in March 2022, and enrolled the first patient in April 2022. We expect to report topline results from the trial in the first half of 2023. Given the ongoing COVID-19 pandemic and the high risk it puts CF patients under, it is difficult to estimate recruitment timelines at this time.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care, and our ability to achieve market acceptance for any of our product candidates that receive marketing approval;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope, progress, costs and results of clinical trials and other research and development activities; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights and defending against any intellectual property-related claims.

A change in the outcome of any of these variables with respect to the development of our product candidates could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we have completed or currently contemplate will be required for the completion of clinical development of any product candidate, we could be required to expend significant additional resources and time on the completion of clinical development of that product candidate.

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

Selling, general and administrative expenses represented 64.9% and 75.4% of our total operating expenses for the three months ended March 31, 2022 and 2021, respectively.

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation not related to research and development activities for personnel in our finance, information technology, commercial, medical affairs and administrative functions, as well as costs related to our contract commercial organization, to provide community-based commercial and sales services. Selling, general and administrative expenses also include costs related to professional fees for auditors, lawyers and tax advisors and consulting fees not related to research and development operations, as well as functions that are partly or fully outsourced by us, such as accounting, payroll processing and information technology.

We expect selling, general and administrative expenses in 2022 to be comparable to 2021.

### **Critical Accounting Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the end of the reporting period, as well as the reported revenues and expenses during the reporting periods and how our estimates and assumptions have changed over each relevant reporting period. However, these estimates and assumptions are subject to uncertainty, due to unknown trends and events and various other factors that we believe to be reasonably likely under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies and estimates are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this filing. However, we believe that the following accounting policies and estimates are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

### **Revenue Recognition**

Under Accounting Standards Codification, or ASC, 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied as services are rendered.

The transaction price that we recognize as revenue reflects the amount we expect with the sale and transfer of control of the product to our customers. Once the customer takes control of the product, our performance obligation under the sale contract is complete and revenue is recorded net of applicable reserves for various types of variable consideration. The types of variable consideration are as follows and are further described in note 2 to our consolidated financial statements.

- Fees-for-service
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- Group Purchasing Organizations, or GPO, administration fees

- Voluntary patient assistance programs

In determining the amounts of variable consideration, we must make significant judgments and estimates. In assessing the amount of net revenue to record, we consider both the likelihood and the magnitude of the revenue reversal. Actual amounts of consideration ultimately received may differ significantly from our estimates. Factors that can impact these estimates include business related dynamics such as; the growth of the markets, and uptake of product acceptance within these markets. If actual results in the future vary from our estimates, we adjust our estimates which would affect net product revenue in the period such variances become known.

***XENLETA Inventory and Purchase Commitments***

Our XENLETA inventory is stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and consists primarily of material costs, third-party manufacturing costs and related transportation costs in our supply chain. Our inventory is subject to expiration dating, which can be extended in certain circumstances. We also have non-cancellable purchase commitments for XENLETA active pharmaceutical ingredient, or API. We continually evaluate forecasted product sales for XENLETA which is used in estimating the need to reserve for estimated excess, slow-moving and obsolete inventory on hand and potential accrued losses on firm purchase commitments. For the three months ended March 31, 2022 and 2021, we recorded \$31 thousand and \$1 thousand, respectively, of non-cash reserves for excess and obsolete inventory due to timing of expiry dating of expiring inventory. To the extent forecasted sales for XENLETA fluctuate based on the evolution of patient demand, there could be additional adjustments to reserves for inventory on hand or adjustments to purchase commitments.

**Results of Operations**

***Comparison of Three Months Ended March 31, 2022 and 2021***

(in thousands)	<b>Three Months Ended December 31,</b>		<b>Change</b>
	<b>2022</b>	<b>2021</b>	
<b>Consolidated operations data:</b>			
Product revenue, net	\$ 7,040	\$ 130	\$ 6,910
Collaboration revenue	629	2,002	(1,373)
Research premium and grant revenue	351	397	(46)
<b>Total revenues</b>	<b>8,020</b>	<b>2,529</b>	<b>5,491</b>
<b>Costs and expenses:</b>			
Cost of revenues	(3,361)	(62)	(3,299)
Research and development expenses	(3,517)	(3,868)	351
Selling, general and administrative expenses	(12,700)	(12,047)	(653)
<b>Total operating expenses</b>	<b>(19,578)</b>	<b>(15,977)</b>	<b>(3,601)</b>
<b>Loss from operations</b>	<b>(11,558)</b>	<b>(13,448)</b>	<b>1,890</b>
<b>Other income (expense):</b>			
Other income (expense), net	308	(122)	430
Interest expense, net	(215)	(221)	6
<b>Loss before income taxes</b>	<b>(11,465)</b>	<b>(13,791)</b>	<b>2,326</b>
Income tax expense	(354)	(190)	(164)
<b>Net loss</b>	<b>\$ (11,819)</b>	<b>\$ (13,981)</b>	<b>\$ 2,162</b>

*Revenues*

Revenues for the three months ended March 31, 2022 were \$8.0 million compared to \$2.5 million for the three months ended March 31, 2021. The \$5.5 million increase was primarily due to \$7.2 million in SIVEXTRO product revenue, net for the three months ended March 31, 2022, offset by a \$1.4 million decrease in collaboration revenues and a \$0.3 million decrease in XENLETA product revenue, net.



*Cost of Revenues*

Cost of revenues for the three months ended March 31, 2022 was \$3.4 million compared to \$62 thousand for the three months ended March 31, 2021. The \$3.3 million increase was primarily due to SIVEXTRO cost, which were not incurred prior to the launch of our own SIVEXTRO NDC on April 12, 2021. Cost of revenues for XENLETA primarily represents direct and indirect manufacturing costs, while cost of product sales for SIVEXTRO represent the actual purchase cost for the finished product from Merck. For the three months ended March 31, 2022 and 2021, cost of revenues include \$31 thousand and \$1 thousand, respectively, of a non-cash reserve adjustment for excess and obsolete XENLETA inventory due to timing of expiring inventory.

*Research and Development Expenses*

Research and development expenses for the three months ended March 31, 2022 were \$3.5 million compared to \$3.9 million for the three months ended March 31, 2021, which represented a 9% decrease. The \$0.4 million decrease was primarily due to a \$0.2 million decrease in research consulting fees, and a \$0.2 million decrease in research materials and purchased services.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses for the three months ended March 31, 2022 were \$12.7 million compared to \$12.0 million for the three months ended March 31, 2021, which represented a 5% increase. The \$0.7 million increase was primarily due to a \$0.4 million increase in staff costs, a \$0.2 million increase in stock-based compensation, and a \$0.1 million increase in advisory and external consultancy expenses primarily related to commercialization activities.

*Other Income (Expense), Net*

Other income (expense), net, decreased by \$0.4 million for the three months ended March 31, 2022 primarily due to remeasurements of our foreign currency account balances.

*Interest Expense, Net*

Interest expense, net was \$0.2 million for each of the three months ended March 31, 2022 and 2021.

*Income Tax Expense*

Our income tax expense for the three months ended March 31, 2022 was \$0.4 million compared to an income tax expense of \$0.2 million for the three months ended March 31, 2021.

## Liquidity and Capital Resources

Since our inception, we have incurred net losses and generated negative cash flows from our operations. To date, we have financed our operations through the sale of equity securities, convertible and term debt financings, research and development support from governmental grants and loans and proceeds from licensing agreements and XENLETA and SEVEXTRO product sales. As of March 31, 2022, we had cash and cash equivalents, restricted cash and short-term investments of \$34.0 million. We will need to obtain substantial additional funding to achieve our business objectives during the next 12 months and beyond. 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. Additionally, our inability to raise funds when needed may cause investors to lose confidence in us and raise substantial doubt about our ability to continue as a going concern, which may cause our ordinary share price to decline.

In September 2021, we entered into a purchase agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which, subject to the terms and conditions, provides that we have the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$23.0 million of our ordinary shares. In addition, under the Purchase Agreement, we agreed to issue a commitment fee of 632,474 ordinary shares, or the Commitment Shares, as consideration for Lincoln Park entering into the Purchase Agreement and for the payment of \$0.01 per Commitment Share. Under the Purchase Agreement, we may from time to time, at our discretion, direct Lincoln Park to purchase on any single business day, or a Regular Purchase, up to (i) 400,000 ordinary shares if the closing sale price of our ordinary shares is not below \$0.25 per share on Nasdaq, (ii) 600,000 ordinary shares if the closing sale price of our ordinary shares is not below \$2.00 per share on Nasdaq or (iii) 800,000 ordinary shares if the closing sale price of our ordinary shares is not below \$3.00 per share on Nasdaq. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases on the terms and subject to the conditions set forth in the Purchase Agreement. In any case, Lincoln Park's commitment in any single Regular Purchase may not exceed \$2.5 million absent a mutual agreement to increase such amount. As of March 31, 2022, we have issued and sold an aggregate of 6,000,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$4.1 million. From April 1, 2022 and through the date of this filing, we had issued and sold an aggregate of 1,200,000 ordinary shares pursuant to the Purchase Agreement and received gross proceeds of \$0.4. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$18.6 million under the Purchase Agreement, subject to the Nasdaq rules which may limit our ability to make sales of our ordinary shares to Lincoln Park in excess of a specified amount without prior shareholder approval.

In May 2021, we entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sale Agreement, with Jefferies, LLC, or Jefferies, as agent, pursuant to which we may offer and sell ordinary shares, from time to time through Jefferies, by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Upon entry into the Sale Agreement, our existing ATM agreement with Jefferies entered into in June 2019 was terminated. We did not incur any termination penalties as a result of the replacement of the prior agreement with Jefferies. As of March 31, 2022, we have issued and sold an aggregate of 19,570,971 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$31.0 million and net proceeds of \$29.8 million, after deducting commissions to Jefferies and other offering expenses. From April 1, 2022 and through the date of this filing, we have issued and sold an aggregate of 276,150 ordinary shares pursuant to the New Sale Agreement and received gross proceeds of \$118 thousand and net proceeds of \$115 thousand, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$10.5 million under the New Sale Agreement.

On December 20, 2019, we issued 1,379,310 ordinary shares and accompanying warrants to purchase up to an aggregate of 1,379,310 ordinary shares. Each share was issued and sold together with an accompanying warrant at a combined price of \$14.50 per security, that generated gross proceeds of \$20.0 million and \$18.3 million net, after deducting the placement agent's fees and offering expenses. On May 29, 2020, we issued in a registered direct offering an aggregate of 4,144,537 ordinary shares with 4,144,537 warrants at a combined price of \$9.1686 per security. The proceeds to us from the offering were \$38.0 million gross and \$35.2 million net, after deducting the placement agent's

fees and offering expenses. Each warrant was immediately exercisable and will expire on the two-year anniversary of the exercise date.

In March 2021, we entered into a securities purchase agreement with certain institutional investors pursuant to which we agreed to issue and sell in a registered direct offering (1) an aggregate of 9,761,010 ordinary shares, \$0.01 nominal value per share, and accompanying warrants to purchase up to an aggregate of 4,880,505 ordinary shares and (2) pre-funded warrants to purchase up to an aggregate of 600,000 ordinary shares and accompanying ordinary share warrants to purchase up to an aggregate of 300,000 ordinary shares. Each share was issued and sold together with an accompanying ordinary share warrant at a combined price of \$2.4525, and each pre-funded warrant was issued and sold together with an accompanying ordinary share warrant at a combined price of \$2.4425. The proceeds to us from the offering were \$25.4 million gross and \$23.4 million net after deducting the placement agent's fees and estimated offering expenses. Each pre-funded warrant had an exercise price per ordinary share equal to \$0.01 and each pre-funded warrant was exercised in full on the issuance date. Each ordinary share warrant has an exercise price per ordinary share equal to \$2.39, was exercisable on the date of issuance and will expire on the five-year anniversary of the date of issuance.

## Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (15,870)	\$ (21,626)
Investing activities	(36)	(120)
Financing activities	2,194	34,930
Effects of foreign currency translation on cash	(164)	244
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>\$ (13,876)</b>	<b>\$ 13,428</b>

### *Operating Activities*

Cash flow used in operating activities for the three months ended March 31, 2022 was \$15.9 million compared to \$21.6 million for the three months ended March 31, 2021, representing a 27% decrease. The \$5.8 million decrease was primarily due to a \$2.4 million decrease in net loss, after adjustments for the impact of non-cash amounts included in net loss in both periods, and by lower working capital of \$3.4 million primarily due to decreases in accounts receivable and lower increases in inventory offset by decreases in accounts payable, accrued expenses and other liabilities.

### *Investing Activities*

Cash flow used in investing activities was primarily for the purchase of property and equipment and was \$35 thousand and \$120 thousand for the three months ended March 31, 2022 and 2021, respectively.

### *Financing Activities*

Cash flow generated from financing activities for the three months ended March 31, 2022 was \$2.2 million from our Purchase Agreement with Lincoln Park, as well as our Sale Agreement. Cash flow generated from financing activities for the three months ended March 31, 2021 was \$34.9 million from our March 2021 financing, as well as our prior ATM agreement with Jefferies.

## Material Cash Requirements

We anticipate that our expenses will increase as we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. In addition, our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

In addition, our expenses will increase if and as we:

- initiate or continue the research and development of XENLETA and CONTEPO for additional indications and of our other product candidates;
- seek to develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- are required by the FDA, EMA or other regulators to conduct additional clinical trials prior to or after approval;
- continue to build or re-build a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize SIVEXTRO, XENLETA and any other product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies, including additional community products;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland;
- incur additional debt;
- establish and expand manufacturing arrangements with third parties; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and our operations as a public company in addition to our commercialization efforts.

As described above, on March 11, 2020, we entered into a Third Amendment to our Loan Agreement with Hercules. Pursuant to the Third Amendment, we repaid to Hercules in March 2020, \$30.0 million of the \$35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. Under the Third Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately \$2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from \$600,000 to \$300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Third Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to \$3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. On June 2, 2021, we entered into a further amendment, or the Fourth Amendment, to our Loan Agreement with Hercules. Pursuant to the Fourth Amendment, the date on which we must commence repaying principal under the Loan Agreement was extended to April 1, 2022, which date may be extended until July 1, 2022, subject to our receipt of a specified amount of additional net financing proceeds and the achievement of a specified product revenue milestone. Additionally, the time during which the Tranche Advance

(as defined in Note 6 to our consolidated financial statements) may be requested by us under the Loan Agreement was extended until the Amortization Date. In addition, pursuant to the Fourth Amendment, the minimum liquidity requirement of \$3.0 million in cash and cash equivalents will be waived at any time we have recognized \$15.0 million of net product revenue during the applicable trailing three months. Based on our current operating plans, we expect that our existing cash, cash equivalents, restricted cash and short-term investments as of the date of this Quarterly Report on Form 10-Q, together with our anticipated SIVEXTRO and XENLETA commercial sales receipts, will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, or equity or debt financings. This estimate also assumes that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

We expect to continue to invest in critical commercial promotion and distribution, medical affairs and other commercialization activities, as well as investing in our supply chain for the commercialization of SIVEXTRO, XENLETA and CONTEPO, if approved. We expect to seek additional funding in future periods to support these activities.

Our future capital requirements will depend on many factors, including:

- the costs and timing of process development and manufacturing scale-up activities associated with XENLETA and CONTEPO;
- the costs to secure supply of SIVEXTRO and costs to sell and market the product in the U.S.;
- the costs, timing and outcome of regulatory review of lefamulin in Europe and for any other indications and CONTEPO;
- the costs of commercialization activities for SIVEXTRO, XENLETA and potentially CONTEPO if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of CONTEPO, if approved;
- the commercial success of SIVEXTRO and XENLETA and the amount and frequency of reorders or product returns by our wholesale customers;
- subject to the resubmission of the CONTEPO NDA and potential receipt of marketing approval, revenue received from commercial sales of CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- the impact of the COVID-19 pandemic;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies, including additional community products;
- the costs related to the promotion, sale and distribution of the products under our distribution agreement with Merck & Co., Inc.;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the need to satisfy interest and principal obligations under our Loan Agreement with Hercules as well as the covenants contained in our Loan Agreement;
- the rate of the expansion of our physical presence in the United States and Ireland; and
- the costs of operating as a public company in the United States.

Our commercial revenues, if any, will be derived from sales of SIVEXTRO, XENLETA, and if approved, CONTEPO or any other products that we successfully develop, in-license or acquire. In addition, SIVEXTRO, XENLETA and, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, 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.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity, warrants or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Additional debt 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.

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, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

In addition, as part of our corporate strategy, we continue to evaluate business development opportunities and potential collaborations. We may further expand our product pipeline through opportunistically in licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that we would market with our commercial infrastructure, including additional community products, which could involve an acquisition of or combination or other strategic transaction with another operating business. To the extent any additional business development opportunity is consummated, our capital expenditures may increase significantly.

We have contractual commitments related primarily to contracts entered into with contract manufacturing organizations and contract research organizations in connection with the commercial manufacturing of XENLETA, the purchase of SIVEXTRO finished product and other research and development activities. The contractual commitments are further described in Note 15 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 and in Note 12 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

## **Capital Expenditures**

Capital expenditures were \$35 thousand and \$0.1 million for the three months ended March 31, 2022 and 2021, respectively. Currently, there are no material capital projects planned in 2022.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to a variety of financial risks in the ordinary course of our business: market risk, credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital given the unpredictability of financial markets. These market risks are principally limited to interest rate and foreign currency fluctuations.

### ***Market Risk***

We do not have any significant credit risk exposure to any single counterparty or any group of counterparties having similar characteristics. The credit risk on liquid funds (bank accounts, cash balances, marketable securities and term deposits) is limited because the counterparties are banks with high credit ratings from international credit rating agencies. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes.

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the euro and the British pound. Our functional currency is the U.S. dollar, but we receive payments and acquire materials, in each of these other currencies. We have not established any formal practice to manage the foreign exchange risk against our functional currency. However, we attempt to minimize our net exposure by buying or selling foreign currencies at spot rates upon receipt of new funds to facilitate committed or anticipated foreign currency transactions.

Interest rate risk may arise from short-term or long-term debt. Our outstanding indebtedness with Hercules bears interest at the greater of 9.80% and 9.80% plus the prime rate of interest minus 5.50%. Based on the current prime rate, our outstanding indebtedness with Hercules bears interest at 9.80%. If the prime rate increases to over 5.50%, the interest on our loan with Hercules will increase.

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.

### ***Liquidity Risk***

Since our inception, we have incurred net losses and generated negative cash flows from our operations. We anticipate based on our current operating plans, that our existing cash, cash equivalents, restricted cash and short-term investments as of the date of this Quarterly Report on Form 10-Q will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings.

We expect to continue to invest in critical commercial and medical affairs activities, as well as investing in our supply chain for the commercialization of SIVEXTRO, XENLETA and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

If we obtain marketing approval for CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant additional commercialization expenses related to distribution and manufacturing. Our expenses will increase if we suffer any delays in our clinical programs, including regulatory delays, or are required to conduct additional clinical trials to satisfy regulatory requirements.

There can be no assurance that we will be successful in acquiring additional capital at a level sufficient to fund our operations or on terms favorable to us. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or our commercialization efforts.

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### **Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) under the supervision and the participation of the Company's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of March 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

##### **Changes in Internal Control over Financial Reporting**

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

## **PART II**

#### **ITEM 1. LEGAL PROCEEDINGS**

None.

#### **ITEM 1A. RISK FACTORS**

*You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*



## **Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never generate profits from operations or maintain profitability.***

Since inception, we have incurred significant operating losses. Our net losses were \$11.8 million for the three months ended March 31, 2022, \$49.5 million for the year ended December 31, 2021 and \$69.5 million for the year ended December 31, 2020. As of March 31, 2022, we had an accumulated deficit of \$607.5 million. To date, we have financed our operations primarily through the sale of our equity securities, convertible and term debt financings and research and development support from governmental grants and loans and proceeds from our licensing agreements and XENLETA and SEVEXTRO product sales. We have devoted most of our efforts to research and development, including clinical trials and the commercial sale of our products. In July 2020, we entered into a Sales Promotion and Distribution Agreement, with subsidiaries of Merck Sharp & Dohme Corp. pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for acute bacterial skin and skin structure infections, or ABSSSIs, caused by certain susceptible Gram-positive microorganisms in the United States and its territories, or the SIVEXTRO Territory. XENLETA is approved in the United States for the treatment of community-acquired bacterial pneumonia, or CABP, in adults. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplify Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years, including in connection with the promotion and distribution efforts for SIVEXTRO, our regulatory approval efforts, supply chain investments and commercialization of XENLETA, and, if it receives marketing approval, the commercialization of CONTEPO. We expect to seek additional funding in future periods to support these activities. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

In addition, our expenses will increase if and as we:

- initiate or continue the research and development of XENLETA and CONTEPO for additional indications and of our other product candidates;
- seek to develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- are required by the FDA, EMA or other regulators to conduct additional clinical trials prior to or after approval;
- continue to build or re-build a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize SIVEXTRO, XENLETA and any other product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies, including additional community products;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland;
- incur additional debt;
- establish and expand manufacturing arrangements with third parties; and

- add operational, financial and management information systems and personnel, including personnel to support our product development and our operations as a public company in addition to our commercialization efforts.

Our ability to generate profits from operations, and to become and remain profitable, depends on our ability to successfully develop and commercialize drugs that generate significant revenue. Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for CONTEPO, and successfully commercialize XENLETA and, if approved, CONTEPO and successfully commercialize SIVEXTRO. In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. This restructuring intended to reduce costs and to align the capabilities of our sales effort with our strategic re-focus on making sales of XENLETA to community health care professionals. This restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of our Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplity Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022. Our ability to generate significant revenue will require us to be successful in a range of challenging activities, including:

- maintaining and expanding a community-based sales effort;
- obtaining marketing approval for CONTEPO;
- establishing and maintaining medical affairs, sales, marketing and distribution capabilities to effectively market and sell SIVEXTRO, XENLETA and CONTEPO, if approved, in the United States;
- establishing and maintaining collaboration, distribution or other marketing arrangements with third parties to commercialize XENLETA in markets outside the United States;
- protecting our rights to our intellectual property portfolio related to XENLETA and CONTEPO;
- minimizing cyber-security and similar risks, which could result in the disclosure of confidential information, disruption of our technology support systems, legal exposure and financial losses;
- assessing any material effects of climate change transition risks, such as policy and regulatory changes, which could impose operational and compliance burdens in certain jurisdictions or impact market trends;
- establishing and maintaining arrangements for the manufacture of and obtaining commercial quantities of SIVEXTRO, XENLETA and CONTEPO, if approved; and
- negotiating and securing adequate reimbursement from third-party payors for SIVEXTRO, XENLETA and CONTEPO, if approved.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to generate profits from operations. Even if we do generate profits from operations, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to generate profits from operations, and to become and remain profitable, would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, conduct commercial activities, maintain our commercial efforts or continue our operations. A decline in the value of our company could also cause our shareholders to lose all or part of their investment.

***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 March 31, 2022, we had cash and cash equivalents, restricted cash and short-term investments of \$34.0 million. Based on our available cash resources and anticipated SIVEXTRO and XENLETA commercial sales receipts, we believe we do not have sufficient cash on hand to support current operations for more than twelve months from the date of filing this Quarterly Report on Form 10-Q. This condition raises substantial doubt about our ability to continue as a going concern within one year after the date the consolidated 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 consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, we cannot guarantee that we will be able to obtain sufficient additional funding when needed or that such funding, if available, will be obtainable.

***We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect to continue to incur substantial costs in connection with our ongoing activities. These activities include the commercialization of SIVEXTRO and XENLETA, the process of obtaining marketing approval for CONTEPO and, possibly, other product candidates or additional indications for our products, and our ongoing research activities. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

Furthermore, we expect to continue to incur additional costs to service our current debt and any potential future draws on the Loan Agreement (as defined below) and costs associated with operating as a public company and as a company with a commercial rather than a research and development focus. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or eliminate our research and development programs or reduce our commercialization efforts.

On March 11, 2020, we entered into an amendment, or the Third Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Third Amendment, we repaid Hercules in March 2020, \$30.0 million of the \$35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. We determined to enter into the Third Amendment following the effectiveness of a performance covenant in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or \$40.0 million, which we refer to as the liquidity requirement. Under the Third Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately \$2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from \$600,000 to \$300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Third Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to \$3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement.

On June 2, 2021, we entered into a further amendment, or the Fourth Amendment, to our Loan Agreement with Hercules. Pursuant to the Fourth Amendment, the date on which we must commence repaying principal under the Loan Agreement was extended to April 1, 2022, which date may be extended until July 1, 2022, subject to our receipt of a specified amount of additional net financing proceeds and the achievement of a specified product revenue milestone.

Additionally, the time during which the Tranche Advance (as defined in Note 6 to our consolidated financial statements) may be requested by us under the Loan Agreement, was extended until the Amortization Date. In addition, pursuant to the Fourth Amendment, the minimum liquidity requirement of \$3.0 million in cash and cash equivalents will be waived at any time we have recognized \$15.0 million of net product revenue during the applicable trailing three months. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales are uncertain. Based on our current operating plans, we expect that our existing cash, cash equivalents, restricted cash and short-term investments as of the date of this Quarterly Report on Form 10-Q, together with our anticipated SIVEXTRO and XENLETA commercial sales receipts, will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, or equity or debt financings. This estimate also assumes that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

We expect to continue to invest in critical commercial and medical affairs activities, as well as investing in our supply chain for the commercialization of SIVEXTRO and XENLETA and the potential commercial launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

Our future capital requirements will depend on many factors, including:

- the costs and timing of process development and manufacturing scale-up activities associated with XENLETA and, if approved, CONTEPO;
- the costs, timing and outcome of regulatory review of CONTEPO;
- the costs of commercialization activities for SIVEXTRO, XENLETA and CONTEPO if we receive marketing approval for CONTEPO, including the costs and timing of establishing product sales, marketing distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of CONTEPO;
- revenue received from commercial sales of SIVEXTRO, XENLETA and, subject to the resubmission of the CONTEPO NDA and potential receipt of marketing approval, CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- the impact of the COVID-19 pandemic;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies, including additional community products;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the costs of our physical presence in the United States, Ireland and Austria;
- interest expense on our debt and the eventual repayment of our debt obligations which began in April 2022;

- the requirement to keep minimum cash balances per the terms of our debt obligations as well as our ability to remain in compliance with our debt covenants;
- the costs of operating as a company with a commercial rather than a research and development focus; and
- the costs of operating as a public company in the United States.

Our commercial revenues will be derived from sales of SIVEXTRO, XENLETA and from CONTEPO, if approved, or any other products that we successfully develop, in-license or acquire. SIVEXTRO, XENLETA or, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Additionally, the reliance on a commercial sales organization may adversely impact our sales of SIVEXTRO and XENLETA. If we fail to generate sufficient revenues from the sale of SIVEXTRO, XENLETA, or the commercialization of CONTEPO, if approved, or any other product candidate that we successfully develop, in-license or acquire, we will need to obtain substantial additional financing to achieve our business objectives.

Adequate additional financing may not be available to us on acceptable terms, or at all. Under General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the ordinary shares held by our non-affiliates. As of March 28, 2022, the aggregate market value of our ordinary shares held by our non-affiliates was approximately \$32.1 million, based on 61,197,667 ordinary shares held by non-affiliates and a price of \$0.525 per share, which was the last reported sale price of our ordinary shares on the Nasdaq Global Select Market on February 9, 2022. We therefore are limited by the Baby Shelf Rule as of the filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, until such time as our public float exceeds \$75.0 million. We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

In addition, as part of our corporate strategy, we continue to evaluate business development opportunities and potential collaborations. We may further expand our product pipeline through opportunistically in-licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that we would market with our commercial infrastructure, including additional community products, which could involve an acquisition of or combination or other strategic transaction with another operating business. To the extent any additional business development opportunity is consummated, our capital expenditures may increase significantly.

***Raising additional capital may cause dilution to our security holders, restrict our operations or require us to relinquish certain rights to our technologies, products or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our products or product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our security holders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our security holders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt service obligations under any debt financings may limit the availability of our cash for other purposes, and we may be unable to make interest payments or repay the principal of such debt financings when due.

In June 2019, we entered into an Open Market Sale Agreement<sup>SM</sup>, or the Jefferies ATM Agreement, with Jefferies, pursuant to which, from time to time, we may offer and sell ordinary shares through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended.

In May 2021, we entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sale Agreement, with Jefferies, as agent, pursuant to which we may offer and sell ordinary shares, nominal value \$0.01 per share, from time to time through Jefferies, by any method permitted that is deemed an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Upon entry into the Sale Agreement, our existing Jefferies ATM Agreement was terminated. We did not incur any termination penalties as a result of the replacement of the Jefferies ATM Agreement. As of the effective date of the termination of the Jefferies ATM Agreement, we had sold an aggregate of 5,925,699 of our ordinary shares pursuant to the Jefferies ATM Agreement for aggregate gross proceeds of \$33.7 million and net proceeds to us of \$31.9 million, after deducting commissions and offering expenses payable by us. The approximately \$16.3 million of ordinary shares that had been available for sale pursuant to the Jefferies ATM Agreement remained unsold at the time of its replacement. The replacement of the Jefferies ATM Agreement terminated any future sales of ordinary shares through the Jefferies ATM Agreement. As of March 31, 2022, we have issued and sold an aggregate of 19,570,971 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$31.0 million and net proceeds of \$29.8 million, after deducting commissions to Jefferies and other offering expenses. From April 1, 2022 and through the date of this filing, we have issued and sold an aggregate of 276,150 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$118 thousand and net proceeds of \$115 thousand, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$10.5 million under the Sale Agreement.

On December 20, 2019, we sold to certain institutional investors in a registered direct offering an aggregate of 1,379,310 ordinary shares, and accompanying warrants to purchase up to an aggregate of 1,379,310 ordinary shares. Each share was issued and sold together with an accompanying warrant at a combined price of \$14.50 per security. The proceeds to us from the offering were \$20.0 million gross and \$18.3 million net, after deducting the placement agent’s fees and other offering expenses. As of March 31, 2022, there were 1,379,310 warrants outstanding from the offering, where each warrant has an exercise price of \$19.00 per share and will expire on the date that is three years and six months after the initial issuance date.

On May 29, 2020, we entered into a securities purchase agreement with certain institutional investors, including Fidelity Management & Research Company, LLC pursuant to which we issued and sold in a registered direct offering an aggregate of 4,144,537 ordinary shares and accompanying warrants to purchase up to an aggregate of 4,144,537 ordinary shares. Each share we issued and sold together with an accompanying warrant at a combined price of \$9.1686. The proceeds to us from the offering were \$38.0 million gross and \$35.2 million net, after deducting the placement agent’s fees and other offering expenses. Each warrant was immediately exercisable and will expire on the two-year anniversary of the issuance date. As of March 31, 2022, there were 4,059,532 warrants outstanding from the offering at an exercise price of \$7.92 per share.

On March 1, 2021, we entered into a securities purchase agreement with certain institutional investors pursuant to which we issued and sold in a registered direct offering (1) an aggregate of 9,761,010 ordinary shares, \$0.01 nominal value per share, and accompanying warrants to purchase up to an aggregate of 4,880,505 ordinary shares and (2) pre-funded warrants to purchase up to an aggregate of 600,000 ordinary shares and accompanying ordinary share warrants to purchase up to an aggregate of 300,000 ordinary shares. Each share was issued and sold together with an accompanying ordinary share warrant at a combined price of \$2.4525, and each pre-funded warrant was issued and sold together with an accompanying ordinary share warrant at a combined price of \$2.4425. The proceeds to us from the offering were \$25.4 million gross and \$23.4 million net after deducting the placement agent’s fees and estimated offering expenses. Each pre-funded warrant had an exercise price per ordinary share equal to \$0.01 and each pre-funded warrant was exercised in full on the issuance date. Each ordinary share warrant has an exercise price per ordinary share equal to \$2.39, is exercisable on the date of issuance and will expire on the five-year anniversary of the date of issuance. As of March 31, 2022, there were 5,180,505 warrants outstanding from the offering at an exercise price of \$2.39 per share.

On September 24, 2021, we entered into a purchase agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which, subject to the terms and conditions, provides that we have the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$23.0 million of our ordinary shares. In addition, under the Purchase Agreement, we agreed to issue a commitment fee of 632,474 ordinary shares, or the Commitment Shares, as consideration for Lincoln Park entering into the Purchase Agreement and for the payment of \$0.01 per Commitment Share. Under the Purchase Agreement, we may from time to time, at our discretion, direct Lincoln Park to purchase on

any single business day, or a Regular Purchase, up to (i) 400,000 ordinary shares if the closing sale price of our ordinary shares is not below \$0.25 per share on Nasdaq, (ii) 600,000 ordinary shares if the closing sale price of our ordinary shares is not below \$2.00 per share on Nasdaq or (iii) 800,000 ordinary shares if the closing sale price of our ordinary shares is not below \$3.00 per share on Nasdaq. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases on the terms and subject to the conditions set forth in the Purchase Agreement. In any case, Lincoln Park's commitment in any single Regular Purchase may not exceed \$2.5 million absent a mutual agreement to increase such amount. As of March 31, 2022, we have issued and sold an aggregate of 6,000,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$4.1 million. From April 1, 2022 and through the date of this filing, we had issued and sold an aggregate of 1,200,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$0.4 million. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$18.6 million under the Purchase Agreement, subject to the Nasdaq rules which may limit our ability to make sales of our ordinary shares to Lincoln Park in excess of a specified amount without prior shareholder approval.

In addition, in connection with the closing of the acquisition of Zavante Therapeutics, Inc., or Zavante, together with its lead product candidate CONTEPO, or the Acquisition, we issued 733,690 of our ordinary shares to former Zavante stockholders as initial upfront consideration and following the one year anniversary of the closing of the Acquisition on July 25, 2019, we issued an additional 81,518 ordinary shares to the former Zavante stockholders that had been subject to reduction in respect of certain indemnification and other obligations pursuant to the Merger Agreement. Such shares are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional \$97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future, and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones. The issuance of our ordinary shares to satisfy the milestone payments will cause dilution to our security holders, and the sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our share price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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, research programs or product candidates or to 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 commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our operations to date have been limited to organizing and staffing our company, developing and securing our technology, raising capital, undertaking preclinical studies and clinical trials of our product candidates, preparing and filing NDAs for our product candidates, the commercial launch of XENLETA and the direct selling of SIVEXTRO. We have not yet demonstrated our ability to conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Also, we may encounter delays or difficulties in our efforts to, or fail to, successfully integrate CONTEPO into our business strategy. Moreover, we are in the process of transitioning from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.***

On March 11, 2020, we entered into the Amendment to the Loan Agreement pursuant to which we agreed to repay to Hercules \$30.0 million of the \$35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement. Following the Prepayment, there remains outstanding \$5.0 million in principal amount under the Loan Agreement, the end of term loan charge payment of \$2.4 million and the Prepayment fee of \$300,000, and we are eligible to request to borrow an additional \$5.0 million subject to the lender's sole discretion. We began to repay the outstanding principal amount under the Loan Agreement in April 2022.

Our obligations under the Loan Agreement are secured by substantially all of our personal property, intellectual property and other assets owned or later acquired by us and our subsidiaries. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- the need to repay our indebtedness by making payment of interest only initially and then interest and principal, which will reduce the amount of funds available to finance our operations, our research and development efforts and our general corporate activities;
- our failure to comply with the restrictive covenants in the Loan Agreement or the occurrence of an event that has a material adverse effect on our business, operations, properties, assets, condition, our ability to pay any amounts due, the collateral securing our obligations under the Loan Agreement or the ability of Hercules to enforce any of its rights under the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness and permit the lender to enforce its security interest in the assets securing such indebtedness, including the cash accounts pledged to it; and
- the need to maintain minimum cash balances under specified circumstances, which restricts our ability to invest in the business and fund our operations.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

***We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due or to comply with minimum cash balance requirements.***

Failure to satisfy our current and future debt obligations under the Loan Agreement, or the occurrence of a material adverse effect as defined in the Loan Agreement, could result in an event of default and, as a result, the lender under the Loan Agreement could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, the lender could seek to enforce their security interests in the assets securing such indebtedness.

***We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.***

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- declare dividends or redeem or repurchase equity interests;
- incur additional indebtedness and liens;



- make loans and investments;
- engage in mergers, acquisitions and asset sales;
- undertake certain transactions with affiliates
- undergo a change in control;
- add or change business locations; and
- settle in cash potential milestone payment obligations that may become payable by us in the future to former security holders of Zavante.

We are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules. Under the Third Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately \$2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from \$600,000 to \$300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Third Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to \$3.0 million in cash and cash equivalents. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. Pursuant to the Fourth Amendment, the date on which we must commence repaying principal under the Loan Agreement was extended to April 1, 2022, which date may be extended until July 1, 2022, subject to our receipt of a specified amount of additional net financing proceeds and the achievement of a specified product revenue milestone. Additionally, the time during which the Tranche Advance (as defined in Note 6 to our consolidated financial statements) may be requested by us under the Loan Agreement was extended until the Amortization Date. In addition, pursuant to the Fourth Amendment, the minimum liquidity requirement of \$3.0 million in cash and cash equivalents will be waived at any time we have recognized \$15.0 million of net product revenue during the applicable trailing three months.

These restrictive covenants may prevent us from undertaking an action that we feel is in the best interests of our business. In addition, if we were to breach any of these restrictive covenants, or if a material adverse effect as defined under the Loan Agreement occurs, Hercules could accelerate our indebtedness under the Loan Agreement or enforce its security interest against our assets, either of which would materially adversely affect our ability to continue to operate our business.

***We have relied on, and expect to continue to rely on, certain government grants and funding from the Austrian government. Should these funds cease to be available, or our eligibility be reduced, or if we are required to repay any of these funds, this could impact our ongoing need for funding and the timeframes within which we currently expect additional funding will be required.***

As a company that carried out extensive research and development activities, we have benefited from the Austrian research and development support regime, under which we were eligible to receive a research premium from the Austrian government equal to 14% (12% for the fiscal years 2016 and 2017 and 10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprised research and development activities conducted in Austria, however, the research premium was also available for certain related third-party expenses with additional limitations. We received research premiums of \$1.4 million for the year ended December 31, 2020 and \$1.3 million for the year ended December 31, 2019. We have not received any research premium for our qualified 2022 and 2021 expenditures as of March 31, 2022. As we expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years or at all, as some research and development activities may no longer be considered to occur in Austria. As research premiums that have been paid out already may be audited by the tax authorities, there is a risk that parts of the submitted cost base may not be considered as eligible and therefore repayments may have to be made.

***The intended efficiency of our corporate structure depends on the application of the tax laws and regulations in the countries where we operate, and we may have exposure to additional tax liabilities or our effective tax rate could change, which could have a material impact on our results of operations and financial position.***

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. We have designed our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our subsidiaries in a way that is intended to enhance our operational and financial efficiency. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If, for one or more of these reasons, tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

A change in the tax law in the jurisdictions in which we do business, including an increase in tax rates, an adverse change in the treatment of an item of income or expense, a decrease in tax rates in a jurisdiction in which we have significant deferred tax assets, or a new or different interpretation of applicable tax law could result in a material increase in tax expense.

### **Risks Related to Product Development and Commercialization**

***Business interruptions resulting from the SARS-CoV-2 infection causing COVID-19 outbreak or similar public health crises have caused a disruption of the development of our product candidates and adversely impacted our business.***

Our business, operations and financial condition and results have been and may continue to be impacted by the COVID-19 pandemic to varying degrees. The pandemic has presented a number of risks and challenges for our business, including, among others:

- impacts due to travel limitations and mobility restrictions;
- manufacturing disruptions and delays, supply chain disruptions and shortages, including challenges related to reliance on third-party suppliers resulting in reduced availability of materials or components used in the development, manufacturing, distribution or administration of our products;
- disruptions to pipeline development and clinical trials, including difficulties or delays in enrolling certain clinical trials, retaining clinical trial participants, accessing needed supplies, and accruing a sufficient number of cases in certain clinical trials;
- decreased product demand, due to reduced numbers of in-person meetings with prescribers, patient visits with physicians, resulting in fewer new prescriptions;
- costs associated with the COVID-19 pandemic, including practices intended to reduce the risk of transmission, increased supply chain costs challenges related to our business development initiatives, including potential delays or disruptions related to regulatory approvals;
- interruptions or delays in the operations of regulatory authorities, which has delayed potential approval of new products we are developing;
- challenges operating in a virtual work environment;
- increased cyber incidents such as phishing, social engineering and malware attacks;

- challenges related to our intellectual property, both domestically and internationally, including in response to any pressure or legal or regulatory action that could potentially result in us not seeking intellectual property protection for, licensing, or agreeing not to enforce or being restricted from enforcing, intellectual property rights related to our products challenges related to conducting oversight and monitoring of regulated activities in a remote or virtual environment;
- challenges related to our human capital and talent development, including challenges in attracting, hiring and retaining highly skilled and diverse workforce;
- challenges related to vaccine mandates and other challenges presented by disruptions to our normal operations in response to the pandemic, as well as uncertainties regarding the duration and severity of the pandemic and its impacts, and government or regulatory actions to contain the virus or control the supply of medicines.

The effects of COVID-19 pandemic also disrupted the FDA's review of our NDA for CONTEPO. On March 10, 2020, the FDA announced that it would restrict travel of its employees to Europe for inspections as a result of the spread of COVID-19. On June 19, 2020 we received a CRL for CONTEPO in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cited observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of our NDA for CONTEPO for the treatment of cUTIs, including AP.

Additionally, certain of the activities of our former collaborator, Sinovant, were delayed in China. If these delays continue and impact Sumitomo Pharmaceuticals (Suzhou)'s, Sinovant's successor, efforts to develop and commercialize lefamulin in China, our receipt of future milestone payments or potential royalties on sales of the China Region Licensed Products may be delayed. Also, the spread of COVID-19 may affect the ability of our third-party manufacturers to supply XENLETA, CONTEPO or any future product candidates. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplify Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022.

Further, the COVID-19 pandemic, and the volatile global economic conditions stemming from the pandemic, could precipitate or amplify the other risks that we identify in this Risk Factors section, which could adversely affect our business, operations and financial condition and results. We are continuing to monitor the latest developments regarding the COVID-19 pandemic and its effects on our business, operations and financial condition and results, and have made certain assumptions regarding the COVID-19 pandemic for purposes of our operational planning and financial projections, including assumptions regarding the duration, severity and the global macroeconomic impact of the pandemic. Despite careful tracking and planning, we are unable to accurately predict the extent of the impact of the pandemic on our business, operations and financial condition and results due to the uncertainty of future developments. In particular, we believe the ultimate impact on our business, operations and financial condition and results will be affected by the speed and extent of the continued spread of the coronavirus globally, the emergence of additional virus variants, the duration of the pandemic, new information regarding the severity and incidence of COVID-19, the safety, efficacy and availability of vaccines and treatments for COVID-19, the rate at which the population becomes vaccinated against COVID-19, the global macroeconomic impact of the pandemic and governmental or regulatory actions to contain the virus or control supply of medicines and vaccines. The pandemic may also affect our business, operations or financial condition and results in a manner that is not presently known to us or that we currently do not consider as presenting significant risks. The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our ordinary share price and trading in our ordinary shares.

***In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort.***

In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. This restructuring reduced costs to align the capabilities of our sales efforts with our strategic re-focus on making sales of XENLETA to community health care professionals. This restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of our Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplify Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022.

***We depend heavily on the success of SIVEXTRO, approved by the FDA for oral and IV use of adults and adolescents for the treatment of ABSSSI, XENLETA, which the FDA has approved for oral and IV use for the treatment of CABP, and CONTEPO, which we are developing for the treatment of cUTI, including AP. If we are unable to obtain marketing approval for CONTEPO, or if we fail in our commercialization efforts for SIVEXTRO, XENLETA or, if approved, CONTEPO, or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the development of XENLETA and, more recently, in CONTEPO. There remains a significant risk that we will fail to successfully develop CONTEPO for cUTI or any other indication and that we may fail to successfully commercialize XENLETA for CABP and SIVEXTRO for ABSSSI.

On August 19, 2019, the FDA approved the oral and IV formulations of XENLETA. On July 28, 2020, the European Commission issued a legally binding decision for approval of the marketing authorization application for XENLETA for the treatment of CAP in adults following a review by the EMA. In July 2020, Sunovion Pharmaceuticals Canada Inc. additionally received approval from Health Canada to market oral and IV formulations of XENLETA for the treatment of CAP in adults, upon receipt of the Notice of Compliance from Health Canada. In mid-2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of IV XENLETA in pediatric subjects from birth to 18 years of age. As a result of COVID-19, research sites were temporarily closed for enrollment in 2020 and 2021 as hospitals suspended access and non-essential clinical research to focus on health care delivery to COVID-19 patients. As of July 2020, trials started to re-open, where allowed by the institution, and initiated screening of potential subjects at sites.

In June 2016, Zavante initiated the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. In April 2019, the FDA issued a CRL in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. In December 2019, we resubmitted our NDA for CONTEPO for the treatment of cUTIs, including AP. On June 19, 2020 we received a second CRL from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cited observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. On October 30, 2020, we participated in a "Type A" meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including our NDA for CONTEPO. On April 14, 2021, the FDA issued industry guidance on remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities during COVID-19 specifying that when it cannot perform a PAI or PLI or when the FDA determines that it would be useful to supplement a planned inspection, the agency will consider using tools other than a physical inspection and select the most appropriate method to address the specific risks that justify the need for the PAI or PLI. The FDA informed us that onsite inspections of our manufacturing partners in Europe are required in order for the FDA to complete the review of a potential CONTEPO NDA resubmission. Due to travel restriction related to the COVID-19

pandemic, the FDA suspended onsite inspections of ex-US manufacturers for all non-COVID products. As a result, we requested an extension of the timeline for a potential CONTEPO NDA resubmission until June 2023, which the FDA granted on March 21, 2022. We are awaiting further clarity from the FDA regarding their ability to complete onsite inspections at our manufacturing partners in Italy and Spain before determining specific timing of the potential NDA resubmission, which we plan to submit promptly once we have clarity from the FDA. The FDA released the Resiliency Roadmap for FDA Inspectional Oversight that describes the systematic approach that FDA will utilize to manage postponed inspections and other oversight activities. The prioritization plan considers public health risks related to conducting an inspection, such as the impact of the product's availability on public health, as well as investigator safety and travel restrictions/advisories. In addition, the FDA informed us that, while they cannot predict when an inspection may occur and when the pandemic may prevent the FDA from completing inspections, tier 1 mission-critical inspections and tier 2 higher priority inspections, which includes PAIs, will continue to be prioritized going forward. We cannot predict the outcome of any further interactions with the FDA or when CONTEPO will receive marketing approval, if at all.

In June 2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. A total of 24 patients are expected to be enrolled at up to ten clinical sites in the United States. As a result of COVID-19, research sites were temporarily closed in 2020 and 2021 and only a minority of sites are currently screening patients and allowing access to the institution. As a result, our development timeline for CONTEPO for use in pediatric patients with cUTIs has been modified to reflect a two-year delay due to COVID-19.

In July 2020, we entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for ABSSSIs, caused by certain susceptible Gram-positive microorganisms in the SIVEXTRO Territory.

We expect to incur significant additional sales, marketing, distribution and manufacturing expenses for the commercialization of SIVEXTRO, XENLETA and CONTEPO, if approved. We expect to continue to invest in critical commercial promotion and distribution, medical affairs and other commercialization activities, as well as investing in our supply chain for the commercialization of SIVEXTRO, XENLETA and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of SIVEXTRO and XENLETA and our obtaining marketing approval for CONTEPO. The success of SIVEXTRO, XENLETA and, if approved, CONTEPO will depend on a number of factors, including the following:

- establishing and maintaining arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- the resubmission of our NDA for CONTEPO and potential receipt of marketing approval from the FDA for CONTEPO for the treatment of cUTI, including AP;
- re-establishing an effective sales and marketing organization to successfully generate recurring sales of SIVEXTRO, XENLETA and, if and when approved, CONTEPO;
- acceptance of SIVEXTRO, XENLETA and, if and when approved, CONTEPO by patients, the medical community and third-party payors, including hospital formularies;
- achieving approval of favorable prescribing information;
- effectively competing with other therapies;

- the continued acceptable safety profile of SIVEXTRO, XENLETA and, if approved, CONTEPO;
- securing contracts to allow SIVEXTRO, XENLETA and, if approved, CONTEPO to be paid for by private and public health insurance plans;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio;
- obtaining and maintaining adequate distribution levels of SIVEXTRO, XENLETA and, if approved, CONTEPO at all appropriate trade channels; and
- resolution of the COVID-19 pandemic.

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

***SIVEXTRO, XENLETA and any other product candidate that receives marketing approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for such products and product candidates, if approved, may be smaller than we estimate.***

SIVEXTRO, XENLETA and any other product candidate that receives marketing approval may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for ABSSI, CABP and cUTI, including generic options, are well established in the medical community, and doctors may continue to rely on these treatments without SIVEXTRO, XENLETA, CONTEPO or any of our other product candidates that receive marketing authorization. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of SIVEXTRO, XENLETA, CONTEPO or any of our other product candidates that receive marketing authorization to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for SIVEXTRO, XENLETA, CONTEPO or any of our other product candidates that receive marketing authorization may fail or may be less successful than we expect. If SIVEXTRO, XENLETA, CONTEPO or any of our other product candidates that receive marketing authorization do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of our products and product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the ability of SIVEXTRO, XENLETA, CONTEPO or any other anti-infective product candidate to limit the development of bacterial resistance in the pathogens it targets;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices, including in comparison to generic competition;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies, physicians to prescribe these therapies and hospitals to approve the cost and use by their physicians of these therapies;

- our investment in and the strength of sales, marketing, patient access and distribution capabilities;
- the availability of third-party coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other approvals of competitive products; and
- obtaining and maintaining adequate distribution of our products to the appropriate trade channels.

Bacteria might develop resistance to SIVEXTRO, XENLETA, CONTEPO or any future product candidates more rapidly or to a greater degree than we anticipate. If bacteria develop resistance or if SIVEXTRO, XENLETA, CONTEPO or any future product candidates is not effective against drug-resistant bacteria, the efficacy of these products or product candidates would decline, which would negatively affect our potential to generate revenues from these products and product candidates.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the EU and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. If the level of reimbursement is below our expectations, our revenue and gross margins would be adversely affected.

Hospital formulary approval of SIVEXTRO, XENLETA, CONTEPO or any future product candidates that receive marketing authorization is an important component of our commercialization strategy. Accordingly, sales of IV formulations of SIVEXTRO, XENLETA, CONTEPO or any future IV product candidates will depend substantially on the extent to which hospital formulary approval is obtained. Hospital formulary approval may depend upon several factors, including the determination that use of a product is:

- safe, effective and medically necessary;
- appropriate for the specific patient population;
- cost-effective; and
- neither experimental nor investigational.

Obtaining formulary approval from third-party payors can be an expensive and time-consuming process that will require us to provide supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to hospital formulary approval. We cannot be certain if and when we will obtain hospital formulary approval to allow us to sell SIVEXTRO, XENLETA, if approved, CONTEPO or any future product candidates that receive marketing authorization into our target markets. Even if we do obtain hospital formulary approval, third-party payors, such as government or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Increasing efforts by hospitals in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit formulary approval. We have experienced and expect to continue to experience pricing pressures in connection with the sale of XENLETA in the hospital setting due to the trend toward reducing hospital costs, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other similar developments could significantly limit the degree of market acceptance of SIVEXTRO, XENLETA, CONTEPO or any of our other product candidates that receive marketing approval. To address this uncertainty, in early 2020 we began to utilize our hospital based sales force to call upon approximately 7,800 high prescriber community doctors in an effort to potentially increase our penetration rates in the community setting while maintaining sales efforts in the hospital setting before determining to terminate our entire sales force. This effort ceased with the termination of our entire hospital-based sales force in April 2020. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. We continue to operate a virtual and in-person sales effort

with community-based expertise with Amplify Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022.

***If we are unable to establish or maintain sales, marketing and distribution capabilities or enter into or maintain sales, marketing and distribution agreements with third parties, we may not be successful in commercializing SIVEXTRO, XENLETA, CONTEPO or any other product candidate if and when they are approved.***

We have a limited sales, marketing, patient access and distribution infrastructure, and as a company we have limited experience in the sale, marketing or distribution of pharmaceutical products and XENLETA is the first product that we are commercializing. To achieve commercial success for SIVEXTRO, XENLETA and any other approved product, we must re-establish and maintain an adequate sales, marketing, commercial operations, patient access and distribution organization or outsource these functions to third parties. We continue to operate a virtual and in-person sales effort with community-based expertise with Amplify Health, which is a contract sales organization, with a small and focused sales effort for SIVEXTRO and XENLETA. We expanded this effort to 60 sales representatives and may expand it further. We also piloted a virtual promotion effort with incremental sales representatives in the third quarter of 2021 and has engaged in-house district managers in April 2022. In addition, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize XENLETA in markets outside the United States. We plan to commercialize CONTEPO, if approved, in the United States with targeted sales efforts, but we do not have the right to commercialize CONTEPO in any markets outside the United States.

There are risks involved with establishing our own sales, marketing, commercial operations, patient access and distribution capabilities and entering into arrangements with third parties to perform these services. If we do not establish adequate sales, marketing, commercial operations, patient access and distribution capabilities prior to or in connection with the commercial launch of any of our products, such products may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community and may fail commercially or be less successful than we expect. If the commercial launch of a product candidate for which we establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales, patient access, commercial operations and marketing personnel;
- our inability to recruit, train and retain adequate numbers of effective headquarter and field personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe SIVEXTRO, XENLETA or any future products;
- the lack of complementary products to be offered by sales personnel, which may put our sales representatives at a competitive disadvantage relative to sales representatives from companies with more extensive product lines;
- the COVID-19 pandemic;
- unforeseen costs and expenses associated with creating an independent sales, marketing, commercial operations, patient access and distribution organization; and
- a change in strategy resulting in the decrease or elimination of sales personnel.



If we enter into arrangements with third parties to perform sales, marketing, commercial operations, patient access and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market, sell and distribute ourselves any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little 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. If we do not re-establish and maintain sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing SIVEXTRO, XENLETA, or, if approved, CONTEPO.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to SIVEXTRO, XENLETA, CONTEPO and any other products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a variety of available therapies marketed for the treatment of ABSSSI, CABP and cUTI. Currently the treatment of ABSSSI, CABP and cUTI is dominated by generic products. For both hospitalized and community patients, combination therapy is frequently used for CABP and at times for cUTI. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients, medical association guidelines and third-party payors for the treatment of CABP and ABSSSI. We also are aware of various drugs under development or recently approved by the FDA for the treatment of CABP and ABSSSI, including omadacycline (Nuzyra approved by the FDA in October 2018 on behalf of Paratek Pharmaceuticals Inc. for both CABP and ABSSSI), delafloxacin (Baxdela approved by the FDA for ABSSSI in June 2017 and expanded for CABP in October 2019 on behalf of Melinta Therapeutics Inc.), and oral nafithromycin (Phase 2 clinical development by Wockhardt Ltd. for CABP). If approved, we expect CONTEPO will face competition from commercially available branded antibiotics for the treatment of UTI such as ceftazidime-avibactam (Avycaz), meropenem-vaborbactam (vabomere), plazomicin (Zemdri), ceftolozane-tazobactam (Zerbaxa), as well as imipenem-cilastatin-relebactam (Recarbrio approved by the FDA in July 2019 on behalf of Merck & Co., Inc.), cefiderocol (Fetroja approved by the FDA in November 2019 on behalf of Shionogi Inc.), or drugs under development such as tebipenem HBr (NDA to FDA for the Treatment of Complicated Urinary Tract Infections including Pyelonephritis in October 2021– Spero Therapeutics), cefepime-taniborbactam (under Phase 3 clinical development by Venatorx Pharmaceuticals), cefepime-enmetazobactam (under Phase 3 clinical development by Allegra Therapeutics), ETX0282-cefpodoxime proxetil (under Phase 1 clinical development by Entasis Therapeutics), sulopenem (under development by Iterum Therapeutics), and BOS-228 (under development by Boston Pharmaceuticals), as well as generically available agents including piperacillin-tazobactam, fluoroquinolones, carbapenems, aminoglycosides, tigecycline, and polymyxins.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors may also obtain marketing approvals for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers. We expect that SIVEXTRO, XENLETA and, if approved, CONTEPO will be priced at a significant premium over competitive generic products. This pricing difference may make it difficult for us to replace existing therapies with SIVEXTRO, XENLETA and CONTEPO. The key competitive factors affecting the success of our products and product candidates are likely to be their efficacy, safety, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approvals from regulatory authorities 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 and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs.

***Even if we are able to successfully commercialize SIVEXTRO, XENLETA, CONTEPO or any other product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products, including XENLETA, vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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, and negatively impact the revenues 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.

Our ability to commercialize SIVEXTRO, XENLETA, CONTEPO or any other product candidate successfully also will depend in part on its availability on hospital formularies and the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A major trend in the healthcare industries in the European Union and the United States and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for SIVEXTRO, XENLETA, CONTEPO or any other product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for SIVEXTRO, XENLETA and CONTEPO may be particularly difficult because of the number of generic drugs, which are typically available at lower prices, that are available to treat ABSSSI, CABP and cUTI. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug, such as SIVEXTRO, XENLETA and CONTEPO. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize SIVEXTRO, XENLETA, CONTEPO or other product candidates for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and particularly in the hospital, coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In

the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products 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.

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and to limit commercialization of SIVEXTRO, XENLETA and any other products that we may develop or in-license.***

We face an inherent risk of product liability exposure related to the testing of XENLETA, CONTEPO and any other product candidate that we develop in human clinical trials and an even greater risk related to the commercial sale of SIVEXTRO, XENLETA and any other products that we may develop or in-license. If we cannot successfully defend ourselves against claims that SIVEXTRO, XENLETA or our other product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for SIVEXTRO, XENLETA, or any other product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We maintain clinical trial liability insurance that covers bodily injury to patients participating in our clinical trials up to a \$10.0 million annual aggregate limit and subject to a per event deductible. This amount of insurance may not be adequate to cover all liabilities that we may incur. We maintain \$10.0 million in product liability insurance coverage for our marketed products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program and a number of other federal and state government pricing programs in the United States in order to obtain coverage for SIVEXTRO and XENLETA by certain government healthcare programs. These programs generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

***If clinical trials of XENLETA, CONTEPO or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, regulatory authorities in the European Union, or other 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 XENLETA, CONTEPO or any other product candidate.***

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and early clinical trials, including Phase 1 clinical trials, in addition to extensive later-stage Phase 3 clinical trials, to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In connection with the ZEUS Study in which CONTEPO met the primary endpoint of statistical non-inferiority versus piperacillin/tazobactam, Zavante conducted a post-hoc primary efficacy analysis of CONTEPO using results of blinded pulsed-field gel electrophoresis molecular typing of urinary tract pathogens. Regulatory authorities typically give greater weight to results from pre-specified analyses and less weight to results from post-hoc, retrospective analyses. While we believe this post-hoc analysis is illustrative information, the FDA may ultimately have a different interpretation of any of our data that may be based on such post-hoc analysis, or the FDA may conduct its own analyses and modify analysis populations which could lead to different numerical results or conclusions.

If we are required to conduct additional clinical trials or other testing or studies of XENLETA, CONTEPO or any other product candidate that we develop beyond those that we contemplate; if we are unable to successfully complete our clinical trials or other testing or studies; if the results of these trials, tests or studies are not positive or are only modestly positive; if there are safety concerns; or if they are otherwise not acceptable to the FDA, we may:

- 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 safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements or restrictions;
- have the product removed from the market after obtaining marketing approval;
- be unable to obtain reimbursement for use of the product; or
- need to raise capital before we otherwise would or on terms less favorable to us.

The occurrence of any of the developments listed above could materially harm our business, financial condition, results of operations and prospects.

***If we experience any of a number of possible unforeseen events in connection with our clinical trials, the potential marketing approval or commercialization of XENLETA, CONTEPO or other product candidates could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, our clinical trials of XENLETA and CONTEPO or other product candidates that could delay or prevent our ability to receive marketing approval or commercialize XENLETA, CONTEPO or our other product candidates, including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health or safety risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- 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;
- ongoing or future restrictions resulting from the COVID-19 pandemic and its collateral consequences may result in internal and external operational delays and limitations; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the trials.

Our product development costs will increase if we experience delays in enrollment in our clinical development program or our non-clinical development program or in obtaining marketing approvals. We do not know whether any additional non-clinical tests or clinical trials will be required, or if they will begin as planned, or if they will need to be restructured or will be completed on schedule, or at all. Significant non-clinical development program delays, including chemistry, manufacturing and control activities, or 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 and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates, including with respect to XENLETA, CONTEPO 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 these clinical trials, including our Phase 1 clinical trial of IV XENLETA in pediatric patients. In addition, the COVID-19 pandemic has resulted in enrollment temporary and long-term suspension globally for many clinical trials. For example, research sites were temporarily closed for enrollment for a large part of 2020, and in part of 2021 for our clinical trial to evaluate CONTEPO for use in pediatric patients with cUTIs.. Some of our competitors have ongoing clinical trials for product candidates that could be competitive with XENLETA and CONTEPO, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- approval of other therapies to treat the disease under investigation;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the time of year in which the trial is initiated or conducted;
- the geographic distribution of global trial sites;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- delays in the receipt of required regulatory approvals, or the failure to receive required regulatory approvals, in the jurisdictions in which clinical trials are expected to be conducted;
- restrictions resulting from the COVID-19 pandemic and its collateral consequences;
- willingness of potential patients to participate in our trials; and
- delays in the receipt of approvals, or the failure to receive approvals, from the relevant institutional review board or ethics committee at clinical trial sites.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

***If serious adverse or undesirable side effects are identified in SIVEXTRO, XENLETA, or CONTEPO or any other product candidate that we develop or following their approval and commercialization, we may need to modify, abandon or limit our development or marketing of that product or product candidate.***

It is impossible to predict when or if the FDA, EMA or other regulators will view any of our product candidates as effective and safe in humans or if we will receive marketing approval for any of our product candidates, and it is impossible to ensure that safety or efficacy issues will not arise following the marketing approval. If our products or product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their marketing or development or limit marketing or development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Similarly, if we are not able to comply with post-approval regulatory requirements, including safety requirements, with respect to XENLETA or any other approved product that we may develop, we could have the marketing approvals for such products withdrawn by regulatory authorities. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound.

In the ZEUS Study, the incidence of premature discontinuation from study drug was low and similar between treatment groups (6.0% in the CONTEPO treatment group compared to 3.9% in the PIP-TAZ treatment group), and the incidence of not completing the study through the last follow-up visit, which occurred on the 24th through 28th day after completion of seven days of treatment with the study drug, or after up to 14 days of treatment for patients with concurrent bacteremia, was 5.2% in the CONTEPO group compared to 0.9% in the PIP-TAZ group. A total of 42.1% CONTEPO patients and 32.0% PIP-TAZ patients experienced at least one treatment-emergent adverse event. Most treatment-emergent adverse events were mild or moderate in severity, and severe TEAEs were uncommon (2.1% of CONTEPO patients and 1.7% of PIP-TAZ patients). The most common TEAEs in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. TEAEs were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and one TEAE in each treatment group was deemed related to study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient), leading to study drug discontinuation in the PIP-TAZ patient. Study drug discontinuations due to the TEAEs were infrequent and similar between treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

The most common laboratory abnormality treatment-emergent adverse events in the ZEUS Study were increases in the levels of alanine aminotransferase, or ALT, (8.6% of CONTEPO patients and 2.6% of PIP-TAZ patients) and aspartate transaminase, or AST, (7.3% of CONTEPO patients and 2.6% of PIP-TAZ patients). None of the ALT or AST elevations were symptomatic or treatment-limiting, and none of the patients met the criteria for Hy's Law. Outside the United States, elevated liver aminotransferases are listed among undesirable effects in the labeling for IV fosfomycin.

In the ZEUS Study, hypokalemia occurred in 71 of 232 (30.6%) CONTEPO patients and 29 of 230 (12.6%) PIP-TAZ patients. Most decreases in potassium levels were mild to moderate in severity. Shifts in potassium levels from normal at baseline to hypokalemia, as determined by worst post-baseline hypokalemia values, were more frequent in the CONTEPO group than the PIP-TAZ group for mild (17.7% compared to 11.3%), moderate (11.2% compared to 0.9%), and severe (1.7% compared to 0.4%) categories of hypokalemia. Hypokalemia was deemed a treatment-emergent adverse event in 6.4% of patients receiving CONTEPO and 1.3% of patients receiving PIP-TAZ, and all cases were transient and asymptomatic.

While no significant cardiac adverse events were observed in the ZEUS Study, post-baseline QT intervals calculated using Fridericia's formula, or QTcF, of greater than 450 to less than or equal to 480 msec (baseline QTcF of less than or equal to 450 msec) occurred at a higher frequency in CONTEPO patients (7.3%) compared to PIP-TAZ patients (2.5%). In the CONTEPO arm, these results appeared to be associated with the hypokalemia associated with the salt load of the IV formulation. Only one patient in the PIP-TAZ arm had a baseline QTcF of less than or equal to 500 msec and a post-baseline QTcF of greater than 500 msec.

If we elect or are forced to suspend or terminate any clinical trial of XENLETA, CONTEPO or any other product candidates that we are developing, the commercial prospects of XENLETA, CONTEPO or such other product candidates will be harmed and our ability to generate product revenues from XENLETA, CONTEPO or any of these other product candidates will be delayed or eliminated. In addition, a higher rate of adverse events in XENLETA or CONTEPO as compared to the standard of care, even if slight, could negatively impact commercial adoption of XENLETA or CONTEPO by physicians. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

#### **Risks Related to Our Dependence on Third Parties**

***Use of third parties to manufacture our product candidates or products may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not own or operate manufacturing facilities for the production of XENLETA or CONTEPO that could be used in product candidate development, including clinical trial supply, or for commercial supply, or for the supply of any other compound that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities and facilities to manufacture any of our product candidates or products on a clinical or commercial scale. We currently rely on third parties for supply of XENLETA and CONTEPO, and our strategy is to outsource all manufacturing, packaging, testing, serialization and distribution of our product candidates and products to third parties. We also procure supply of SIVEXTRO from Merck & Co., Inc.

We have entered into agreements, and expect to enter into additional agreements, with third-party manufacturers for the long-term commercial supply of XENLETA and CONTEPO. For example, prior to June 2015, we obtained the pleuromutilin starting material for the clinical trial supply of XENLETA from a single third-party manufacturer, Sandoz GmbH, or Sandoz, a division of Novartis AG, or Novartis. We were required to identify and enter into a commercial supply agreement with an alternative supplier that provides pleuromutilin starting material for the commercial supply of XENLETA as a result of Novartis discontinuing its manufacture of pleuromutilin starting material.

Another third-party manufacturer synthesizes XENLETA starting from pleuromutilin and a readily accessible chiral building block and provides our supply of the active pharmaceutical ingredient, or API. We have initiated engagement with a potential secondary supplier to synthesize XENLETA, with a preliminary technology transfer and pilot scale manufacture. However, our current operating plans do not include completing technology transfer, scale-up and validation of this potential secondary supplier until they have demonstrated that they can successfully manufacture the API at pilot scale and until we obtain additional funding. We engage separate manufacturers to provide tablets, sterile vials, and sterile diluent that we are using in our clinical trials of XENLETA. We have entered into commercial supply agreements with these same manufacturers to support the commercialization of XENLETA in the United States and, if approved outside of the United States, to support future demand outside of the United States. We also entered into a long-term commercial supply agreement with Arran Chemical Company Limited, or Arran, for the supply of the chiral acid starting material required in the synthesis of XENLETA API and a commercial packaging and supply agreement with Sharp Corporation for the secondary packaging of XENLETA for distribution in the United States.

In addition, we have entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to us, on an exclusive basis, the API mixture for CONTEPO in support of our NDA filing and, if CONTEPO is approved, will supply the commercial API mixture for CONTEPO in the United States. We have also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply us with certain technical documentation and data as required for our NDA filing for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, if approved. We entered into a commercial packaging agreement with AndersonBrecon, Inc. for the commercial packaging and serialization of CONTEPO. Alternatively, we have engaged Sharp Corporation for the secondary packaging and serialization of CONTEPO completed under our existing commercial packaging and supply agreement with Sharp Corporation. We also entered into a manufacturing and supply agreement with Fisiopharma S.r.l.,



or Fisiopharma, for the supply, on a minimum commitment basis, of a percentage of our commercial requirements of CONTEPO in bulk drug vials for the United States as well as the supply of bulk drug vials of CONTEPO in connection with the submission of an NDA.

We may be unable to maintain our current arrangements for commercial supply, or conclude agreements for commercial supply with additional third-party manufacturers, or we may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- reliance on the third party for the timely supply of our products or product candidates;
- an event at one of our manufacturers or suppliers causing an unforeseen disruption of the manufacture or supply of our products or product candidates;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or results in an interruption to the supply chain for our products.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products. Such failure could also result in the delay of our obtaining regulatory approval of our product candidates. Also, the spread of COVID-19 may affect the ability of our third-party manufacturers to supply SIVEXTRO, XENLETA, CONTEPO or any future product candidates.

In April 2019, the FDA issued a CRL in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. Specifically, the CRL requested us to address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer prior to the FDA approving the NDA. In December 2019, we resubmitted our NDA for CONTEPO for the treatment of cUTIs, including AP. On June 19, 2020 we received a second CRL from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cited observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of our NDA for CONTEPO for the treatment of cUTIs, including AP. On October 30, 2020, we participated in a "Type A" meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the our NDA for CONTEPO for the treatment of cUTIs, including AP. On April 14, 2021, the FDA issued industry guidance on remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities during COVID-19 specifying that when it cannot perform a PAI or a PLI or when the FDA determines that it would be useful to supplement a planned inspection, the agency will consider using tools other than a physical inspection and select the most appropriate method to address the specific risks that justify the need for the PAI or PLI. The FDA informed us that onsite inspections of our manufacturing partners in Europe are required in order for the FDA to complete the review of a potential CONTEPO NDA resubmission. Due to travel restriction related to the COVID-19 pandemic, the FDA suspended onsite inspections of ex-US manufacturers for all non-COVID products. As a result, we requested an extension of the timeline for a potential CONTEPO NDA resubmission until June 2023, which the FDA granted on March 21, 2022. We are awaiting further clarity from the FDA regarding their ability to complete onsite inspections at our manufacturing partners in Italy

and Spain before determining specific timing of the potential NDA resubmission, which we plan to submit promptly once we have clarity from the FDA. The FDA released the Resiliency Roadmap for FDA Inspectional Oversight that describes the systematic approach that FDA will utilize to manage postponed inspections and other oversight activities. The prioritization plan considers public health risks related to conducting an inspection, such as the impact of the product's availability on public health, as well as investigator safety and travel restrictions/advisories. In addition, the FDA informed us that, while they cannot predict when an inspection may occur and when the pandemic may prevent the FDA from completing inspections, tier 1 mission-critical inspections and tier 2 higher priority inspections, which includes PAIs, will continue to be prioritized going forward. Our contract manufacturers continue to interact with FDA to discuss its plans for conducting inspections at their sites. If these manufacturing issues are not resolved to the FDA's satisfaction, or if we or any of our third-party manufacturers, or suppliers are the subject of any other open or unresolved regulatory inspections, inspection reports, or FDA Form 483s identifying noncompliance with applicable regulations, we would be delayed in obtaining or may fail to obtain regulatory approval of our product candidates, including CONTEPO.

Our product candidates and any products that we have developed or may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our non-clinical testing and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. For example, there are only a limited number of known manufacturers that produce the pleuromutilin starting material used in the synthesis of XENLETA. In early 2015, Novartis completed the sale of its animal health division, including its veterinary products, to a third party. As a result, we were required to identify an alternative supplier for pleuromutilin starting material for XENLETA. If we are not able to obtain adequate supplies of our product candidates or products, or the drug substances used to manufacture them, it will be more difficult for us to develop or commercialize our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates and products may adversely affect our revenues and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis. In addition, slower than forecasted commercialization of our products in approved territories, or delayed introduction of our product in approved territories, or disruptions in the supply of our approved products may adversely affect our revenue and profit margins. Moreover, disruption in the supply of our approved product may impact the availability of our approved products at retail pharmacies and may adversely impact our reputation and the willingness of physicians to prescribe our products, which could materially harm our business, financial condition, results of operations and prospects. In addition, our failure or potential failure to comply with contractual minimum order commitments or minimum revenue commitments with our third party suppliers could impact the uninterrupted supply of our products and/or subject us to additional costs. For example, in August 2021, we entered into an amendment to our supply agreement for the API for XENLETA to reduce our minimum purchase obligations under the supply agreement in exchange for cash payments to the supplier and a royalty on net sales of XENLETA in the United States.

***We have entered into a Sales Promotion and Distribution Agreement with Merck & Co. related to the promotion, distribution and sale of SIVEXTRO. If our collaboration with Merck is not successful, we may incur significant expenses related to the distribution of SIVEXTRO without realizing any value from the agreement.***

In July 2020, we entered into the Distribution Agreement with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for ABSSSIs, caused by certain susceptible Gram-positive microorganisms in the SIVEXTRO Territory.

Under the Distribution Agreement and subject to the fulfillment of certain conditions, including our engaging sufficient sales representatives, restrictions relating to travel and physician office access in the SIVEXTRO Territory due to COVID-19 having continued to decrease in a sufficient portion of the SIVEXTRO Territory so as not to hinder the successful detailing of SIVEXTRO, we have been granted the right to initially promote SIVEXTRO in the SIVEXTRO Territory and, upon satisfaction of additional conditions, including an increase in the number of our sales representatives,

the right to exclusively distribute SIVEXTRO in the SIVEXTRO Territory, including the sole right and responsibility to fill orders with respect to SIVEXTRO in the SIVEXTRO Territory. In April 2021, we successfully satisfied those conditions, including the increase in the number of sales representatives, and began filling orders of SIVEXTRO with our own Nabriva NDC.

A subsidiary of Merck will sell, and we have agreed to purchase, SIVEXTRO at specified prices in such quantities as we may specify. Although we are entitled, subject to applicable law, to determine the final selling prices of SIVEXTRO in our sole discretion, subject to an overall annual limit on price increases, we may not be able to sell SIVEXTRO at prices high enough to recoup our investment in a sales force and other commercialization activities. In addition, we will rely on a subsidiary of Merck to supply SIVEXTRO to us, who in turn, relies on third party manufacturers for the production, packaging, and serialization of SIVEXTRO for our distribution. Relying on a third-party manufacturer subjects us to a number of additional risks, including the risk that we may not have sufficient supply of SIVEXTRO available for sale. See “Risk Factors—Risks Related to Our Dependence on Third Parties—Use of third parties to manufacture our product candidates or products may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which could delay, prevent or impair our development or commercialization efforts.”

***We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. We expect to continue to rely on such third parties in conducting our clinical trials of XENLETA and CONTEPO, and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. 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 reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Similar GCP and transparency requirements apply in the European Union. Failure to comply with such requirements, including with respect to clinical trials conducted outside the European Union, can also lead regulatory authorities to refuse to take into account clinical trial data submitted as part of an MAA.

Furthermore, third parties that we rely on for our clinical development activities may also have relationships with other entities, some of which may be our competitors. 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 will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

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 our products, producing additional losses and depriving us of potential product revenue.

***We have entered into and may enter into additional collaborations with third parties for the development or commercialization of XENLETA, CONTEPO and our other product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

We are commercializing XENLETA and expect to commercialize CONTEPO, if approved, in the United States with targeted sales and marketing efforts. Outside the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize XENLETA. For example, we are party to a license agreement with Sumitomo Pharmaceuticals (Suzhou), pursuant to which we granted Sumitomo Pharmaceuticals (Suzhou) certain rights to manufacture and commercialize XENLETA in the People's Republic of China, Hong Kong, Macau and Taiwan and we have also entered into a license agreement with Sunovion pursuant to which we granted Sunovion certain rights to commercialize XENLETA in Canada. We also may seek third-party collaborators for development and commercialization of other product candidates or for XENLETA for indications other than CABP.

Our likely future collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under our license agreements with Sumitomo Pharmaceuticals (Suzhou) and Sunovion, we have, and under any such arrangements we enter into with any third parties in the future we will likely have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our current collaborations pose, and any future collaborations likely will pose, numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or 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, product and product candidate priorities, available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may need to conduct clinical trials, and these clinical trials may not be successful;
- 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- 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;
- collaborators may not properly maintain or defend 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 the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborator and us as to the ownership of intellectual property arising during the collaboration;
- we may grant exclusive rights to our collaborators, which would prevent us from collaborating with others;
- collaborators may be unable to enforce our intellectual property rights in territories where we have licensed, or may license, them such rights, which may expose us to material adverse tax and other consequences;
- disputes may arise between the collaborators and us that result in the delay or termination of the development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; 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;
- collaborators may elect to delay commercialization in an effort to gain more commercially favorable product pricing and reimbursement in their territory.

For example, under our license agreement with Sumitomo Pharmaceuticals (Suzhou), if any court, tribunal or governmental agency in the People's Republic of China, Hong Kong, Macau or Taiwan determines that the exclusive license granted to Sumitomo Pharmaceuticals (Suzhou) pursuant to the license agreement is not sufficiently exclusive such that Sumitomo Pharmaceuticals (Suzhou) does not have sufficient rights to enforce the licensed patent rights in such territories, we and our subsidiary, Nabriva Therapeutics GmbH, have agreed to take such commercially reasonable steps as Sumitomo Pharmaceuticals (Suzhou) reasonably requests to grant Sumitomo Pharmaceuticals (Suzhou) such rights. If a court in such jurisdictions were to determine that our license to Sumitomo Pharmaceuticals (Suzhou) was not sufficiently exclusive and that Sumitomo Pharmaceuticals (Suzhou) did not have the rights to enforce the licensed patent rights in the licensed territories, Sumitomo Pharmaceuticals (Suzhou) may require us to take such actions that it deems reasonable but that we do not and which may have a material adverse effect on our business, including requiring us to make changes to our organizational structure that may result in adverse tax and other consequences, or to conduct other activities that may cause us to incur significant expenses.

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 were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

***If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.***

The commercialization of XENLETA, potential commercialization of CONTEPO, if approved, and the development and potential commercialization of other product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to further collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we intend to seek to commercialize XENLETA through a variety of types of additional collaboration arrangements outside the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for additional collaborations outside greater China and Canada will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the

likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. In addition, armed hostilities, acts of terrorism and other violence, or general political instability, in the jurisdictions where we seek to enter collaborations, or in neighboring jurisdictions, may prevent us from establishing a collaboration in such jurisdictions. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Mergers and acquisitions in the pharmaceutical and biotechnology industries may also reduce the number of potential collaborators with whom we could partner. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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 may 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 additional 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 and generate product revenue.

***We enter into various contracts in the normal course of our business in which we agree to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.***

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sub licensees' exercise of rights under the agreement. With respect to our commercial agreements, we have agreed to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we typically agree to indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage or not covered by insurance, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator or other third party to indemnify us and the collaborator or other third party is denied insurance coverage or otherwise does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

#### **Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain patent protection for our technology, products and product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology, products and product candidates may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology, products and product candidates. We seek to protect our

proprietary position by filing patent applications in the United States, Europe and in certain additional foreign jurisdictions related to our novel technologies, products and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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, if we license technology, products or product candidates from third parties, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, these patents and applications may not be prosecuted, maintained and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology, products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. In addition, China and certain other developing countries, where we currently have a number of licensed patents and licensed patent applications, currently affords less protection to a company's intellectual property than some other jurisdictions. Furthermore, certain 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. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could also limit our potential revenue opportunities. As such, the lack of strong patent and other intellectual property protection in China and elsewhere may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. We also may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. For example, we have received a Notice of Request for Invalidation of our lefamulin compound patent in China in October 2021. We filed a response defending the validity of our patent, and the petitioner withdrew his invalidation request in January 2022, so this matter is concluded. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us,

without payment to us, or result in our inability to manufacture or commercialize products and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology, products or product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or any licensed patents by developing similar or alternative technologies, products or product candidates in a non-infringing manner. In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Legal and regulatory developments in the European Union and elsewhere may also result in clinical trial data submitted as part of an MAA becoming publicly available. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the European Union and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products and product candidates, or limit the duration of the patent protection of our technology, products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter such infringement or unauthorized use, we may be required to file claims, which can be expensive, time consuming and a distraction to management. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging our patents, trademarks, copyrights or other intellectual property are invalid or unenforceable or that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, product candidates and technology, including interference, derivation, *inter partes* review or post-grant review proceedings before the USPTO. The risks of being involved in such litigation and proceedings may increase as our product candidates approach commercialization, and as we gain greater visibility as a public company with commercial products. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of all such intellectual property rights potentially relating to our products and product candidates. Any freedom-to-operate search or analysis previously



conducted may not have uncovered all relevant patents and patent applications, and there may be pending or future patent applications that, if issued, would block us from commercializing SIVEXTRO<sup>®</sup>, XENLETA<sup>®</sup> or CONTEPO<sup>™</sup>. Thus, we do not know with certainty whether SIVEXTRO, XENLETA, CONTEPO or any other product candidate, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, or to avoid or settle litigation, we could be required to obtain a license to continue developing and marketing our technology, products and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial payments. We could be forced, including by court order, to cease commercializing the infringing technology, products or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our technology, products and product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

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 proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees 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. Our pleuromutilin business was founded as a spin-off from Sandoz. Although all patents and patent applications are fully owned by us and were either filed by Sandoz with all rights fully transferred to us, or filed in our sole name, because we acquired certain of our patent rights from Sandoz, we must rely on their prior practices, with regard to the assignment of such intellectual property. Similarly, for any patents and patent applications we acquired from Zavante in connection with the Acquisition, we must rely on Zavante's prior practices with regard to the assignment of intellectual property.

Our and their assignment agreements may not be self-executing or may be breached, and 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. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of

their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology, products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, know-how, technology and other proprietary information, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, we cannot guarantee that we have executed these agreements with each party that may have or has had access to our trade secrets and other confidential information or that the agreements we have executed will provide adequate protection. 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 inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be obtained or independently developed by a competitor, our competitive position would be harmed.

***We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.***

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign 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. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

#### **Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters**

***Even if we complete the necessary non-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, in particular in the United States or the European Union, we will not be able to commercialize our product candidates in those markets, and our ability to generate revenue will be materially impaired.***

XENLETA, CONTEPO, and any other product candidates that we develop, 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, in the case of XENLETA, by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. On August 19, 2019, we received approval from the FDA to market the oral and intravenous formulations of XENLETA to treat CABP in the United States. Further, on July 28, 2020, the European Commission issued a legally binding decision for approval of the marketing authorization application for XENLETA for the treatment of community-acquired pneumonia in adults following a review by the European Medicines Agency. Sunovion Pharmaceuticals Canada Inc. additionally received approval from Health Canada to market oral and intravenous formulations of XENLETA for the treatment of community-acquired pneumonia in adults, with the Notice of Compliance from Health Canada dated July 10, 2020. We

have entered into a license and commercialization agreement in March 2019 with Sunovion Pharmaceuticals Canada Inc. for XENLETA in Canada. In September 2021, we and Sumitomo Pharmaceuticals (Suzhou) announced the approval received by Sumitomo Pharmaceuticals (Suzhou) to market oral and intravenous formulations of XENLETA for the treatment of community-acquired pneumonia in adults in Taiwan. We have not received approval to market XENLETA in any jurisdiction other than those mentioned above or for any other indication, and we have not received approval to market CONTEPO or any of our other product candidates from regulatory authorities in any jurisdiction, and we do not intend to seek approval to market CONTEPO outside the United States. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. Specifically, the Complete Response Letter requested us to address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer prior to the FDA approving the NDA. In December 2019, we resubmitted the NDA for CONTEPO. On June 19, 2020 we received a second Complete Response Letter from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cited observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of our NDA for CONTEPO for the treatment of cUTI, including AP.

Even after obtaining marketing approval for XENLETA, we have limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and we have and expect to continue to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that XENLETA, CONTEPO or any of our other product candidates are not effective or only moderately effective, or have undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

The FDA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from non-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***Our failure to obtain marketing approval in jurisdictions other than the United States and Europe would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and Europe would not assure approval of product candidates in other jurisdictions.***

In order to market and sell XENLETA and our other product candidates in jurisdictions other than the United States, Canada and Europe, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval or approvals from regulatory authorities in the European Union. The regulatory approval process outside the United States, Canada and Europe generally includes all of the risks associated with obtaining FDA approval or approvals from regulatory authorities in the European Union. In addition, some countries outside the United States, Canada and Europe require approval of the sales

price of a drug before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement and a product may not be approved for sale in the country until it is also approved for reimbursement. We may not obtain marketing, pricing or reimbursement approvals outside the United States, Canada and Europe on a timely basis, if at all. Approval by the FDA or regulatory authorities in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and Europe does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or regulatory authorities in the European Union. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and Europe do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom and European Union entered into a Trade and Cooperation Agreement in connection with Brexit that sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

***Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

XENLETA and any other product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. 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 or to the conditions of approval. In addition, laws and regulations govern the distribution and tracing of prescription drugs and prescription drug samples, including the Prescription Drug Marketing Act of 1976 and the Drug Supply Chain Security Act, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the United States federal level and set minimum standards for the regulation of drug distributors by the states.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs subject to the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers'

communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Accordingly, we may not promote XENLETA in the United States for use in any indications other than the treatment of CABP, and all promotional claims must be consistent with the FDA-approved labeling of XENLETA.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

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

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

Similar restrictions apply to the approval of our products in the EU. 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 EU'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 EU and are also subject to EU member state laws.

Accordingly, with respect to XENLETA and any other product candidates for which we receive marketing approval, we and our 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 are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products, including XENLETA, withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

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

Disruptions at the FDA and other agencies have delayed the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which has adversely affected our business. The FDA announced that in order to bring new therapies to patients sick with COVID-19 as quickly as possible, it has redeployed medical and regulatory staff from other areas to work on COVID-19 therapies. On June 19, 2020 we received a second Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP due to issues at our third party manufacturers that could not be inspected by the FDA owing to operational restrictions placed on the FDA by COVID-19. Additionally, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

***A Fast Track or Priority Review designation by the FDA may not lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates.***

If a product candidate is intended for the treatment of a serious or life threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply to the

FDA for fast track designation. For fast track products, sponsors may have greater interactions with the FDA, and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The FDA has designated the IV formulation of CONTEPO as a qualified infectious disease product, or QIDP, and granted a fast track designation for this formulation of CONTEPO.

Further, if FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. CONTEPO has been granted priority review by the FDA.

We may seek these and other expedited review designations for our product candidates. The FDA has broad discretion with respect to whether or not to grant these designations to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a fast track or breakthrough therapy designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. As a result, while we may seek and receive these designations for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw these designations if it believes that the designation is no longer supported by data from our clinical development program.

***Designation of CONTEPO as a Qualified Infectious Disease Product does not assure FDA approval of this product candidate.***

A QIDP is an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens". Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted an additional period of five years of regulatory exclusivity. Even though we have received a QIDP designation for CONTEPO, there is no assurance that CONTEPO will be approved by the FDA.

***If the FDA does not conclude that our product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more and entail greater complications and risks than anticipated, and may not be successful.***

We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States in October 2018, and we resubmitted the NDA in December 2019, utilizing Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. We have not conducted a comprehensive freedom-to-operate review with regard to CONTEPO.

Accordingly, we may invest a significant amount of time and expense in the development of CONTEPO or any other product candidate we may develop and experience significant delays and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application also may not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Thus, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

If the FDA does not conclude that CONTEPO, or any of our other product candidates for which we may utilize the 505(b)(2) pathway, satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates, including CONTEPO, under Section 505(b)(2) are not as we expect, the approval pathway for CONTEPO and any of our other product candidates for which we may utilize the 505(b)(2) pathway will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

***Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which in the event of a violation could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any of our products, including SIVEXTRO, XENLETA, and product candidates, including CONTEPO, for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute SIVEXTRO, XENLETA, and any other products for which we obtain marketing approval. Restrictions under applicable federal, state, and foreign healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, 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, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes 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;



- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, and foreign anti-corruption laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

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 may require product 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.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We have developed and implemented a corporate compliance program designed to ensure that we will market and sell any approved products in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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 significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties 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, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we 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.

***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 the Centers for Medicare & Medicaid Services, or 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 FSS 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 FCA 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. Our collaborators are also subject to similar requirements outside of the U.S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

***Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our products and product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of CONTEPO or any of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products, including SIVEXTRO, XENLETA, or product candidates, including CONTEPO, for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. Pursuant to subsequent legislation, however, these Medicare sequester reductions have been suspended through the end of March 2022. From April 2022 through June 2022 a 1% sequester cut will be in effect, with the full 2% cut resuming thereafter. 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.

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 for Jobs Act, or TCJA, in 2017, 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. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June

17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge 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 rescinded those orders and 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 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. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

In addition, the Centers for Medicare & Medicaid Services, or 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, or PA, and step therapy, or 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" 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.

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.

***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.***

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 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

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. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 have also been delayed by the Biden administration until January 1, 2023.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs HHS to create a plan within 45 days to combat “excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging.” On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical 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.

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.

In other countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Also, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***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 GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking 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 4% of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations 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 European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General are 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 the 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 (i.e. “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, preparing for and complying with these 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 increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

We cannot assure stockholders 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 shareholders 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.

***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, or FCPA, the Irish Criminal Justice (Corruption Offenses) Act, 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 and other anti-corruption laws 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. For example, 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.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations currently, and may in the future, involve the use of hazardous and flammable materials, including chemicals

and medical and biological materials, and produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or disposal of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We also maintain a general liability program for some of the risks, but our insurance program includes limited environmental damage coverage, which has an annual aggregate coverage limit of \$2.0 million. Although we maintain an umbrella policy with an annual aggregate coverage limit of \$10.0 million, which may provide some environmental coverage, we do not maintain a separate policy covering environmental damages.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, 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.

Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.***

We are increasingly dependent upon technology systems and data to operate our business. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that our office-based employees work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect the service reliability and threaten the confidentiality, integrity and availability of information. Cyber-



attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development programs and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

***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.***

Certain countries in which we operate have, or are developing, laws protecting the confidentiality of certain patient health information. European Union member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

For example, the European Union General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition.

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

#### **Risks Related to Our Acquisition of Zavante**

***We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.***

On July 24, 2018, we completed the acquisition of Zavante pursuant to the Merger Agreement. Our ability to realize the anticipated benefits of the Acquisition is expected to entail numerous material potential difficulties, including, among others:

- any delay or failure in obtaining marketing approvals for CONTEPO, or any delay or failure to commercialize CONTEPO in the United States thereafter;
- increased scrutiny from third parties, including regulators, legislative bodies and enforcement agencies, including with respect to product pricing and commercialization matters;
- changes in laws or regulations that adversely impact the anticipated benefits of the Acquisition;
- challenges related to the perception by patients, the medical community and third-party payors of CONTEPO for the treatment of cUTIs;

- disruptions to our manufacturing arrangements with third-party manufacturers, including our manufacturing and supply arrangements with respect to CONTEPO and disruptions to our third-party distribution channel;
- difficulties in managing the expanded operations of a larger and more complex company following the Acquisition;
- difficulties in achieving the anticipated business opportunities and growth prospects from the Acquisition;
- the size of the treatable patient population for CONTEPO may be smaller than we believe it is;
- difficulties in attracting and retaining key personnel; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the Acquisition.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially adversely impact our business, financial condition and results of operations.

The upfront consideration for the Acquisition was comprised of 815,209 of our ordinary shares, including the 81,518 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us, subject to the terms and conditions of the Merger Agreement, up to \$97.5 million in contingent consideration, of which \$25.0 million would become payable upon the first approval of a new drug application from the FDA, for CONTEPO for any indication, or the Approval Milestone Payment, and an aggregate of up to \$72.5 million would become payable upon the achievement of specified net sales milestones, or the Net Sales Milestone Payments, with the first commercial milestone becoming payable when CONTEPO exceeds \$125.0 million in net sales in a calendar year. At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in ordinary shares, except as otherwise provided in the Merger Agreement. The issuance of our ordinary shares in connection with the closing of the Acquisition was dilutive to our existing shareholders, and the future issuance of our ordinary shares to satisfy our milestone payment obligations would be further dilutive to our then existing shareholders.

Also, following the Acquisition, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Acquisition. Prior to the Acquisition, former Zavante stockholders and SG Pharmaceuticals, Inc. entered into a stock purchase agreement, dated as of May 5, 2015, or the Stock Purchase Agreement, pursuant to which SG Pharmaceuticals, Inc. acquired all of the outstanding capital stock of Zavante from the Zavante selling stockholders and SG Pharmaceuticals, Inc., subsequently merged with and into Zavante, with Zavante as the surviving entity. Pursuant to the Stock Purchase Agreement, Zavante (as successor to SG Pharmaceuticals, Inc.) is obligated to make milestone payments payable in cash to the selling stockholders of \$3.0 million upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments that may be settled in ordinary shares of up to \$26.0 million in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments to the selling stockholders of a mid-single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. The Stock Purchase Agreement also provides that Zavante will pay to the selling stockholders a mid-single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the Cures Act) related to a Zavante Product.

In addition, we expect to incur expenses related to the continued development, regulatory approval process and commercialization with respect to CONTEPO. Zavante has entered into a manufacturing and supply agreement with Fisiopharma, pursuant to which Zavante has an obligation to purchase a minimum percentage of its commercial requirements of CONTEPO in the United States. Zavante has also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA, or an abbreviated new drug application for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, and which provides for payments to Laboratorios ERN, S.A. of a one-time cash payment upon the first commercial sale of CONTEPO and subsequent quarterly payments thereafter based on the number of vials of CONTEPO sold in the United States during each quarter. Zavante has also entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to Zavante, on an exclusive basis, a blend of fosfomicin disodium and succinic acid, or API Mixture, for CONTEPO and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United States.

Because we have limited financial resources, by investing in the Acquisition, we may forgo or delay pursuit of other opportunities that may have proven to have greater commercial potential. Further, it is possible that undisclosed, contingent, or other liabilities or problems may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

All of these factors could decrease or delay the expected accretive effect of the Acquisition and negatively impact our share price. As a result, it cannot be assured that the Acquisition will result in the full realization of the benefits anticipated from the Acquisition or in the anticipated time frames or at all.

#### **Risks Related to Employee Matters**

##### ***Our future success depends on our ability to attract, retain and motivate key executives and qualified personnel.***

We are highly dependent on the principal members of our management team. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance on any of our executive officers. The unplanned loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified personnel, including in the United States and Ireland where we have key business processes, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Our functional teams are small and therefore attrition can lead to gaps in institutional knowledge and risks to running the business. In addition, we rely 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 employed by companies other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we cannot recruit and retain qualified personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

##### ***In 2020, we reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.***

In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. Additional reductions in headcount occurred in the third quarter including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. The restructuring was intended to reduce costs and to align the capabilities of our sales efforts with our strategic re-focus on making sales of XENLETA to community health care professionals, as well as our business development strategy to in-license additional community products, such as SIVEXTRO and additional community products. The restructuring resulted in the termination of long-

term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the restructuring described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, the restructuring may result in employees who were not affected by the reduction in headcount seeking alternate employment, which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company. If our management is unable to effectively manage this transition and restructuring and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

### **Risks Related to Ownership of Our Ordinary Shares**

#### ***The price of our ordinary shares may be volatile and fluctuate substantially.***

The trading price of our ordinary shares has been and is likely to continue to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The market price for our ordinary shares may be influenced by many factors, including:

- our ability to successfully commercialize the oral and IV formulations of XENLETA for the treatment of CABP and the IV formulation of CONTEPO, if approved;
- our ability to promote and distribute SIVEXTRO;
- our ability to obtain FDA approval of CONTEPO for the treatment of cUTIs, including AP;
- our ability to successfully implement our proposed business strategy;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory delays and greater government regulation of potential products due to adverse events;
- regulatory or legal developments in the United States, the European Union and other countries or regions;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products, including additional community products;
- one or more of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- our ability to comply with the restrictive covenants under our Loan Agreement and avoid an event of default that may lead to an acceleration of the amounts due under the Loan Agreement;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- perception and market performance of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- activism by any single large shareholder or combination of shareholders;
- our need to raise additional funds;
- our ability to meet the minimum listing requirements for continued listing on The Nasdaq Global Select Market;
- the societal and economic impact of public health epidemics, such as the ongoing COVID-19 pandemic;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to successfully commercialize SIVEXTRO, XENLETA or, if approved, CONTEPO or any of our other product candidates or if our securities experience volatility for any reason. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources. For example, we and our Chief Executive Officer, our former Chief Medical Officer and former Chief Financial Officer were named as defendants in a purported class action lawsuit following our announcement in April 2019 that the FDA issued a CRL in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form.

***The number of ordinary shares underlying our outstanding warrants is significant in relation to our currently outstanding ordinary shares, which could have a negative effect on the market price of our ordinary shares and make it more difficult for us to raise funds through future equity offerings.***

As part of our March 2021 registered direct offering we issued warrants to purchase up to an aggregate of 5,180,505 ordinary shares at an exercise price of \$2.39 per share. As part of our May 2020 registered direct offering, we issued warrants to purchase an aggregate of up to 4,144,537 ordinary shares at an exercise price of \$7.92 per share. As part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 1,379,310 ordinary shares at an exercise price of \$19.00 per share. As of the date of this Quarterly Report on Form 10-Q, there

were 10,619,347 warrants outstanding from the three offerings and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each of the December 2019 warrants was initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. Each of the May 2020 warrants was immediately exercisable and will expire on the two-year anniversary of the date of issuance. Each of the March 2021 warrants was immediately exercisable and will expire on the five-year anniversary of the date of issuance. We have registered the issuance of shares upon exercise of these warrants under a registration statement under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our ordinary shares to decline significantly. Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might otherwise occur.

We may also find it more difficult to raise additional equity capital while these warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. In addition, the exercise of these warrants would result in a significant increase in the number of our outstanding ordinary shares, which could have the effect of significantly diluting the interest of our current shareholders, and following such exercise the former holders of such warrants could have significant influence over our company as a result of the ordinary shares they acquire upon such exercise.

***If we fail to meet the requirements for continued listing on The Nasdaq Global Select Market, our ordinary shares could be delisted from trading, which would decrease the liquidity of our ordinary shares and our ability to raise additional capital.***

Our ordinary shares are currently listed for quotation on The Nasdaq Global Select Market. We are required to meet specified requirements in order to maintain our listing on The Nasdaq Global Select Market, including, among other things, a minimum bid price of \$1.00 per share.

On April 29, 2020, we received written notice from The Nasdaq Stock Market LLC, or Nasdaq, indicating that, based on the closing bid for the last 30 consecutive business days, we were not in compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Global Select Market, as set forth in Listing Rule 5450(a)(1), or the Bid Price Rule. On December 2, 2020, our board of directors effected a one-for-ten reverse stock split of our ordinary shares for the purpose of regaining compliance with the Bid Price Rule. On December 17, 2020, we received notification from Nasdaq that for 10 consecutive business days, the closing bid price of our ordinary shares had been at \$1.00 per share or greater, confirming that we had regained compliance with the Bid Price Rule.

On January 4, 2022, we again received written notice from Nasdaq indicating that, based on the closing bid for the last 30 consecutive business days, we were not in compliance with the Bid Price Rule. The Notice does not result in the immediate delisting of our ordinary shares from The Nasdaq Global Select Market. In accordance with Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days to regain compliance with the Bid Price Rule. As a result, we will have until July 5, 2022, or the Compliance Date, to regain compliance with the Bid Price Rule. To regain compliance, the closing bid price of our ordinary shares must be at least \$1.00 per share for a minimum of ten consecutive business days on or before the Compliance Date. If we do not regain compliance with the Bid Price Rule by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our ordinary shares to the Nasdaq Capital Market, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Rule. To effect such a transfer, we would also need to pay an application fee to Nasdaq and provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. If we do not qualify for the additional compliance period or fail to regain compliance during the additional 180-day period, then Nasdaq will notify us of its determination to delist our ordinary shares, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq hearing panel. In addition to continuing to monitor the closing bid price of our ordinary shares, we expect to consider available options to regain compliance with the Bid Price Rule. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule.

If we do not regain compliance with the Bid Price Rule by the Compliance Date or if in the future we fail to satisfy The Nasdaq Global Select Market's other continued listing requirements, we may transfer to The Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. A transfer of our listing to The Nasdaq Capital Market or having our ordinary shares trade on the OTC Bulletin Board could adversely affect the liquidity of our ordinary shares. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our ordinary shares, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our ordinary shares to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our share price.

There are many factors that may adversely affect our minimum bid price, including those described throughout this section titled "Risk Factors". Many of these factors are outside our control. As a result, we may not be able to comply with the Bid Price Rule in the long term. Any potential delisting of our ordinary shares from The Nasdaq Global Select Market would likely result in decreased liquidity and increased volatility for our ordinary shares and would adversely affect our ability to raise additional capital or enter into strategic transactions. Any potential delisting of our ordinary shares from The Nasdaq Global Select Market would also make it more difficult for our shareholders to sell their ordinary shares in the public market.

***Our ordinary shares do not trade on any exchange outside of the United States.***

Our ordinary shares are listed only in the United States on The Nasdaq Global Select Market, and we have no plans to list our ordinary shares in any other jurisdiction. As a result, a holder of ordinary shares outside of the United States may not be able to effect transactions in our ordinary shares as readily as the holder may if our ordinary shares were listed on an exchange in that holder's home jurisdiction.

***Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.***

Sales of a substantial number of our ordinary shares, or the perception in the market that these sales could occur, could reduce the market price of our ordinary shares. We had 61,725,236 ordinary shares outstanding as of March 31, 2022. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

Future issuances of ordinary shares pursuant to our equity incentive plans could also result in a reduction in the market price of our ordinary shares. We have filed registration statements on Form S-8 registering all of the ordinary shares that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume, notice and manner of sale limitations applicable to affiliates. The majority of ordinary shares that may be issued under our equity compensation plans remain subject to vesting in tranches over a four-year period. As of March 31, 2022, an aggregate of 587,726 options to purchase our ordinary shares had vested and become exercisable although these options all have an exercise price that is higher than the recent market trading prices of our ordinary shares.

In addition, on June 25, 2019, we entered into the Jefferies ATM Agreement, with Jefferies, pursuant to which, from time to time, we may offer and sell ordinary shares, for aggregate gross sale proceeds of up to \$50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended.

On May 6, 2021, we entered into the Sale Agreement with Jefferies, as agent, pursuant to which we may offer and sell ordinary shares, nominal value \$0.01 per share for aggregate gross sale proceeds of up to \$50.0 million, from time to time through Jefferies, by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. Upon entry into the Sale Agreement, our existing Jefferies ATM Agreement was terminated. We did not incur any termination penalties as a result of the replacement of

the Jefferies ATM Agreement. As of the effective date of the termination of the Jefferies ATM Agreement, we had sold an aggregate of 5,925,699 of our ordinary shares pursuant to the Jefferies ATM Agreement for aggregate gross proceeds of \$33.7 million and net proceeds to us of \$31.9 million, after deducting commissions and offering expenses payable by us. The approximately \$16.3 million of ordinary shares that had been available for sale pursuant to the Jefferies ATM Agreement remained unsold at the time of its replacement. The replacement of the Jefferies ATM Agreement terminated any future sales of ordinary shares through the Jefferies ATM Agreement.

As of March 31, 2022, we have issued and sold an aggregate of 19,570,971 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$31.0 million and net proceeds of \$29.8 million, after deducting commissions to Jefferies and other offering expenses. From April 1, 2022 and through the date of this filing, we have issued and sold an aggregate of 276,150 ordinary shares pursuant to the Sale Agreement and received gross proceeds of \$118 thousand and net proceeds of \$115 thousand, after deducting commissions to Jefferies and other offering expenses. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$10.5 million under the Sale Agreement.

On September 24, 2021, we entered into a purchase agreement, or Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which, subject to the terms and conditions, provides that we have the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to \$23.0 million of our Ordinary Shares. In addition, under the Purchase Agreement, we agreed to issue a commitment fee of 632,474 Ordinary Shares, or the Commitment Shares, as consideration for Lincoln Park entering into the Purchase Agreement and for the payment of \$0.01 per Commitment Share. Under the Purchase Agreement, we may from time to time, at our discretion, direct Lincoln Park to purchase on any single business day, or a Regular Purchase up to (i) 400,000 Ordinary Shares if the closing sale price of our Ordinary Shares is not below \$0.25 per share on Nasdaq, (ii) 600,000 Ordinary Shares if the closing sale price of our Ordinary Shares is not below \$2.00 per share on Nasdaq or (iii) 800,000 Ordinary Shares if the closing sale price of our Ordinary Shares is not below \$3.00 per share on Nasdaq. In any case, Lincoln Park's commitment in any single Regular Purchase may not exceed \$2,500,000 absent a mutual agreement to increase such amount. As of March 31, 2022, we have issued and sold an aggregate of 6,000,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$4.1 million. From April 1, 2022 and through the date of this filing, we had issued and sold an aggregate of 1,200,000 ordinary shares pursuant to the Purchase Agreement and received net proceeds of \$0.4 million. As of the date of this filing, we may issue and sell ordinary shares for gross proceeds of up to \$18.6 million under the Purchase Agreement, subject to the Nasdaq rules which may limit our ability to make sales of our ordinary shares to Lincoln Park in excess of a specified amount without prior shareholder approval.

As part of our March 2021 registered direct offering we issued warrants to purchase up to an aggregate of 5,180,505 ordinary shares at an exercise price of \$2.39 per share. As part of our May 2020 registered direct offering, we issued warrants to purchase an aggregate of up to 4,144,537 ordinary shares at an exercise price of \$7.92 per share. As part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 1,379,310 shares of ordinary shares at an exercise price of \$19.00 per share. As of the date of this Quarterly Report on Form 10-Q, there were 10,619,347 warrants outstanding from the three offerings and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each of the December 2019 warrants was initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. Each of the May 2020 warrants was immediately exercisable and will expire on the two-year anniversary of the date of issuance. Each of the March 2021 warrants was immediately exercisable and will expire on the five-year anniversary of the date of issuance. We have registered the issuance of shares upon exercise of these warrants under a registration statements under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of these warrants or sale of the shares issuable upon exercise of these warrants, or the perception that sales of these shares could occur, could cause the market price of our ordinary shares to decline significantly.

Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might have otherwise occurred.



If a large number of our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

The upfront consideration for the Acquisition was comprised of 815,209 of our ordinary shares, including 81,518 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Merger Agreement. Such shares are able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional \$97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future, and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones.

The sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our share price. Such a decline will adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

***We are a “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 Exchange Act. We may remain a smaller reporting company until we have a non-affiliate public float in excess of \$250 million and annual revenues in excess of \$100 million, or a non-affiliate public float in excess of \$700 million, each as determined on an annual basis. For so long as we remain a smaller reporting company, we are permitted and may 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;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation; and
- reduced disclosure about our executive compensation arrangements.

We cannot predict whether investors will find our ordinary shares less attractive if we rely on such 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 the market price of our ordinary shares may be more volatile.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, security holders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As a growing company, implementing and maintaining effective controls may require more resources, and we may encounter internal control integration difficulties. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, as a smaller reporting company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer a smaller reporting company. To achieve compliance with Section 404 within the prescribed period, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will 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 that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***United States investors may have difficulty enforcing judgments against us, our directors and executive officers.***

We are incorporated under the laws of Ireland, and our registered offices and a substantial portion of our assets are located outside of the United States. As a result, it may not be possible to effect service of process on our directors, executive officers, or us in the United States or to enforce judgments obtained in courts in the United States against such persons or us based on civil liability provisions of the securities laws of the United States.

There is no treaty between Ireland and the United States providing for the reciprocal enforcement of judgments obtained in the other jurisdiction and Irish common law rules govern the process by which a U.S. judgment may be enforced in Ireland. The following requirements must be met as a precondition before a U.S. judgment will be eligible for enforcement in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive, and the decree must be final and enforceable in the court which pronounces it;
- the judgment must be provided by a court of competent jurisdiction, and the procedural rules of the court giving the foreign judgment must have been observed;
- the U.S. court must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules; and
- jurisdiction must be obtained by the Irish courts over judgment debtors in enforcement proceedings by service in Ireland or outside Ireland in accordance with the applicable court rules in Ireland.

Even if the above requirements have been met, an Irish court may exercise its right to refuse to enforce the U.S. judgment if the Irish court is satisfied that the judgment (1) was obtained by fraud; (2) is in contravention of Irish public policy; (3) is in breach of natural justice; or (4) is irreconcilable with an earlier judgment. By way of example, a judgment of a U.S. court of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts on the grounds of public policy if that U.S. judgment includes an award of punitive damages. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere.

***We do not expect to pay dividends in the foreseeable future.***

We have not paid any dividends on our ordinary shares since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that earnings, if any, will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from “distributable reserves”. In addition,

the terms of the Loan Agreement with Hercules currently, and the terms of any future debt agreements may in the future, preclude us from paying dividends. As a result, capital appreciation, if any, of our ordinary shares will be the sole source of gain for holders of our ordinary shares for the foreseeable future.

***We are exposed to risks related to currency exchange rates.***

A portion of our expenses are denominated in currencies other than the U.S. dollar. Because our consolidated financial statements are presented in U.S. dollars, changes in currency exchange rates have had and could have a significant effect on our operating results. Exchange rate fluctuations between foreign currencies and the U.S. dollar create risk in several ways, including the following:

- weakening of the U.S. dollar may increase the U.S. dollar cost of overseas research and development expenses;
- strengthening of the U.S. dollar may decrease the value of our revenues denominated in other currencies; and
- the exchange rates on non-U.S. dollar transactions and cash deposits can distort our financial results.

***As a holding company, our operating results, financial condition and ability to pay dividends or other distributions are entirely dependent on funding, dividends and other distributions received from our subsidiaries, which may be subject to restrictions.***

Our ability to pay dividends or other distributions and to pay our obligations in the future will depend on the level of funding, dividends and other distributions, if any, received from our subsidiaries and any new subsidiaries we establish in the future. The ability of our subsidiaries to make loans or distributions (directly or indirectly) to us may be restricted as a result of several factors, including restrictions in financing agreements and the requirements of applicable law and regulatory and fiscal or other restrictions. In particular, our subsidiaries and any new subsidiaries may be subject to laws that restrict dividend payments, authorize regulatory bodies to block or reduce the flow of funds from those subsidiaries to us, or limit or prohibit transactions with affiliates. Restrictions and regulatory action of this kind could impede access to funds that we may need to make dividend payments or to fund our own obligations.

Furthermore, we may guarantee some of the payment obligations of certain of our subsidiaries from time to time. These guarantees may require us to provide substantial funds or assets to our subsidiaries or their creditors or counterparties at a time when we are in need of liquidity to fund our own obligations.

***The ownership percentage of our shareholders may be diluted in the future which could dilute the voting power or reduce the value our outstanding ordinary shares.***

As with any publicly traded company, the ownership percentage of our shareholders may be diluted in the future because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we intend to continue to grant to our directors, officers and employees. From time to time, we may issue additional options or other share awards to our directors, officers and employees under our benefits plans.

In addition, our articles of association authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred shares having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of the ordinary shares. Additionally, we may issue and sell our ordinary shares under our Jefferies ATM Agreement or the Purchase Agreement with Lincoln Park from time to time, and we may issue additional ordinary shares as contingent consideration upon the achievement of certain regulatory and commercialization milestones, subject to the terms and conditions of the Merger Agreement. See “—Risks Related to Ownership of our Ordinary Shares—Substantial future

*sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.”*

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation. We are incorporated as a public limited company under Irish law.***

The rights of our shareholders are governed by our memorandum and articles of association and Irish law. The rights associated with our ordinary shares are different to the rights generally associated with shares held in a U.S. corporation. Material differences between the rights of shareholders of a U.S. corporation and the rights of our shareholders include differences with respect to, among other things, distributions, dividends, repurchases and redemptions, bonus issues, the election of directors, the removal of directors, the fiduciary and statutory duties of directors, conflicts of interests of directors, the indemnification of directors and officers, limitations on director liability, the convening of annual meetings of shareholders and special shareholder meetings, notice provisions for meetings, the quorum for shareholder meetings, the adjournment of shareholder meetings, the exercise of voting rights, shareholder suits, rights of dissenting shareholders, anti-takeover measures and provisions relating to the ability to amend the articles of association.

***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 board of directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory preemption 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. Accordingly, our articles of association contain, as permitted by Irish company law, provisions authorizing our board of directors to issue new shares, and to disapply statutory preemption rights. The authorization of our board of directors to issue shares and the disapplication of statutory preemption 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 preemption rights at our 2021 Annual General Meeting of Shareholders, or the 2021 Annual Meeting, and to extend that authorization to the increase in authorized share capital that was approved by our shareholders at the 2021 Annual Meeting. Our shareholders renewed the authorization of our board of directors to issue shares; however, although we received over 67% support of the votes cast on renewing the pre-emption rights opt-out authority, 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 originally convened an Extraordinary General Meeting of Shareholders, or EGM, on December 22, 2021 but was ultimately adjourned to March 24, 2022 to allow us to solicit from our shareholders the additional proxies necessary to obtain approval of the sole proposal to grant the board of directors authority under Irish law to allot and issue ordinary shares (including rights to acquire ordinary shares) for cash without first offering those ordinary shares to our existing shareholders pursuant to the statutory pre-emption right that would otherwise apply. On March 24, 2022, our shareholders approved the dis-application of statutory pre-emption rights for an additional five year term.

The authorization of our board of directors to issue shares and the disapplication of statutory preemption rights must both be renewed by the shareholders at least every five years, or at the time our shareholders approve an increase in our authorized share capital. We cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our ordinary shares. As a result of this limitation, we may be limited in the amount of ordinary shares we may sell 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. In the event we are not able to obtain such shareholder approval of the disapplication of pre-emption rights, when needed, we will be limited in the amount of ordinary shares we may sell in any capital raising transaction without first offering those shares to all of our existing shareholders.

***Irish law differs from the laws in effect in the U.S. with respect to defending unwanted takeover proposals and may give our board less ability to control negotiations with hostile offerors.***

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013. Under those Irish Takeover Rules, the board is not permitted to take any action that might frustrate an offer for our ordinary shares once the board 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 ordinary shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the board has reason to believe an offer is or may be imminent. These provisions may give the board less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

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

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of a company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for our outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. The Irish Takeover Rules could therefore discourage an investor from acquiring 30% or more of our outstanding ordinary shares, unless such investor was prepared to make a bid to acquire all outstanding ordinary shares.

Certain separate concert parties will also be presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of the company. The application of these presumptions may result in restrictions upon the ability of any of the concert parties and members of our board of directors to acquire more of our securities, including under the terms of any executive incentive arrangements. We may consult with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities if necessary, although we are unable to provide any assurance as to whether the Irish Takeover Panel would overrule this presumption.

***We will be exposed to the risk of future changes in law, which could materially adversely affect us.***

We are subject to Irish law. As a result, we are subject to the risk of future adverse changes in Irish law (including Irish corporate and tax law). In addition, we and our subsidiaries are also subject to the risk of future adverse changes in Austrian and U.S. law, as well as changes of law in other countries in which we and our subsidiaries operate.

***Future adverse changes in law could result in our not being able to maintain a worldwide effective corporate tax rate that is competitive in our industry.***

While we believe that being incorporated in Ireland should not affect our ability to maintain a worldwide effective corporate tax rate that is competitive in our industry, we cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we will operate. The tax laws of Ireland, Austria, the United States, and other jurisdictions could change in the future, and such changes could cause a material change in our worldwide effective corporate tax rate. In particular, legislative action could be taken by Ireland, Austria, the United States or other jurisdictions which could override tax treaties upon which we expect to rely and adversely affect our effective tax rate. As a result, our actual effective tax rate may be materially different from our expectation.

***The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.***

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. New statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have prospective or retroactive application to us and our shareholders.

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

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain significant shareholders over a rolling three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our share ownership, some of which would be outside our control. If our ability to use our net operating losses and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes to offset our future taxable income. In addition, there is also a risk that due to changes in laws and regulations, such as suspensions on the use of net operating losses, or other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities.

***U.S. persons who own 10 percent or more of our shares may be subject to U.S. federal income taxation on certain of our foreign subsidiaries’ income even if such income is not distributed to such U.S. persons.***

A foreign corporation is treated as a “controlled foreign corporation”, or CFC, for U.S. federal income tax purposes if, on any day during a taxable year, “United States shareholders” (as defined below) own (directly, indirectly or constructively within the meaning of Section 958 of the Code) more than 50% of the total combined voting power of all classes of our voting shares or more than 50% of the total value of all of our shares. A “United States shareholder” of a foreign corporation is a U.S. person who owns (directly, indirectly or constructively within the meaning of Section 958 of the Code) at least 10% of the total combined voting power of voting shares of such non-U.S. corporation or at least 10% of the total value of shares of all classes of stock of such non-U.S. corporation.

As a result of the Tax Act, all of our non-U.S. subsidiaries will be treated as CFCs.

Any United States shareholder who owns our shares (directly or indirectly within the meaning of Section 958(a) of the Code) on the last day in such taxable year must include in its gross income for U.S. federal income tax purposes its pro rata share (based on direct or indirect ownership of value) of the non-U.S. subsidiaries’ “subpart F income”, regardless of whether that income was actually distributed to such U.S. person (with certain adjustments). “Subpart F income” of a CFC generally includes among other items passive income, such as dividends, interest, royalties, rents, annuities and net gains from commodities, foreign currency and securities transactions and from sales of property that produced, or was held for the production of, passive income (or no income).

United States shareholders must also include in their gross income for U.S. federal income tax purposes their pro rata share of a CFC’s “global intangible low tax income”, or GILTI. In general terms, GILTI is the net income of the CFCs (other than income already included in United States shareholders’ taxable income) that exceeds 10% of the CFCs’ bases in depreciable tangible assets. GILTI is treated in a manner similar to subpart F income.

In addition, if a U.S. person disposes of shares in a non-U.S. corporation and the U.S. person was a United States shareholder at any time when the corporation was a CFC during the five-year period ending on the date of

disposition, any gain from the disposition will generally be treated as a dividend to the extent of the U.S. person's share of the corporation's undistributed earnings and profits that were accumulated during the period or periods that the U.S. person owned the shares while the corporation was a CFC (with certain adjustments). Also, a U.S. person may be required to comply with specified reporting requirements, regardless of the number of shares owned.

***A transfer of our ordinary shares, other than a transfer effected by means of the transfer of book-entry interests in the Depository Trust Company, 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, or DTC, will not be subject to Irish stamp duty. However, if you hold our ordinary shares directly rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of our ordinary shares.

***Our ordinary shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.***

Irish capital acquisitions tax, or 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. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of €335,000 in respect of taxable gifts or inheritances received from their parents.

***Our business and operations could be negatively affected if we become subject to shareholder activism, which could cause us to incur significant expense, hinder execution of our business strategy and impact our share price.***

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. If we become the subject of certain forms of shareholder activism, such as proxy contests, the attention of our management and our board of directors may be diverted from execution of our business strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

***We may be classified as a passive foreign investment company for one or more of our taxable years, which may result in adverse U.S. federal income tax consequence to U.S. holders.***

A corporation organized outside the United States generally will be classified as a "passive foreign investment company", or PFIC, for U.S. federal income tax purposes (1) in any taxable year in which (A) at least 75% of its gross income is passive income or (B) on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income, and (2) as to a given holder who was a holder in such taxable year and regardless of such corporation's income or asset composition, in any subsequent taxable year, unless certain elections are made by that holder that allow the holder to discontinue that classification as to that holder, generally at a substantial tax cost to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents, annuities and net gains from commodities, foreign currency and securities transactions and from sales of property that produced, or was held for the production of, passive income (or no income).

Based on our gross income and average value of our gross assets for each relevant taxable year, and given the nature of our business, we do not believe that we were a PFIC for any such taxable year from our initial public offering through the year ended December 31, 2021, although there is no assurance that the IRS will agree with this conclusion. Our status in any taxable year (determined without regard to our status in any prior taxable year) will depend on our assets and activities in that year, and because this is a factual determination made annually after the end of the year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any other taxable year. In

particular, in many cases the gross value of our assets may be inferred from the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies can be especially volatile. In other cases, factors external to our specific circumstances may make the presumptive relationship between the gross value of our assets and our market capitalization unreliable, in which case the gross value of our individual assets, based upon valuation methods suitable for use in U.S. federal tax matters (the choice of which may vary from taxable year to taxable year), will govern the determination of our status. While, based on the market price of our ordinary shares, we would be treated as a PFIC in 2021, we believe that the market price rendered an unreliable valuation of our gross assets during that year. Based on our valuation of our gross assets taking into account our specific circumstances, we believe that we were not a PFIC in 2021. There is no assurance, however, that the IRS will agree with our valuation.

If we are treated as a PFIC for the taxable year ending December 31, 2022, or any other taxable year during which a U.S. holder held or holds our ordinary shares, certain adverse U.S. federal income tax consequences generally will apply to the U.S. holder. We currently intend to make available, upon request, the information necessary to permit a U.S. holder to make a valid qualified electing fund, or QEF, election, which may mitigate some of the adverse U.S. federal income tax consequences applicable to a U.S. holder of ordinary shares if we are a PFIC for a given taxable year. However, we may choose not to provide such information at a future date.

### **General Risk Factors**

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter such infringement or unauthorized use, we may be required to file claims, which can be expensive, time consuming and a distraction to management. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging our patents, trademarks, copyrights or other intellectual property are invalid or unenforceable or that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

***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 incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company we incur, and particularly after we are no longer a smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance, and if such insurance becomes prohibitively expensive, this could make it more difficult for us to attract and retain qualified members of our board.



**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**Recent Sales of Unregistered Securities**

We did not sell any of our equity securities or any options, warrants, or rights to purchase our equity securities during the three months ended March 31, 2022 that were not registered under the Securities Act of 1933, as amended, and that have not otherwise been described in a Current Report on Form 8-K or a Quarterly Report on Form 10-Q.

**Purchase of Equity Securities**

We did not purchase any of our equity securities during the period covered by this Quarterly Report on Form 10-Q.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.1	<a href="#">Side Agreement to Manufacturing Services Agreement, dated November 19, 2021, by and among Nabriva Therapeutics Ireland DAC and Patheon UK Ltd.</a>	10-K	001-37558	03/29/2022	10.58
10.2	<a href="#">Form of Contingent RSU Award Agreement under the 2020 Share Incentive Plan, as amended</a>	10-K	001-37558	03/29/2022	10.57
31.1	<a href="#">Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
					X
31.2	<a href="#">Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
					X
32.1	<a href="#">Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
					X
32.2	<a href="#">Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
					X
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, formatted in inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2022 and December 31, 2021, (ii) Consolidated Statements of Operations for the three months ended March 31, 2022 and 2021, (iii) Consolidated Statements of Cash Flows for the three months ended March 31, 2022 and 2021, (iv) Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2022 and 2021 and (v) Notes to Unaudited Consolidated Financial Statements.				
					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 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.

Date: May 5, 2022

NABRIVA THERAPEUTICS plc

By: /s/ Theodore Schroeder

\_\_\_\_\_  
Theodore Schroeder  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 5, 2022

By: /s/ Daniel Dolan

\_\_\_\_\_  
Daniel Dolan  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

## CERTIFICATIONS

I, Theodore Schroeder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva 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.

/s/ Theodore Schroeder

Theodore Schroeder  
Chief Executive Officer  
(Principal Executive Officer)

Dated: May 5, 2022

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## CERTIFICATIONS

I, Daniel Dolan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva 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.

/s/ Daniel Dolan

\_\_\_\_\_  
Daniel Dolan  
Chief Financial Officer  
(Principal Financial Officer)

Dated: May 5, 2022

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**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 Nabriva Therapeutics plc (the "Company") for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Theodore Schroeder, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Theodore Schroeder

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Theodore Schroeder  
*Chief Executive Officer*  
*(Principal Executive Officer)*

Dated: May 5, 2022

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**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 Nabriva Therapeutics plc (the “Company”) for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Daniel Dolan, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Daniel Dolan

\_\_\_\_\_  
Daniel Dolan  
*Chief Financial Officer*  
*(Principal Financial Officer)*

Dated: May 5, 2022

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