UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2018

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: 001-36889

SteadyMed Ltd.

(Exact name of registrant as specified in its charter)

Israel	**2834**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

5 Oppenheimer Street
Rehovot 7670105, Israel
925-272-4999
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period than the registrant was required to submit and post 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 ☐ (Do not check if a smaller reporting company)	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 May 1, 2018, there were 26,572,719 outstanding ordinary shares, par value NIS 0.01 per share, of SteadyMed Ltd.

Table of Contents

STEADYMED LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE PERIOD ENDED MARCH 31, 2018

Table of Contents

PART 1. FINANCIAL INFORMATION
Item 1. Financial Statements

STEADYMED LTD. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF MARCH 31, 2018

UNAUDITED

IN U.S. DOLLARS

INDEX

Table of Contents

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except share and share data)

	March 31, 2018 Unaudited	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 26,639	$ 32,453
Other accounts receivable and prepaid expenses	501	507
Total current assets	27,140	32,960
Long term deposit	72	73
Severance pay fund	155	151
Property and equipment, net	5,798	5,307
Total assets	33,165	38,491
LIABILITIES AND SHAREHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade payables	1,345	1,291
Other accounts payable and accrued expenses	1,845	1,465
Total current liabilities	3,190	2,756
NON-CURRENT LIABILITIES:		
Accrued severance pay	211	203
Liability related to warrants	15,544	11,343
Other accounts payable	385	378
Total non-current liabilities	16,140	11,924
COMMITMENTS AND CONTINGENT LIABILITIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares of NIS 0.01 par value - Authorized: 50,000,000 at March 31, 2018 and December 31, 2017; Issued and outstanding: 26,572,719 at March 31, 2018 (unaudited) and December 31, 2017	69	69
Additional paid-in capital	136,496	136,117
Accumulated deficit	(122,730)	(112,375)
Total shareholders' equity	13,835	23,811
Total liabilities and shareholders' equity	$ 33,165	$ 38,491

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
U.S. dollars in thousands (except share data)

	Three months ended March 31,	
	2018	2017
	Unaudited	
Revenues	$ —	$ 315
Operating expenses:		
Research and development	3,921	4,101
Sales and marketing	136	588
General and administrative	2,023	1,316
Total operating expenses	6,080	6,005
Total operating loss	6,080	5,690
Financial expenses, net	4,159	12,721
Loss before taxes on income	10,239	18,411
Taxes on income	116	148
Net loss	$ 10,355	$ 18,559
Net loss per share:		
Basic and diluted net loss per Ordinary Share	$ 0.39	$ 0.92
Weighted-average number of Ordinary Shares used to compute basic and diluted net loss per share	26,572,719	20,139,826

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
U.S. dollars in thousands (except share data)

	Ordinary Shares		Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount			
Balance as of December 31, 2017	26,572,719	$ 69	$ 136,117	$ (112,375)	$ 23,811
Stock-based compensation	—	—	379	—	379
Net loss	—	—	—	(10,355)	(10,355)
Balance as of March 31, 2018 (unaudited)	26,572,719	$ 69	$ 136,496	$ (122,730)	$ 13,835

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Three months ended March 31,	
	2018	2017
	Unaudited	
Cash flows from operating activities:		
Net loss	$ (10,355)	$ (18,559)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	379	245
Depreciation and impairment of fixed assets	258	186
Accrued severance pay, net	4	9
Increase in fair value of warrants to purchase Ordinary Shares	4,201	12,715
Decrease (increase) in other accounts receivable and prepaid expenses	7	(33)
Decrease in deferred revenue	—	(315)
Increase (decrease) in trade payables	54	(1,553)
Increase (decrease) in other accounts payable and accrued expenses	120	(672)
Net cash used in operating activities	(5,332)	(7,977)
Cash flows from investing activities:		
Purchase of property and equipment	(482)	(717)
Decrease in long-term deposit	—	58
Net cash used in investing activities	(482)	(659)
Net decrease in cash and cash equivalents	(5,814)	(8,636)
Cash and cash equivalents at the beginning of the period	32,453	23,215
Cash and cash equivalents at the end of the period	$ 26,639	$ 14,579
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment	$ 267	$ 31
Cash paid during the period:		
Cash paid for taxes	$ 16	$ 166

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 1: - GENERAL

a. SteadyMed Ltd. (the "Company" or "SteadyMed") was incorporated and is located in Israel, commenced its operations on June 15, 2005 and, together with its wholly-owned subsidiary, SteadyMed Therapeutics, Inc. ("Inc."), and Inc.'s wholly-owned subsidiary, SteadyMed U.S. Holdings, Inc. ("Holdings"), is a specialty pharmaceutical company focused on the development and commercialization of therapeutic product candidates that address the limitations of market-leading products in certain orphan and other well-defined high-margin specialty markets. The Company's primary focus is to obtain approval in the United States for the sale of Trevyent® for the treatment of pulmonary arterial hypertension ("PAH").

On June 30, 2017, the Company filed a New Drug Application ("NDA") for Trevyent, with the United States Food and Drug Administration ("FDA"). On August 28, 2017, the Company received a Refusal to File letter from the FDA, stating that based on a preliminary review of the NDA, the FDA had determined that it is not sufficiently complete to permit a substantive review. The FDA requested further information on certain device specifications and performance testing and has requested additional design verification and validation testing on the final, to-be-marketed Trevyent product. A Type a meeting with the FDA to gain further clarification on the additional information required for resubmission and acceptance of the NDA took place on November 1, 2017. Management believes that the meeting was constructive and that the Company will be able to sufficiently address the FDA's concerns. The Company revised its operating plan and is focused on re-submitting the NDA in the fourth quarter of 2018.

The Company is also at an earlier stage of development with two products for the treatment of post-surgical and acute pain in the home setting. Its product candidates are enabled by its proprietary PatchPump®, which is a discreet, water resistant and disposable drug administration technology that is aseptically prefilled with liquid drug at the site of manufacture and pre-programmed to deliver an accurate, steady flow of drug to a patient, either subcutaneously or intravenously.

Inc. and Holdings are located in the United States, and commenced operations on January 1, 2012 and March 25, 2015, respectively. The principal executive officers of the Company are located in the offices of Inc. and Holdings, and Inc.'s and Holdings' principal business activities are to provide executive management, treasury and administrative support functions to the Company.

b. The Company is devoting substantially all of its efforts toward research, development, regulatory approvals and marketing of Trevyent®. In the course of such activities, the Company expects operating losses for the foreseeable future. For the three months ended March 31, 2018, the Company incurred operating losses of $6,080 and negative cash flows from operating activities of $5,332.

Until the Company has positive cash flows from operating activities, it will need to raise significant additional capital by way of the exercise of the remaining outstanding warrants issued in the 2016 and 2017 private placements, another private placement of debt and/or equity and/or a secondary public offering to allow the Company to continue as a going concern. These factors raise substantial doubt about the Company's ability to continue as a going concern. There is no assurance, however, that the Company will be successful in obtaining an adequate level of financing for its long-term needs, and therefore, there is a substantial doubt in the Company's ability to continue as a going concern.

The accompanying financial statements in this quarterly report do not include any adjustments to reflect the possible future effects on recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 1: - GENERAL (Cont.)

c. On June 28, 2015, the Company entered into an Exclusive License and Supply Agreement (the "Agreement") with Cardiome Pharma Corp. and Correvio International Sárl (hereinafter collectively referred to as "Cardiome") pursuant to which an exclusive royalty bearing license to certain of the Company's patents relating to Trevyent® ("License") was granted to Cardiome in order to develop and commercialize Trevyent, if approved for the treatment of PAH, in certain regions outside the United States, specifically, Europe, Canada and the Middle East (the "Regions"). During March 2018, Cardiome licensed the Canadian rights to Trevyent to Cipher Pharmaceuticals.

The Company provided certain services for Cardiome through the fourth quarter of 2017. Cardiome is responsible for the regulatory submissions and approvals and commercialization of Trevyent in the Regions. In addition, the Company has agreed to supply Trevyent as finished goods to Cardiome upon commercialization of Trevyent® in the Regions ("Supply Services"). Cardiome made a $3,000 upfront payment to the Company (the "Upfront") and the Agreement provides for future regulatory, third-party payor reimbursement approval and commercialization milestone payments to be achieved by Cardiome of up to $9,250 and a scaling royalty ranging from the low teens to mid-teens percent on future Trevyent sales by Cardiome in the Regions. In addition, there is a fixed price on finished goods to be supplied by the Company as part of the Supply Services.

d. On April 29, 2018 United Therapeutics Corporation and the Company signed a definitive merger agreement under which United Therapeutics will acquire the Company (See also Note 10).

NOTE 2: - UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with Article 10 of Regulation S-X, "Interim Financial Statements" and the rules and regulations for Form 10-Q of the SEC. Pursuant to those rules and regulations, the Company has condensed or omitted certain information and footnote disclosure it normally includes in its annual consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles ("US GAAP"). In the opinion of management, the Company has made all adjustments (consisting only of normal, recurring adjustments, except as otherwise indicated) considered necessary for a fair presentation of the Company's consolidated financial position as of March 31, 2018. Consolidated results of operations and consolidated cash flows for the three months periods ended March 31, 2018 and 2017, have been included. The results for the three months period ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ended December 31, 2018. The accompanying unaudited interim consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), on March 30, 2018 with the SEC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 3: - SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies applied in the audited annual consolidated financial statements of the Company, as disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2018 pursuant to the Exchange Act, are applied consistently in these unaudited interim consolidated financial statements, except for:

a. Revenue recognition:

In May 2014, FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09), an updated standard on revenue recognition and issued subsequent amendments to the initial guidance in March 2016, April 2016, May 2016 and December 2016 within ASU 2016-08, 2016-10, 2016-12, and 2016-20, respectively. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. The Company may enter into contracts that can include various combinations of products and services, which are generally capable of being distinct and accounted for as separate performance obligations. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company adopted ASU 2014-09 effective January 1, 2018, using the modified retrospective transition method. The impact of the adoption of this standard on the Company's accumulated deficit as of January 1, 2018 was nil.

The Company allocates the total consideration under each arrangements to the related performance obligations using the best estimate of the standalone selling price of each distinct good or service in the contract. The Company will recognize revenues for its arrangements over time or at a point in time depending on its evaluation of when the customer obtains control of the promised goods or services.

b. Recently issued accounting standards:

1. In February 2016, FASB issued ASU 2016-02-Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840. The standard is effective on January 1, 2019, with early adoption permitted. We are currently anticipates adopting the new standard effective January 1, 2019 and is evaluating the impact of the adoption of this standard on its consolidated financial statements.

2. In May 2017, the FASB issued ASU No. 2017-09, "Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 was issued to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in ASC 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under ASC 718. The amendments in ASU 2017-09 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. The Company is evaluating the impact of the adoption of this standard on its consolidated financial statements.

3. In July 2017, FASB issued ASU No. 2017-11, Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging, which changes the accounting treatment and the earnings per share calculation for certain instruments with down round features. The amendments in this update should be applied using a cumulative-effect adjustment as of the beginning of the fiscal year of adoption or retrospective adjustment to each period presented. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those periods. We are in the process of determining the impact the adoption will have on its consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 4: - WARRANTS TO PURCHASE ORDINARY SHARES

In August 2016 and April 2017, as part of its financing rounds, the Company issued 6,554,016 and 2,515,775 warrants to purchase Ordinary Shares of the Company, nominal value NIS 0.01 per share with an exercise price of $3.5995 and $6.785 per warrant, respectively. The warrants are exercisable immediately upon issuance and may be exercised at any time prior to August 2021 and April 2022, respectively. Subsequent to March 31, 2018, all the warrant agreements were amended conditioned on the closing of United Therapeutics' acquisition of the Company. (See also Note 10).

On May 25, 2017, 1,351,766 warrants that were issued in August 2016 were exercised into ordinary shares.

The Company accounted for the warrants according to the provisions of ASC 480 "Distinguishing Liabilities from Equity" and ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" and due to certain terms and conditions, the warrants classified as a liability. As of March 31, 2018, the Company is using both market approach and Monte Carlo option pricing model in estimating the fair value of the warrants. The assumptions used under the market approach reflect the consideration to the warrants holders upon consummation of the merger agreement under which United Therapeutics will acquire the Company (See also Note 10). The following assumptions were used in the Monte Carlo option pricing model and the fair value of the warrants.

Warrants issued on August 2016:

	March 31, 2018 Unaudited	December 31, 2017
Risk-free interest rate [1]	2.48%	2.12%
Expected volatility [2]	76.4%	76.3%
Expected life (in years) [3]	3.34	3.59
Expected dividend yield [4]	0%	0%
Fair value per warrant:	$ 2.13	$ 1.60

Warrants issued on April 2017:

	March 31, 2018 Unaudited	December 31, 2017
Risk-free interest rate [1]	2.48%	2.12%
Expected volatility [2]	76.4%	76.3%
Expected life (in years) [3]	4.07	4.32
Expected dividend yield [4]	0%	0%
Fair value per warrant:	$ 1.77	$ 1.20

(1) Risk free interest rate based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.

(2) Expected volatility was calculated based on actual historical share price movements of companies in the same industry over a term that is equivalent to the expected term of the warrants.

(3) Expected life was based on the contractual term of the warrants.

(4) Expected dividend yield was based on the fact that the Company has not paid dividends to its shareholders in the past and does not expect to pay dividends to its shareholders in the future.

The Company re-measured these warrants at fair value as of March 31, 2018 and consequently during the three months periods ended March 31, 2018, the Company recorded $4,201 as a financial exspenses as a result of increase in the warrants' fair value predominantly due to the terms of the amended warrant agreements (See also Note 10). Total fair value of the warrants as of March 31, 2018, is $15,544.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 5: - FAIR VALUE MEASUREMENT

The Company applies ASC 820, "Fair Value Measurements and Disclosures", ("ASC 820"), which defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The hierarchy is broken down into three levels based on the inputs as follows:

Level 1: Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level 2: Observable inputs that reflect quoted prices for identical assets or liabilities in markets that are not active; quoted prices for similar assets or liabilities in active markets; inputs other than quoted prices that are observable for the assets or liabilities; or inputs that are derived principally from or corroborated by observable market data by correlation or other means.
Level 3: Unobservable inputs reflecting the Company's own assumptions incorporated in valuation techniques used to determine fair value. These assumptions are required to be consistent with market participant assumptions that are reasonably available.

The availability of observable inputs can vary from investment to investment and is affected by a wide variety of factors, including, for example, the type of investment, the liquidity of markets and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment and the investments are categorized as Level 3.

The carrying amounts of cash and cash equivalents, other accounts receivable, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments. Money Market Funds were classified as Level 1, Reverse Repurchase Agreements were classified as Level 2 as the fair value is determined using a discounted cash flow model with all significant inputs derived from or corroborated with observable market data. Warrants to purchase Ordinary Shares were classified as Level 3 as the fair value is determined using a Monte Carlo option pricing model, which takes into account the anti-dilution features of the warrants and certain subjective assumptions made by Management.

The Company's financial assets and liabilities that are measured at fair value on a recurring basis, consisted of the following types of instruments as of the following dates:

Assets:

	March 31, 2018			
	Fair value measurements			
	Unaudited			
Description	Fair value	Level 1	Level 2	Level 3
Reverse Repurchase Agreements	$ 24,405	$ —	$ 24,405	$ —
Money Market Funds	279	279	—	—
Total financial assets	$ 24,684	$ 279	$ 24,405	$ —

	December 31, 2017			
	Fair value measurements			
Description	Fair value	Level 1	Level 2	Level 3
Reverse Repurchase Agreements	$ 30,407	$ —	$ 30,407	$ —
Money Market Funds	185	185	—	—
Total financial assets	$ 30,592	$ 185	$ 30,407	$ —

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 5: - FAIR VALUE MEASUREMENT (Cont.)

Liabilities:

	March 31, 2018			
	Fair value measurements			
	Unaudited			
Description	Fair value	Level 1	Level 2	Level 3
Warrants to purchase Ordinary Shares	$ (15,544)	$ —	$ —	$ (15,544)
Total financial liabilities	$ (15,544)	$ —	$ —	$ (15,544)

	December 31, 2017			
	Fair value measurements			
Description	Fair value	Level 1	Level 2	Level 3
Warrants to purchase Ordinary Shares	$ (11,343)	$ —	$ —	$ (11,343)
Total financial liabilities	$ (11,343)	$ —	$ —	$ (11,343)

The following tabular presentation reflects the components of the liability associated with such warrants to purchase Ordinary Shares as of March 31, 2018:

	Fair value of warrants to purchase Ordinary Shares
Balance at January 1, 2018	$ 11,343
Decrease in the fair value of the warrants (see Note 4)	4,201
Balance at March 31, 2018 (unaudited)	$ 15,544

NOTE 6: - COMMITMENTS AND CONTINGENT LIABILITIES

a. The Company's lease agreement for the Israeli offices expire on December 31, 2018. The Company has an option to extend the lease term for an additional three periods of twelve months each. Inc.'s lease agreement for its U.S. offices has a four-year term ending May 2019. The Company's total future minimum aggregate lease commitments under non-cancelable operating lease agreements as of March 31, 2018 is $413.

b. During the years 2005- 2010, the Company received grants under the royalty-bearing programs administered by the Israel Innovation Authority (the "IIA"), (previously the Office of the Chief Scientist ("OCS")), and from the Incubator, RAD BioMed Ltd. In May 2015, the IIA approved the Company's request to transfer manufacturing rights outside of Israel, noting that the Company would be required to pay an increased royalty rate without providing any specifics. Therefore, if income will be generated from the funded research program, the Company will be obligated to pay royalties on such revenue at a rate between 3% to 4% for the first three years and between 3.5% to 4.5% commencing the fourth year (based on the portion of manufacturing out of Israel while non-product related revenues are subject to the lower end of the ranges) and up to 150% to 300% of the amount received, linked to the LIBOR. The revenues under the Agreement with Cardiome are subject to royalties under the above programs andall such royalties due have been paid. As of March 31, 2018, the total amount of grants received from the IIA and the Incubator, including interest, was $786 and total royalties paid were $90.

In the event that intellectual property rights are deemed to be transferred out of Israel, the grants received from the IIA and the Incubator may become a loan to be repaid immediately at up to 600% of the grants amounts. Currently, the Company's management believes no intellectual property has been transferred out of Israel and disclosure of the Company's know how is made solely in connection with the transfer of manufacturing rights of the Company's products to subcontractors. Accordingly, no provision has been recorded in such respect.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 6: - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)

c. Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancellable commitments to suppliers for purchases totaling $1,031 as of March 31, 2018.

NOTE 7: - SHAREHOLDERS' EQUITY

Stock-based compensation:

On June 18, 2009, a Stock Option Plan (the "2009 Plan") was adopted by the Board of Directors of the Company. The 2009 Plan was adopted in accordance with the amended sections 102 and 3(i) of Israel's Income Tax Ordinance. Under the 2009 Plan, options to purchase Ordinary Shares of the Company may be granted to employees, advisors, directors, consultants and service providers of the Company or any subsidiary or affiliate. The default vesting schedule is up to three years, subject to the continuation of employment or service and each option granted under the 2009 Plan may be exercised into Ordinary Shares during a period of seven years from the date of grant, unless a different term is provided in the option agreement. On April 30, 2013, the 2013 Stock Incentive Sub Plan (the "2013 Sub Plan") was adopted by the Board of Directors of the Company, which set forth the terms for the grant of stock awards to Inc.'s employees or US non- employees.

On February 20, 2015, the Company's Board of Directors approved the replacement of the 2009 Plan and 2013 Sub Plan by adopting the Amended and Restated 2009 Stock Incentive Plan (the "Amended and Restated Plan"). This action was approved by the shareholders on March 1, 2015. The Amended and Restated Plan also allows the issuance of Restricted Stock Units ("RSUs") and under the Amended and Restated Plan, each option may be exercised into Ordinary Shares during a period of ten years from the date of grant, unless a different term is provided in the option agreement.

Transactions related to the grant of options to employees and directors under the Amended 2009 Stock Plan during the three months ended March 31, 2018, were as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
	Unaudited			
Options outstanding at January 1, 2018	2,057,862	$ 4.03	6.12	$ 1,384
Options forfeited	(122,663)	—	—	—
Options outstanding at end of the period	1,935,199	4.03	6.00	139
Options vested at end of the period	1,266,337	$ 4.17	4.32	$ 81

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the deemed fair value of the Company's Ordinary Shares on the last day of the three months period ended March 31, 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2018. This amount is impacted by the changes in the fair market value of the Company's shares.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 7: - SHAREHOLDERS' EQUITY (Cont.)

A summary of RSUs activity during the three months ended March 31, 2018, were as follows:

	Number of RSU's	Weighted average grant date fair value	Aggregate intrinsic value
		Unaudited	
Unvested at January 1, 2018	247,095	$ 3.32	$ 914
RSUs forfeited	(11,850)	—	—
Unvested at at end of the period	235,245	$ 3.33	$ 765

A portion of the RSUs will vest on June 30, 2018 and and the remainder will vest on the approval of the Trevyent NDA by the FDA.

On December 12, 2017, the Board of Directors reserved an additional 805,593 Ordinary Shares out of its authorized and unissued share capital for future option grants. As of March 31, 2018, the Company has 1,385,938 Ordinary Shares available for future grant under the Amended and Restated Plan.

As of March 31, 2018, the total unrecognized estimated compensation cost related to non-vested stock options and RSUs granted prior to that date was $2,248, which is expected to be recognized over a weighted average period of approximately 1.89 years.

	Three months ended March 31,	
	2018	2017
	Unaudited	
Research and development	$ 91	$ 46
Sales and marketing	17	14
General and administrative	271	185
	$ 379	$ 245

NOTE 8: - SELECTED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Financial expenses, net:

	Three months ended March 31,	
	2018	2017
	Unaudited	
Financial expenses:		
Reevaluation of fair value of warrants to purchase Ordinary Shares	$ 4,201	$ 12,715
Interest expense and bank fees	7	9
Foreign currency translation adjustments	43	15
	4,251	12,739
Financial income:		
Interest income	(92)	(18)
Total financial expense, net	$ 4,159	$ 12,721

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 9: - LITIGATION

a. On May 31, 2017, United Therapeutics Corporation ("United Therapeutics") filed a motion to appeal with the U.S. Court of Appeals for the Federal Circuit regarding a Final Written Decision of the Patent Trial and Appeal Board (the "PTAB") for an IPR petition filed by the Company on October 21, 2015. The IPR petition sought to invalidate U.S. Patent No. 8,497,393 (the "393 Patent") owned by United Therapeutics, which expires in December 2028 and covers a method of making treprostinil, the active pharmaceutical ingredient in United Therapeutics' drug, Remodulin. The Final Written Decision for the IPR petition issued by the PTAB on March 31, 2017, found that all claims of the '393 Patent are not patentable. The Appellate Court heard oral arguments from the parties on November 7, 2017. On November 14, the Court of Appeals upheld the PTAB ruling in our favor without issuing an opinion. On February, 9, 2018, United Therapeutics Therapeutics filed a writ of certiorari with the U.S. Supreme Court asking for a review of the appellate ruling in view of another case pending before the Supreme Court challenging the constitutionality of IPR proceedings. On April 24, 2018, the Supreme Court ruled that IPRs are constitutional in the above pending case, and United Therapeutics Therapeutics has told the Company that it will withdraw the petition.

b. The Company has a commercial dispute with one of its suppliers as a result of the Company's termination of a development agreement in 2017, whereby the supplier alleges wrongful termination and certain breaches of the agreement by the Company. As of March 31, 2018, the Company believes that the claims have no merit and the dispute is in its early stages.

NOTE 10 — SUBSEQUENT EVENTS

On April 29, 2018, the Company entered into a definitive merger agreement (the "Merger Agreement") with United Therapeutics and Daniel 24043 Acquisition Corp. Ltd., a company organized under the laws of Israel and wholly-owned subsidiary of United Therapeutics (the "Merger Sub"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth therein the Merger Sub will merge with and into the Company, with the Company continuing as the surviving entity and becoming a wholly-owned, indirect subsidiary of United Therapeutics. The transaction is valued at $216 million, including the $75 million in contingent consideration.

As a result of the merger, and subject to the terms and conditions of the Merger Agreement, (a) each outstanding ordinary share of SteadyMed (other than any shares held as treasury stock, all of which will be cancelled) will be converted into the right to receive (1) $4.46 in cash ("Closing Cash Consideration"), subject to applicable tax withholding, without interest, plus (2) one contractual contingent value right (each, a "CVR"), which will represent the right to receive $2.63 in cash ("Contingent Consideration") upon the achievement of a milestone related to the commercialization of Trevyent® (the "Milestone"), subject to applicable tax withholding, without interest, (b) each outstanding in-the-money SteadyMed stock option, whether vested or unvested, that has not previously been exercised prior to the merger will be converted into the right to receive (1) a cash payment equal to (x) the excess, if any, of Closing Cash Consideration over the exercise price payable under such option, multiplied by (y) the total number of shares subject to such option immediately prior to the merger and (2) a number of CVRs equal to the total number of shares subject to such option immediately prior to the merger, (c) each outstanding out-of-the-money SteadyMed stock option, whether vested or unvested, that has not previously been exercised prior to the merger will be converted into the right to receive a cash payment, if and when the Milestone is achieved, equal to (x) the excess, if any, of the sum of (1) Closing Cash Consideration and (2) the Contingent Consideration actually payable per CVR over the exercise price payable under such option, multiplied by (y) the total number of shares subject to such option immediately prior to the merger (and any out-of-the-money options with an exercise price equal to or greater than $7.09 will be cancelled at the merger without any consideration payable therefor), (d) each outstanding SteadyMed restricted share unit, whether vested or unvested, will be converted into the right to receive (1) a cash payment equal to (x) the Closing Cash Consideration, multiplied by (y) the total number of shares subject to such restricted share unit and (2) a number of CVRs equal to the total number of shares subject to such restricted share unit, (e) each outstanding warrant to purchase SteadyMed ordinary shares, as amended, issued pursuant to subscription agreements dated April 20, 2017 will be converted into the right to receive $2.33 for each share subject to such warrant immediately prior to the merger and (f) each outstanding warrant to purchase SteadyMed ordinary shares, as amended, issued pursuant to subscription agreements dated July 29, 2016 will be converted into the right to receive $2.71 for each share subject to such warrant immediately prior to the merger.

The merger is subject to customary closing conditions, including approval by SteadyMed's shareholders and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, and is expected to be completed in the third quarter of 2018.

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") pursuant to the Securities Exchange Act of 1934, as amended ("Exchange Act").

Special note regarding forward-looking statements

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of therapeutic product candidates that address the limitations of market-leading products in certain orphan and other well-defined, high-margin specialty markets. Our primary focus is to obtain approval for the sale of Trevyent® for the treatment of pulmonary arterial hypertension, or PAH, in the United States. Two other product candidates for the treatment of post-surgical and acute pain in the home setting, which we call our At Home Patient Analgesia products, or AHPA, are at an earlier stage of development. Our product candidates are enabled by our proprietary PatchPump, which is a discreet, water-resistant and disposable drug administration technology that is aseptically pre-filled with liquid drug at the site of manufacture and pre-programmed to deliver an accurate, steady flow of drug to a patient, either subcutaneously or intravenously.

On June 30, 2017, we announced the submission of an NDA to the United States Food and Drug Administration (the "FDA") for our lead drug product candidate, Trevyent, for the treatment of Pulmonary Arterial Hypertension (PAH). On August 28, 2017, we received a Refusal to File letter from the FDA, stating that based on a preliminary review of the NDA, the FDA determined that the NDA is not sufficiently complete to permit a substantive review. The FDA has requested further information on certain device specifications and performance testing and has requested additional design verification and validation testing on the final, to-be-marketed Trevyent product. In September, the Company requested a Type A meeting with the FDA to gain further clarification on the additional information required for resubmission and acceptance of the NDA.That meeting took place on November 1, 2017. Management believes that the meeting was constructive and that the Company will be able to sufficiently address the FDA's concerns. The Company revised its operating plan and is focused on re-submitting the NDA in the fourth quarter of 2018.

On June 28, 2015, we entered into an Exclusive License and Supply Agreement with Cardiome Pharma Corp. and Correvio International Sarl (collectively, "Cardiome"), pursuant to which we granted to Cardiome an exclusive license to develop and commercialize Trevyent in Europe, Canada, and the Middle East. In consideration for the exclusive license, we received a non-refundable up-front payment of $3 million. Additionally, we are eligible to receive (i) future regulatory, third-party payor reimbursement and commercialization milestone payments of up to $9.25 million that do not require performance by us, (ii) scaling royalties ranging from the low teens to the mid-twenty percent on future Trevyent sales by Cardiome and (iii) a fixed price (based on a cost-plus margin) on our supply of Trevyent finished product to Cardiome. See also Notes 1c and 2j to the consolidated financial statements enclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2018 for details on the Exclusive License and Supply Agreement with Cardiome. In March 2018, Cardiome sublicensed the Canadian rights to Trevyent to Cipher Pharmaceuticals.

Other than our arrangement with Cardiome, we own global development and commercialization rights to Trevyent. If approved by the United States Food and Drug Administration ("FDA"), we expect to commercialize Trevyent for PAH in the United States with a contract commercial organization of approximately 25 individuals targeting the approximately 200 PAH treatment centers in the United States.

We have not received regulatory approvals to sell Trevyent or any of our other product candidates, and we have not generated any sales through March 31, 2018. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue to develop and seek regulatory approval for our product candidates.

Prior to our Initial Public Offering ("IPO"), we primarily financed our operations, including the development of Trevyent and the scaling up of manufacturing, through the sale of Convertible Preferred Shares. All of our Convertible Preferred Shares were automatically converted into ordinary shares upon the closing of our IPO on March 25, 2015.

Recent Developments

Merger Agreement

On April 29, 2018, we entered into a definitive merger agreement with United Therapeutics and Daniel 24043 Acquisition Corp. Ltd., a wholly-owned subsidiary of United Therapeutics (which we refer to as the Merger Sub), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth therein the Merger Sub will merge with and into the Company, with the Company continuing as the surviving entity and becoming a wholly-owned, indirect subsidiary of United Therapeutics. The transaction is valued at $216 million, including the $75 million in contingent consideration. The merger is expected to be completed in the third quarter of 2018, subject to a number of closing conditions discussed below.

As a result of the merger, and subject to the terms and conditions of the Merger Agreement, (a) each outstanding ordinary share of SteadyMed (other than any shares held as treasury stock, all of which will be cancelled) will be converted into the right to receive (1) $4.46 in cash ("Closing Cash Consideration"), subject to applicable tax withholding, without interest, plus (2) one contractual contingent value right (each, a "CVR"), which will represent the right to receive $2.63 in cash ("Contingent Consideration") upon the achievement of a milestone related to the commercialization of Trevyent® (the "Milestone"), subject to applicable tax withholding, without interest, (b) each outstanding in-the-money SteadyMed stock option, whether vested or unvested, that has not previously been exercised prior to the merger will be converted into the right to receive (1) a cash payment equal to (x) the excess, if any, of Closing Cash Consideration over the exercise price payable under such option, multiplied by (y) the total number of shares subject to such option immediately prior to the merger and (2) a number of CVRs equal to the total number of shares subject to such option immediately prior to the merger, (c) each outstanding out-of-the-money SteadyMed stock option, whether vested or unvested, that has not previously been exercised prior to the merger will be converted into the right to receive a cash payment, if and when the Milestone is achieved, equal to (x) the excess, if any, of the sum of (1) Closing Cash Consideration and (2) the Contingent Consideration actually payable per CVR over the exercise price payable under such option, multiplied by (y) the total number of shares subject to such option immediately prior to the merger (and any out-of-the-money options with an exercise price equal to or greater than $7.09 will be cancelled at the merger without any consideration payable therefor), (d) each outstanding SteadyMed restricted share unit, whether vested or unvested, will be converted into the right to receive (1) a cash payment equal to (x) the Closing Cash Consideration, multiplied by (y) the total number of shares subject to such restricted share unit and (2) a number of CVRs equal to the total number of shares subject to such restricted share unit, (e) each outstanding warrant to purchase SteadyMed ordinary shares, as amended, issued pursuant to subscription agreements dated April 20, 2017 (the "2017 Warrants") will be converted into the right to receive $2.33 for each share subject to such warrant immediately prior to the merger and (f) each outstanding warrant to purchase SteadyMed ordinary shares, as amended, issued pursuant to subscription agreements dated July 29, 2016 (the "2016 Warrants") will be converted into the right to receive $2.71 for each share subject to such warrant immediately prior to the merger.

Each party's obligation to complete the Merger is subject to the satisfaction or waiver of a number of closing conditions, including, among others, approval and adoption of the Merger Agreement and each Ancillary Agreement (as defined in the Merger Agreement) by holders of a majority of the outstanding SteadyMed ordinary shares voted at a SteadyMed shareholders meeting duly called and held, provided that either (a) holders of at least a majority of the outstanding SteadyMed ordinary shares that are held by persons that do not have a "personal interest" (as defined in Section 1 of the Israeli Companies Law, 1999) in the Merger Agreement or any Ancillary Agreement (the "Disinterested Voting Shares") that are voted at such shareholders meeting vote to approve and adopt the Merger Agreement and each Ancillary Agreement, excluding abstentions, or (b) the total number of Disinterested Voting Shares that are voted against the Merger Agreement and each Ancillary Agreement does not exceed two percent of the aggregate voting rights of SteadyMed. Other closing conditions include, among others: (a) the expiration or termination of the waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), (b) no governmental authority shall have enacted, entered or enforced any law which prohibits or makes illegal the consummation of the Merger and no temporary restraining order, preliminary or permanent injunction or other judgment, order or decree issued by any court of competent jurisdiction which prohibits or makes illegal the consummation of the Merger shall remain in effect, and (c) at least 50 days shall have passed after the filing of the merger proposal with the Registrar of Companies of the State of Israel and at least 30 days shall have elapsed after the approval of the Merger by the shareholders of each of SteadyMed and Merger Sub. United Therapeutics' obligation to complete the Merger is additionally subject to the satisfaction or waiver of certain additional conditions, including, among others (a) subject to certain materiality qualifications, the accuracy of SteadyMed's representations and warranties made in the Merger Agreement, (b) the compliance by SteadyMed, in all material respects, with its obligations under the Merger Agreement, (c) the absence of any "material adverse effect" (as defined in the Merger Agreement) on SteadyMed occurring after the date of the Merger Agreement that is continuing as of the merger, (d) SteadyMed's unrestricted cash net of unpaid transaction expenses, indebtedness and certain other liabilities, as of the closing date, being greater than or equal to a minimum amount as specified in the Merger Agreement and (e) a tax ruling regarding withholding in connection with the Merger having been obtained from the Israeli Tax Authority and remain in effect. Consummation of the Merger is not subject to any financing condition.

The Merger Agreement contains customary representations, warranties and covenants made by SteadyMed and United Therapeutics. SteadyMed has agreed, among other things, (a) subject to certain exceptions, to conduct its business in the ordinary course between the execution of the Merger Agreement and the merger and not to take specified actions during such period, (b) not to solicit, initiate, endorse or knowingly encourage or knowingly facilitate any inquiry or proposal that is reasonably likely to lead to any "acquisition proposal" (as defined in the Merger Agreement), subject to certain exceptions, (c) not to enter into, continue or otherwise participate in any discussions or negotiations regarding, or furnish to any person information with respect to any "acquisition proposal," subject to certain exceptions, (d) subject to certain exceptions, for the board of directors of SteadyMed to recommend that the SteadyMed shareholders approve and adopt the Merger Agreement and each ancillary agreement and not withdraw or modify such recommendation and (e) to file a proxy statement and cause a special shareholders' meeting to be held regarding the approval of the Merger Agreement and each ancillary agreement.

The Merger Agreement contains certain termination rights for both SteadyMed and United Therapeutics, and further provides that, upon termination of the Merger Agreement under specified circumstances, SteadyMed may be required to pay United Therapeutics a termination fee of $4.5 million.

Contingent Value Right Agreement

At or prior to the time of the merger, United Therapeutics will enter into a Contingent Value Rights Agreement (the "CVR Agreement") and will ensure that a duly qualified rights agent executes and delivers the same. Each CVR represents the right to receive the Contingent Consideration, if on or prior to the 5th anniversary of the merger, a total of 3,000 "initial treatment visits" have occurred in the United States following receipt of the first approval by the Food and Drug Administration of a New Drug Application for the Trevyent® product (combining the PatchPump® delivery device with treprostinil) for treatment of pulmonary arterial hypertension (the "Product"). An "initial treatment visit" means a visit by a member of the clinical staff of a specialty pharmacy to a patient to whom the Product has been prescribed, during which the initial treatment of such patient with such product is administered, subject to the exceptions described in the CVR Agreement.

The right to the Contingent Consideration represented by a CVR issued under the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement.

Warrant Amendment Agreements

SteadyMed and all holders of the 2016 Warrants and 2017 Warrants have entered into amendments to such warrants (the "Warrant Amendments"). Under the Warrant Amendments, in the event the Merger is consummated by December 31, 2018, Section 5(c) of each of the 2016 Warrants and 2017 Warrants will be null and void, such warrants will not be assumed by United Therapeutics or Merger Sub, and instead the Warrants will be cancelled and converted into the right to receive $2.33 for each share issuable upon exercise of a 2017 Warrant and $2.71 for each share issuable upon exercise of a 2016 Warrant. If SteadyMed, United Therapeutics or the Merger Sub agree to pay any holder of a 2016 Warrant or 2017 Warrant consideration that is greater than the consideration payable under the applicable Warrant Amendment, or on terms more favorable in any material respect, then the price payable under the Warrant Amendments, or the terms of the Warrant Amendments, will be automatically adjusted to give the holders thereof the benefit of such greater consideration and/or more favorable terms. The Warrant Amendments will terminate if the Merger is not consummated by December 31, 2018.

Voting Agreement

Certain shareholders of the Company have each entered into a voting agreement with United Therapeutics (the "Voting Agreements"). The Voting Agreements place certain restrictions on the transfer of the shares of SteadyMed held by the respective signatories thereto and include covenants as to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger.

The preceding summaries do not purport to be complete and are qualified in their entirety by reference to the Merger Agreement, form of CVR Agreement, form of Voting Agreement and forms of Warrant Amendment, which are filed as Exhibits 2.1, 2.2, 2.3, 10.1 and 10.2, respectively, to our Current Report on Form 8-K filed with the SEC on April 30, 2018.

First Three Months of 2018 and Other Recent Highlights

Financial overview

Summary

The financial data is based on the consolidated financial statements of Ltd., its wholly-owned subsidiary, SteadyMed Therapeutics, Inc. ("Inc."), and Inc.'s wholly owned subsidiary, SteadyMed U.S. Holdings, Inc. ("Holdings"). Ltd. is an Israeli incorporated company with offices in Rehovot, Israel. Inc. and Holdings, a Delaware corporations with offices in San Ramon, California, USA. Ltd. is predominantly engaged in research and development activities, and Inc. and Holdings provide the executive management, treasury, marketing and business development and administrative support functions.

Since inception, the Company has generated net losses from operations, and, as of March 31, 2018, we had an accumulated deficit of $122.7 million, primarily as a result of research and development and general and administrative expenses. In the future we may generate revenue from a variety of sources, including product revenues, license fees, milestone payments and research and development payments in connection with existing and potential future strategic partnerships. See also Note 1c to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1.

While Trevyent is a late-stage development candidate, it has not been approved by the FDA. Our two AHPA programs are at an earlier stage of development and may never be successfully developed or commercialized. Accordingly, we expect to incur significant and increasing losses from operations for the foreseeable future as we seek to obtain FDA approval of Trevyent, complete our pre-commercialization plan and commercialize Trevyent. There can be no assurance that we will ever generate significant revenue or profits.

Revenue recognition

Trevyent, our lead product candidate, has not been approved for commercialization. During 2015, we received a nonrefundable up-front payment in the amount of $3.0 million from Cardiome associated with the Trevyent license granted to Cardiome. We recognized the payment as revenue on a straight-line basis over a period during which we were obligated to provide certain services, which was ended in the fourth quarter of 2017. During the three-month periods ended March 31, 2018 and 2017, we recognized revenue of $0 thousand and $315 thousand, respectively, from the Upfront payment.

Components of operating expenses

Our current operating expenses consist of three components: research and development expenses, sales and marketing expenses, and general and administrative expenses.

Research and development expenses

Our research and development expenses consist of costs incurred in connection with the development of our product candidates and technology platform, including:

- Fees incurred to subcontractors, consultants and advisors in connection with research and development of our PatchPump technology, implementing infrastructure for manufacturing, pre-clinical and clinical studies and regulatory compliance;
- Salaries and other related costs; and
- Direct and indirect expenses required for operation and maintenance of laboratories and research and development offices, such as supplies and material, rent, utilities, depreciation and other expenses.

Research and development expenses are charged to the statement of comprehensive loss as incurred. The following table discloses the breakdown of research and development expenses for the three months period ended March 31, 2018 and 2017.

	Three months ended March 31,	
	2018	2017
	Unaudited	
Cost of third party subcontractors and materials	$ 2,560	$ 2,768
Salaries and related personnel	909	925
Travel	85	125
Depreciation and impairment of fixed assets	253	182
Overhead	114	101
Total	$ 3,921	$ 4,101

We expect research and development expenses to be our largest category of operating expenses and to remain a significant expense through the conduct of post-approval marketing studies on Trevyent.

Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success or failure of each product candidate, as well as an ongoing assessment as to each product candidate's commercial potential and the Company's ability to finance its programs.

Sales and marketing expenses

Sales and marketing expenses consist primarily of salaries and other personnel related costs, market awareness campaigns, market research, trade shows and advertising, facility costs not otherwise included in research and development and general and administrative expenses, and pre-commercialization and commercialization expenses incurred through InVentiv Healthcare (now Syneos Health), the Company's commercialization partner. As a result of receiving the Refusal to File ("RTF") letter from the FDA, we have deferred significant sales and marketing expenses for the foreseeable future and in the fourth quarter of 2017 laid off our Vice President of Commercial Operations and our Vice President of PH Patient Advocacy and Community Relations.

General and administrative expenses

General and administrative expenses consist principally of salaries and other personnel related costs in executive and administrative positions, legal, accounting and other professional services, compensation to our board of directors, D&O insurance, and facility costs not otherwise included in research and development and sales and marketing expenses.

Financial expenses, net

Financial expenses, net consists mainly of the following:

- Revaluation of fair value of warrants to purchase Ordinary Shares granted to investors on August 4, 2016 in the first tranche of the Private Placement and in the 2017 Private Placement on April 25, 2017, which are re-measured at each reporting period at fair value until they are exercised or expired and the related issuance costs of such warrants. (See also Note 4 to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1).
- Interest income from cash and cash equivalents.
- Gains and losses from foreign currency translation adjustments.

For more information refer to Note 8 to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1.

Results of Operations

Comparison of the three months periods ended March 31, 2018 and 2017

	Three months ended March 31,	
	2018	2017
	Unaudited	
Revenues	$ —	$ 315
Operating expenses:		
Research and development	3,921	4,101
Sales and marketing	136	588
General and administrative	2,023	1,316
Total operating expenses	6,080	6,005
Total operating loss	6,080	5,690
Financial expenses, net	4,159	12,721
Loss before taxes on income	10,239	18,411
Taxes on income	116	148
Net loss	$ 10,355	$ 18,559

Revenues

During the three months ended March 31, 2017, the Company recognized $0.3 million from the $3.0 million Upfront payment associated with the Cardiome license agreement. During the fourth quarter of 2017, such revenue was fully recognized. The Company had no revenue for the three months ended March 31, 2018.

Research and development expenses

Research and development expenses were $3.9 million during the three months ended March 31, 2018, compared to $4.1 million during the same period in 2017, which reflects a decrease of $0.2 million or 4%. The decrease was principally due to a decrease in subcontractor expenses.

Sales and marketing expenses

Sales and marketing expenses were $0.1 million during the three months ended March 31, 2018, compared to $0.6 million during the same period in 2017, which reflects a decrease of $0.5 million or 77%. The decrease was principally due to decreases in consulting fees and salary expenses related to a decrease in headcount, all associated with the scaling back of the pre-commercialization plan for Trevyent in response to the RTF letter from the FDA for the Trevyent NDA.

General and administrative expenses

General and administrative expenses were $2.0 million during the three months ended March 31, 2018 compared to $1.3 million in the same period in 2017, which reflects an increase of $0.7 million, or 54%. The increase was principally due to an increase of $0.5 million in legal fees related to the recently-announced Merger Agreement with United Therapeutics.

Financial expenses, net

Financial expenses, net amounted to $4.2 million during the three months ended March 31, 2018. This expense was mainly due to a $4.2 million increase in the fair value of warrants to purchase Ordinary Shares. As of March 31, 2018 the Company is using both market approach and Monte Carlo option pricing model in estimating the fair value of the warrants. The increase in the warrants' fair value is predominantly attributable to assumptions used under the market approach that reflected consideration to be paid to the warrant holders upon consummation of the merger agreement under which United Therapeutics will acquire the Company (See also Note 10 to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1). Financial expenses, net, amounted to $12.7 million during the three months ended March 31, 2017 mainly due to an expense of $12.7 million from revaluation of fair value of the warrants to purchase Ordinary Shares, predominantly attributable to a significant increase in the company's share price during the period.

Taxes on income

Taxes on income principally consists of the taxes incurred in Inc. and Holdings as a result of the cost plus service agreement with Ltd.

Net loss

Due to the factors described above, the most significant of which was the financial expenses, net related to the revaluation of fair value of the warrants to purchase Ordinary Shares our net loss decreased by $8.2 million or 44% from $18.6 million in the three months ended March 31, 2017 to $10.4 million in the three months ended March 31, 2018.

Cash Flows

The tables below set forth our significant sources and uses of cash for the periods set forth below.

Comparison of the three months ended March 31, 2018 and 2017

	Three months ended March 31,	
	2018	2017
	Unaudited	
Net cash used in:		
Operating activities	$ (5,332)	$ (7,977)
Investing activities	(482)	(659)
Net decrease in cash and cash equivalents	$ (5,814)	$ (8,636)

Net Cash Used in Operating Activities

Net cash used in operating activities of $5.3 million during the three months ended March 31, 2018 was primarily a result of a net loss of $10.4 million offset by revaluation of fair value of warrants to purchase Ordinary Shares in the amount of $4.2 million, stock-based compensation expense of $0.4 million, depreciation and impairment of fixed assets of $0.3 million and trade payables and other accounts payable and accrued expenses of $0.2 million. Net cash used in operating activities of $8.0 million during the three months ended March 31, 2017 was primarily a result of a net loss of $18.6 million, a decrease in trade payables of $1.6 million, a decrease in other accounts payables and accrued expenses of $0.7 million and a decrease in deferred revenue of $0.3 million offset by the revaluation of fair value of warrants to purchase Ordinary Shares in the amount of $12.7 million, stock-based compensation expense of $0.2 million and depreciation of $0.2 million.

Net Cash Used in Investing Activities

Net cash used in investing activities of approximately $0.5 million and $0.7 million during the three months ended March 31, 2018 and 2017 respectively, consisted primarily of investment in equipment and machinery used in our development activities.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, our operations have been financed primarily through private placements of convertible preferred shares, an initial public offering of ordinary shares, and two private placements of ordinary shares (with resale registration statements in effect). At March 31, 2018, we had approximately $26.6 million in cash and cash equivalents.

We have incurred losses and cumulative negative cash flows from operations since our inception in June 2005 through March 31, 2018 and we had an accumulated deficit of approximately $122.7 million as of March 31, 2018. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development and potential commercialization of Trevyent and incur additional costs associated with being a public company.

Recent Private Placement Financings

In August 2016, we raised approximately $19.6 million of net proceeds from the sale of our Ordinary Shares and warrants to purchase our Ordinary Shares in the first tranche of a Private Placement. The Company filed a registration statement for the resale of the shares and warrant shares issued in the Private Placement on September 2, 2016 which was declared effective on September 21, 2016.

In April 2017, we raised approximately $28.1 million of net proceeds from the sale of Ordinary Shares in the 2017 Private Placement and warrants to purchase Ordinary Shares The Company filed a registration statement for the resale of the shares and warrant shares issued in the Private Placement on May 24, 2017 which was declared effective on June 6, 2017.

Going Concern; Future Funding Requirements

Our current cash and cash equivalents are expected to support our operations into the second quarter of 2019.

Since inception the Company has had net losses and negative cash flows from operating activities. Until the Company has positive cash flows from operating activities, it will need to raise significant additional capital by way of the exercise of the remaining outstanding warrants issued in the 2016 and 2017 Private Placements, another private placement of debt and/or equity and/or a secondary public offering to allow the Company to continue as a going concern.

There is no assurance, however, that we will be successful in obtaining an adequate level of financing for our long-term needs, and therefore, there is a substantial doubt in our ability to continue as a going concern.

The unaudited interim consolidated financial statements in this quarterly report do not include any adjustments that may be necessary should we be unable to obtain such funding and continue as a going concern. If we raise additional funds through the issuance of equity, the percentage ownership of current shareholders could be reduced, and such securities might have rights, preferences or privileges senior to our ordinary shares. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may not be able to obtain regulatory approval and/or commercialize Trevyent, continue development of other or future product candidates or take advantage of prospective business endeavors or opportunities, which could significantly and materially restrict our ability to achieve commercial revenues. If we are unable to obtain the necessary funding when needed, we may have to cease operations.

If we do obtain such funding in the near term, we anticipate needing subsequent funding to fund operations because we do not know when, or if, we will generate any revenue from sales of our products and we do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of Trevyent. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we proceed with preparations to launch Trevyent. We also expect to continue incurring additional costs associated with operating as a public company, including additional Sarbanes Oxley compliance costs. Further, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution costs. We therefore anticipate that we will need substantial additional funding to support our continuing operations.

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

- The outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals for Trevyent;
- The clinical outcomes, cost and timelines for developing future product candidates beyond Trevyent;
- The costs associated with securing and establishing contract commercialization and manufacturing capabilities;
- Market acceptance of our product candidates;
- The costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- Our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- Our need and ability to hire additional management and scientific and medical personnel;
- The effect of competing technological and market developments;
- Our need to implement and enhance internal systems and infrastructure; and
- The economic and other terms, timing and success of any collaboration, licensing, distribution or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. 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 other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances 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.

There can be no assurance that such additional funding, if available, can be obtained on terms acceptable to us. If we are unable to obtain additional financing, future operations would need to be scaled back or discontinued.

On April 29, 2018 United Therapeutics Corporation and the Company signed a definitive merger agreement under which United Therapeutics will acquire the Company (See also Note 10 to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1).

Government Grants from the Office of the Chief Scientist and Incubator

During the years 2005- 2010 we received grants under the royalty-bearing programs administered by the Israel Innovation Authority (the "IIA"), (previously the Office of the Chief Scientist ("OCS")), and from the Incubator, RAD BioMed Ltd. in Israel. The requirements and restrictions for such grants are found in the Encouragement of Research and Development Law, 5744-1984, and related regulations or, collectively, the R&D Law.

In May 2015, the IIA approved our request to transfer manufacturing rights outside of Israel, noting that the Company would be requested to pay an increased royalty rate without providing any specifics. When revenues are generated from the funded research program, we will be committed to pay royalties on such revenue at a rate of 3% to 4% for the first three years and between 3.5% to 4.5% commencing the fourth year (based on the portion of manufacturing out of Israel while non-product related revenues are subject to the lower end of the ranges) and up to between 150% to 300% of the amount received, linked to the LIBOR. As revenue recognized from the Upfront payment received under the Cardiome agreement in the amount of $3 million, royalties at a rate of 3% of such revenue became payable and were paid. The total amount of grants received from the IIA and the Incubator as of March 31, 2018, is $786 thousand including interest.

In the event that intellectual property rights are deemed to be transferred out of Israel, the grants from the IIA and the Incubator may become loans to be repaid immediately at up to 600% of the grant amounts. Currently, the Company's management believes no intellectual property has been transferred out of Israel and disclosure of the Company's know how is made solely in connection with the transfer of manufacturing rights of the Company's products to subcontractors. Accordingly, no provision has been recorded.

In addition, we must abide by other restrictions associated with receiving grants under the R&D Law that continue to apply following full repayment of the grants to the IIA. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our know-how outside of Israel by requiring us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. In addition, any change of control and any change of ownership of our Ordinary Shares that would make a non-Israeli citizen or resident an "interested party" as defined in the R&D Law requires prior written notice to the IIA. If we fail to comply with the R&D Law, we may be subject to criminal charges.

Contractual Obligations and Commitments

The following table summarizes our monetary contractual obligations and commitments including payables and accrued expenses as of March 31, 2018 (in thousands) and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Total	Less Than a Year	2 - 3 Years	4 - 5 Years	More Than Five Years
Contractual Obligations:					
Operating lease obligations[1]	$ 413	$ 371	$ 42	$ —	$ —
Purchase obligations[2]	3,518	3,518	—	—	—
Employees and payroll accruals	703	703	—	—	—
Other long-term commitment[3]	56	—	—	—	56
Unrecognized tax benefits[4]	385	—	—	—	385
Total contractual cash obligations	$ 5,075	$ 4,592	$ 42	$ 0	$ 441

[1] Represents operating lease costs, consisting of leases for office space in Rehovot, Israel and San Ramon, California. On August 2017, the Company extended its lease agreement for the Israeli offices by 12 months ending December 31, 2018. On May 1, 2015, Inc. signed a lease agreement for new office space in San Ramon, California for a period of three years, which term was increased to four years in an amendment dated May 29, 2015.

[2] Consists of payables and accrued expenses included in our balance sheet as of March 31, 2018 and future monetary obligations resulting from contracts and outstanding purchase orders.

[3] Our obligation for accrued severance pay under Israel's Severance Pay Law as of March 31, 2018 was approximately $211 thousand, of which approximately $155 thousand was funded through deposits in severance pay funds, leaving a net obligation of approximately $56 thousand.

[4] Unrecognized tax benefits under ASC 740-10 "Income Taxes," are due upon settlement and we are unable to reasonably estimate the ultimate amount or timing of settlement.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined SEC rules.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Note 2 to the consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 30, 2018 and Note 3 to the unaudited interim consolidated financial statements enclosed in this report in Part 1 Item 1 describe the significant accounting policies and methods used in the preparation of the Consolidated Financial Statements as of March 31, 2018. Critical accounting policies and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of the matters that are inherently uncertain.

JOBS Act Accounting Election

Section 107 of the Jumpstart Our Business Startups ("JOBS") Act permits emerging growth companies, such as us, to take advantage of the extended transition period in Section 13(a) of the Exchange Act, for adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Issued Accounting Pronouncements

We have reviewed recent accounting pronouncements and concluded that some of them may be applicable to our business in the future and some of them have no material effect on the consolidated financial statements as a result of their future adoption.

1. In February 2016, FASB issued ASU 2016-02-Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840. The standard is effective on January 1, 2019, with early adoption permitted. We are currently anticipates adopting the new standard effective January 1, 2019 and is evaluating the impact of the adoption of this standard on its consolidated financial statements.

2. In May 2017, the FASB issued ASU No. 2017-09, "Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 was issued to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in ASC 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under ASC 718. The amendments in ASU 2017-09 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. The Company is evaluating the impact of the adoption of this standard on its consolidated financial statements.

3. In July 2017, FASB issued ASU No. 2017-11, Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging, which changes the accounting treatment and the earnings per share calculation for certain instruments with down round features. The amendments in this update should be applied using a cumulative-effect adjustment as of the beginning of the fiscal year of adoption or retrospective adjustment to each period presented. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those periods. We are in the process of determining the impact the adoption will have on its consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We have little exposure to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our functional currency is the U.S. dollar, and the majority of our cash is held in U.S. dollars. Part of our expenses is denominated in other currencies, mainly New Israeli Shekels, (NIS), Euro, and Pounds Sterling, and we make currency conversions as needed to settle such liabilities. We do not carry any securities for trading purposes or for investment purposes, so we have no interest rate risk.

Foreign Currency Exchange Risk

Approximately 41% and 48% of our operating expenses in the three months ended March 31, 2018 and 2017 respectively were in non-U.S. Dollar denominated currencies, mainly Israeli Shekel (NIS) and Pounds Sterling (GBP). NIS-denominated expenses consist primarily of Ltd.'s personnel and overhead costs and GBP-denominated expenses consist of R&D subcontractors. Our consolidated results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. Based on 2017 and the three months ended March 31, 2018 segmentation, the effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would have approximately 5% impact on our historical operating expenses.

Inflation Risk

We do not believe that inflation had a material effect on our business, financial condition or results of operations in the last two fiscal years. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through hedging transactions. Our inability or failure to do so could harm our business, financial condition and results of operations.

Segment Information

We have one primary business activity and operate in one reportable segment.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of March 31, 2018, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. 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 are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 9—*Litigation,* to our unaudited interim consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

Item 1A. Risk Factors

Investing in our ordinary shares involves a high degree of risk, including those described below. You should consider carefully the following risks, together with all the other information in this report, including our financial statements, related notes and the statement regarding forward looking statements above. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our ordinary shares could decline and you could lose part or all of your investment.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2017.

Risks Related to our Potential Merger with United Therapeutics Corporation*

If the proposed merger is not completed, our business could be materially and adversely affected and our stock price could decline.*

On April 29, 2018, we entered into a definitive merger agreement with United Therapeutics Corporation and Daniel 24043 Acquisition Corp. Ltd., a wholly-owned subsidiary of United Therapeutics (which we refer to as the Merger Sub), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth therein the Merger Sub will merge with and into the Company, with the Company continuing as the surviving entity and becoming a wholly-owned, indirect subsidiary of United Therapeutics. The transaction is valued at $216 million, including the $75 million in contingent consideration. The merger is subject to customary closing conditions, including approval by SteadyMed's shareholders and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. The merger is expected to be completed in the third quarter of 2018 for a per share price of $4.46 in cash at closing and an additional per share price of $2.63 in cash upon the achievement of a milestone related to the commercialization of Trevyent®.

The merger is subject to customary closing conditions, including approval by SteadyMed's shareholders and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. Therefore, the merger may not be completed or may not be completed as quickly as expected. If the merger agreement is terminated, the market price of our ordinary shares will likely decline, as we believe that our market price reflects an assumption that the merger will be completed. For example, on April 27, 2018, the closing price for our ordinary shares was $2.65, and on the trading day following the announcement of our entering into the merger agreement, our share price increased to a closing price of $4.70 per share. In addition, our share price may be adversely affected as a result of the fact that we have incurred and will continue to incur significant expenses related to the merger that will not be recovered if the merger is not completed. If the merger agreement is terminated under certain circumstances, we may be obligated to pay United Therapeutics a termination fee of $4.5 million. As a consequence of the failure of the merger to be completed, as well as of some or all of these potential effects of the termination of the merger agreement, our business could be materially and adversely affected.

The fact that there is a merger pending could have an adverse effect on our business and results of operations.*

While the merger is pending, it creates uncertainty about our future. We are subject to a number of risks that may adversely affect our business and results of operations, including:

- the diversion of management and employee attention may detract from our ability to to obtain regulatory approval for and, if approved, to successfully commercialize Trevyent in a timely manner;
- we have incurred and will continue to incur significant expenses related to the merger;

- the merger agreement restricts us from engaging in business activities outside of our ordinary course of business without United Therapeutics' permission and, if we determine that doing so would be advantageous and United Therapeutics does not consent, we would not be able to pursue those advantageous activities; and

- we may be unable to respond effectively to competitive pressures, industry developments and future opportunities

If the merger occurs, our shareholders will not be able to participate in any upside to our business other than through the CVRs; if the required commercialization milestone under the CVRs is not achieved, shareholders may not realize any value from the CVRs.*

Upon consummation of the merger, our shareholders will receive a per share price of $4.46 in cash at closing and a contractual contingent value right, or a CVR, to receive an additional per share price of $2.63 in cash if a milestone related to the commercialization of Trevyent® is achieved, but will not receive any shares of United Therapeutics. Even if our business following the merger performs well, our current shareholders will not receive any additional consideration or be able to share in the increased value of our business by virtue of being equity owners. If the milestone related to the commercialization of Trevyent® is not achieved within 5 years, no payment will be made under the CVRs and the CVRs will have no value.

Risks Related to the Development and Commercialization of our Product Candidates

Our success depends heavily on the successful development, regulatory approval and commercialization of our lead product candidate, Trevyent.

We do not have any products that have been granted regulatory approval. We cannot commercialize Trevyent or any other or future product candidates in the United States without first obtaining regulatory approval for the product from the FDA, nor can we or existing or future partners commercialize Trevyent or any other or future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes years to complete and approval is never guaranteed. Specifically, in August 2017, the FDA issued a Refuse to File, or RTF, letter concerning our June 2017 Trevyent NDA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review. In November 2017, we held a Type A meeting with the FDA to discuss the RTF and to gain clarification on the additional information required for resubmission and possible acceptance of the NDA. We expect to resubmit the NDA for the subcutaneous administration of Trevyent during the fourth quarter of 2018. As a result of these and other uncertainties in the FDA review process, our near-term prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for and, if approved, to successfully commercialize Trevyent in a timely manner.

Obtaining regulatory approval for marketing of any product candidate in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Further, because Trevyent combines a drug product and a delivery device, the approval of Trevyent by a regulatory authority will require the review of components that are regulated under different types of regulatory requirements. The need for oversight and review by different bureaus/centers within the regulatory authority could result in time delays with respect to the anticipated marketing approval for Trevyent and additional costs in development and preparation of responses to the regulatory authority while our product submissions are under review.

Even if we were to successfully obtain approval for one or more of our product candidates from the FDA and comparable regulatory authorities outside the United States, any approval might contain significant limitations related to use restrictions or may be subject to burdensome and costly post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue our operations. Also, any regulatory approval of our product candidates, once obtained, may be withdrawn by the regulatory authority.

Furthermore, even if we obtain regulatory approval, commercial success will depend on how successfully we are able to address a number of challenges, including the following:

- Development and ongoing management of our commercial organization in the United States, including management and oversight of third-parties under contract with us to build and manage that organization;

- Establishment of commercial collaborations with partners, including Cardiome Pharma Corporation, our Trevyent partner in Europe;
- Establishment of commercially viable pricing and obtaining approval for adequate reimbursement from third-party and government payors;
- The ability of our third-party manufacturers to manufacture quantities of Trevyent or any other or future product candidates using commercially viable processes at a scale sufficient to meet anticipated demand and that are compliant with applicable regulations;
- Our success in educating physicians, other health care professionals and patients about the benefits, administration and use of Trevyent or any other or future product candidates;
- The availability, actual advantages, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments; and
- The effectiveness of Cardiome's marketing, sales and distribution strategy and operations, and those of other potential commercial collaborators.

Many of these factors are beyond our control. If we or any commercialization partners are unable to successfully commercialize Trevyent, or any future product candidates, we may not be able to earn sufficient revenues to continue our business.

If the FDA does not conclude that Trevyent or our other product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for Trevyent or our other product candidates under Section 505(b)(2) are not as we expect, the approval pathway would likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated and in either case may not be successful.

We will seek FDA approval through the Section 505(b)(2) regulatory pathway for Trevyent and for future product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated for a product, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval, and complications and risks associated with FDA approval, would substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all.

Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that Trevyent or our other product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). For example, several companies have previously petitioned the FDA regarding the constitutionality of allowing others to rely upon FDA findings that are based on their proprietary data. 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 require that we generate full data regarding safety and effectiveness for previously approved active ingredients and delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We also intend to seek approval of any other drug product candidates through the Section 505(b)(2) regulatory pathway. These product candidates, such as our AHPA programs, are at an earlier stage of development than Trevyent and are subject to even greater uncertainty, over what we must do on our development program in order to secure approval under Section 505(b)(2).

We are required to make certifications with respect to certain patents listed in the FDA Orange Book. If the owner of those patents initiates a lawsuit against us, the approval pathway would likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated.*

Because we will resubmit a Section 505(b)(2) NDA to the FDA for Trevyent and we plan to submit a Section 505(b)(2) NDA to the FDA for each of our future product candidates, we will be required to make certifications concerning any patents listed for the reference drug product in the FDA list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. The reference drug product for Trevyent is Remodulin, and there are currently seven patents published in the Orange Book in connection with Remodulin. As such, we will be required to make certifications with respect to the listed patents, including in some instances that Trevyent will not infringe the listed patents and/or that the listed patents are invalid and/or unenforceable. The owner of the listed patents may initiate a patent infringement lawsuit in response to the certifications, which would automatically prevent the FDA from providing final approval of the NDA for Trevyent until the earlier of 30 months after the patent holder's receipt of the certifications, expiration of the listed patents, or a decision in the infringement lawsuit favorable to us.

If the patent owner initiates an infringement lawsuit, the marketing approval of Treyvent in the United States could be significantly delayed and we may face significant costs in defense of the lawsuit. Further, there is no guarantee that we would be successful in defending a patent infringement case. If we are not successful, the FDA cannot grant final approval for Trevyent under Section 505(b)(2) until all listed patents have expired, which could be 2029.

Accordingly, the proposed time frame for marketing approval of Trevyent may be delayed by as long as 30 months, pursuant to an automatic stay, or longer if we have to wait for the expiration of any of the Orange Book patents. This delay could have a significant material adverse effect on our business, prospects and financial condition. Moreover, if there is an adverse outcome in a patent infringement lawsuit, it could result in substantial damages.

United Therapeutics Corporation, the owner of the patents published in the Orange Book in connection with Remodulin, filed a lawsuit against Sandoz, Inc. based on Sandoz's earlier submission of its abbreviated NDA, or ANDA, to the FDA and its certification with respect to the Remodulin patents. On August 29, 2014, the court found that Sandoz infringed one of the patents, patent U.S. Patent No. 6,765,117, and that the effective date of any FDA approval for Sandoz to sell its generic version of Remodulin should be no earlier than the expiration of that patent, which is scheduled to expire on October 24, 2017. The court also found that Sandoz did not infringe other asserted patents. In September 2014, United Therapeutics filed a separate lawsuit filed against Sandoz in the same U.S. District Court, alleging infringement of U.S. Patent No. 8,497,393.

On September 30, 2015, United Therapeutics announced that it had entered into a Settlement Agreement with Sandoz in both cases. Under the Settlement Agreement, United Therapeutics granted to Sandoz a non-exclusive license to manufacture and commercialize the generic version of Remodulin, as described in Sandoz's ANDA filing, in the United States beginning on June 26, 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Sandoz any rights other than those required to launch Sandoz's generic version of Remodulin. In accordance with the Settlement Agreement, the parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

United Therapeutics also filed a lawsuit against Teva Pharmaceuticals USA, Inc. on September 2, 2014, alleging infringement of five United Therapeutics patents based on Teva's submission of its ANDA to the FDA seeking approval of a generic form of Remodulin. On January 15, 2016, United Therapeutics announced that it had entered into a Settlement Agreement with Teva. Under the Settlement Agreement, United Therapeutics granted Teva a non-exclusive license beginning on December 23, 2018 to manufacture and commercialize in the United States, the generic version of Remodulin described in Teva's ANDA, although Teva may be permitted to enter the market earlier under certain circumstances.

Teva and Sandoz relied on ANDAs, which were required to have the same labeling to the referenced listed drug, Remodulin. A 505(b)(2) NDA applicant, such as for our NDA for Trevyent, does not have these same requirements. We are not seeking approval as a generic to be automatically substituted for Remodulin, as would be the case for ANDAs. The likelihood of United Therapeutics filing suit against us is therefore not determined by their actions with respect to Sandoz and Teva; however, there can be no assurances that a lawsuit will not be filed against us.

In October 2015, we filed an Inter Partes Review with the Patent Trial and Appeal Board, or PTAB, of the United States Patent and Trademark Office to invalidate the U.S. Patent No. 8,497,393 granted to United Therapeutics. This patent relates to a process to prepare prostacyclin derivatives such as treprostinil. Treprostinil is used in Trevyent. The PTAB initiated the Inter Parties Review in April 2016 and on March 31, 2017, the PTAB ruled in our favor, invalidating all of the claims of the '393 patent. United Therapeutics appealed the ruling to the Circuit Court of Appeals in Washington, D.C., and a hearing on the matter was held on November 7, 2017. On November 14, the Court of Appeals upheld the PTAB ruling in our favor without issuing an opinion. On February, 9, 2018, United Therapeutics filed a writ of certiorari with the U.S. Supreme Court asking for a review of the appellate ruling in view of another case pending before the Supreme Court challenging the constitutionality of Inter Partes Review proceedings. On April 24, 2018, the Supreme Court, in the other case pending, found Inter Partes Review is constitutional, and rejected the challenge. In view of that decision, SteadyMed has asked United Therapeutics to withdraw its petition, and United has agreed to do so.

In March 2017, United Therapeutics was issued two continuation patents to the '393 patent discussed above, U.S. Patent No. 9,593,066 and 9,604,901. In July 2017, United Therapeutics was issued U.S. Patent No. 9,713,599 concerning Remodulin. We will be required to make certifications with respect to these three new patents in our NDA for Trevyent. If United Therapeutics chooses to litigate these patents, management is hopeful these patents will be invalidated like the '393 patent or we will be found not to have infringed them, but there can be no assurance of ultimate success in this regard.

The regulatory approval processes of the FDA and comparable authorities outside the United States are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable authorities outside the United States is unpredictable and typically takes many years. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of any clinical trials that we propose to conduct or require us to conduct additional clinical trials;
- We may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- The FDA or comparable regulatory authorities outside the United States may disagree with our interpretation of data from preclinical studies or clinical trials;
- The data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- The FDA or comparable regulatory authorities outside the United States may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- The approval policies or regulations of the FDA or comparable regulatory authorities outside the United States may change significantly in a manner rendering our clinical data insufficient for approval.

Specifically, in August 2017, the FDA issued a Refuse to File letter to us concerning our June 2017 Trevyent NDA. The FDA determined that our NDA was not sufficiently complete to permit a substantive review. In November 2017, we had a Type A meeting with the FDA to discuss the letter and to gain clarification on the additional information required for resubmission and acceptance of the NDA. The meeting was constructive and management believes that we will be able to sufficiently address the FDA's concerns, and re-submit the NDA during the fourth quarter of 2018.

Failing to obtain regulatory approval to market any of our product candidates would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, such regulatory approval may be for more limited indications than we request, may impact the price we intend to charge for our products, may be contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates in one or more jurisdictions, our revenue will be dependent, to a significant extent, upon the size of the markets in the jurisdictions for which we gain regulatory approval.

Even if Trevyent and our other or future product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, pharmacies, hospital administrators, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

Some of the existing therapies for PAH have well-established market positions and familiarity with physicians, healthcare payors and patients. If we are unable to achieve significant differentiation for Trevyent from existing and widely accepted therapies for PAH, our opportunity for Trevyent to be commercialized successfully, if approved, would be adversely affected.

If Trevyent or any future product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, pharmacies, hospital administrators, patients, caregivers, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- convenience and ease of administration of the product candidates compared to alternative treatments;
- the prevalence and severity of any side effects;
- their efficacy and potential advantages compared to alternative treatments;
- the willingness of physicians, nurses, pharmacies and other health care providers to change their current treatment practices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the strength of marketing and distribution support; and
- the price we charge for our product candidates.

Trevyent has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale.

We have never manufactured Trevyent on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for Trevyent there is no assurance that our manufacturer will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand.

If our suppliers are unable to produce sufficient quantities of any approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Trevyent may fail to offer material commercial advantages over other injectable prostacyclin therapies.

The convenience and possible safety advantages that we believe Trevyent would offer, if approved by regulatory authorities, may fail to materialize, or may not be recognized by patient, caregivers or physicians. For example, patients may have invested significantly in pumps and equipment and be comfortable with their preparation of other injectable prostacyclin therapies, such as Remodulin, making it more difficult to convince a prescribing physician that these patients should switch to Trevyent. We do not have clinical evidence that removal of meta-cresol from our formulation of treprostinil will reduce or eliminate the experience of injection site reaction seen with Remodulin when administered subcutaneously. The convenience advantages of Trevyent may not be sufficient to either move market share to us or expand the population of PAH patients being prescribed treprostinil.

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 specialty pharmaceutical products is highly competitive. We face competition with respect to Trevyent, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell PAH and pain management products to our target patient groups. These companies typically have a greater ability to reduce prices for their competing drugs in an effort to gain or retain market share and undermine the value proposition that we might otherwise be able to offer to payors. 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.

For Trevyent, we expect to compete with existing infusion treatments for PAH patients with Class II-IV symptoms as well as known products under development, including Remodulin (treprostinil) sold by United Therapeutics and other prostacyclins such as Veletri (epoprostenol) sold by Actelion Ltd., Flolan (epoprostenol) sold by GlaxoSmithKline PLC, and generic epoprostenol sold by Teva Pharmaceutical Industries Ltd. In addition, Sandoz and Teva have filed an ANDA for a generic form of treprostinil, which we expect will be launched in the second half of 2018.

Under a separate collaboration between United Therapeutics and Medtronic, Inc., a specially designed delivery catheter is being developed to enable use of an implantable pump, the Synchromed pump, for the delivery of treprostinil. This collaboration is subject to settlement of a consent decree between Medtronic and the FDA regarding the Synchromed pump and the resolution of a Class I recall for that pump. In addition, use of the Synchromed pump for the delivery of treprostinil is subject to regulatory approval and the FDA informed Medtronic in March 2016 that its premarket approval application was not approvable as submitted. Medtronic's premarket approval application, or PMA, for the device was approved by the FDA in December 2017. United Therapeutics resubmitted its NDA for the use of Remodulin in the implantable pump on January 30, 2018, and anticipates a two-month review period. In January 2015, United Therapeutics further announced that it had entered into an agreement with DEKA Research & Development Corp. for the development of a prefilled, semi-disposable pump system for the subcutaneous delivery of Remodulin, known as RemUnity. United Therapeutics is currently engaged in engineering, design and development efforts to optimize the RemUnity system to deliver treprostinil in pre-filled reservoirs, and intends to complete human factor studies and functionality testing in subjects before submitting an application to the FDA to approve the pre-filled RemUnity system. If approved, RemUnity would be in direct competition with Trevyent.

United Therapeutics is also engaged in pre-clinical development of a new prodrug of treprostinil called RemoPro, which is intended to enable subcutaneous delivery without the site pain currently associated with subcutaneous Remodulin. A prodrug is a metabolically inactive compound that, after administration, metabolizes into an active compound. RemoPro is intended to be inactive in the subcutaneous tissue, which should decrease or eliminate site pain. Once RemoPro is absorbed into the blood, it metabolizes into treprostinil.

Many of our competitors, including United Therapeutics and other large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. There may also be companies unknown to us that are engaged in the development of products that are potentially competitive with those that we are developing. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our ordinary shares.

Our operations to date have been limited to developing Trevyent, our enabling PatchPump technology, and, to a much lesser extent, our AHPA product candidates. In addition, as a development-stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. Nor have we demonstrated an ability to obtain regulatory approval for or to commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing a significant number of pharmaceutical products.

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

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused principally on Trevyent. As a result, we may forego or delay pursuit of opportunities with other product candidates, including our AHPA products, or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We rely, or intend to rely, on third parties to manufacture Trevyent. The development and commercialization of our product candidates could be stopped or delayed if any such third party fails to provide us with sufficient quantities of product or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.

We lack the resources and the capability to manufacture Trevyent. Instead, we rely on our third-party contract manufacturers, component fabricators and secondary service providers. The facilities used by our third-party contract manufacturers, component fabricators and secondary service providers must successfully pass inspections by the applicable regulatory authorities, including the FDA, after we resubmit our NDA to the FDA and if it is accepted for filing by the FDA. We are currently completely dependent on our third-party contract manufacturers, component fabricators and secondary service providers for the production of Trevyent in accordance with applicable guidelines and regulations, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

Although we have entered into an agreement for the development and manufacture of certain Trevyent components and for registration lot production our third-party manufacturers may not perform as agreed, may be unable to comply with these applicable guidelines and regulations and with FDA, state and foreign regulatory requirements or may terminate their agreements with us. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, our NDA and MAA will not be approved. In addition, although we are ultimately responsible for ensuring product quality, we have no direct day-to-day control over our third-party manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. If our third-party manufacturers are unable to satisfy the regulatory requirements for the manufacture of our products, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities. The number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. We might be unable to identify manufacturers for long-term commercial supply on acceptable terms or at all. Manufacturers are subject to ongoing periodic announced and unannounced inspections by the FDA and other governmental authorities to ensure compliance with government regulations. If the FDA or other regulatory authority has any concerns following an inspection of these manufacturing facilities, the facility may be ordered to cease operations until such issues are resolved, which could have a material adverse effect on our business.

The active pharmaceutical ingredient, or API, for Trevyent will be manufactured for us by a third-party manufacturer using a unique, patented method of synthesis. We do not have an exclusive relationship with this manufacturer, which means this manufacturer could sell the treprostinil API to our competitors, which may have their own delivery systems and could compete against Trevyent. If for any reason this third-party manufacturer is unable to supply API for Trevyent to us, we do have a back-up supplier of AP Trevyent.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers, component fabricators and secondary service providers must comply with applicable guidelines and regulations.

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced U.S. federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our contract manufacturers, component fabricators or secondary service providers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers, component fabricators or secondary service providers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Any adverse developments affecting commercial manufacturing of our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products or product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products or product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, prospects, financial condition and results of operations.

We will need to rely on third-party specialty channels to distribute Trevyent to patients. If we are unable to effectively establish and manage this distribution process, the commercial launch and sales of Trevyent may be delayed or compromised.

We plan to contract with and rely on third-party specialty pharmacies to distribute Trevyent. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions, which require a high level of patient education and ongoing management. If we are unable to effectively establish and manage this distribution process, the commercial launch and sales of Trevyent will be delayed or compromised and our results of operations may be harmed.

In addition, the use of specialty pharmacies involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using our product candidates, or complaints regarding our product candidates;
- not effectively sell or support our product candidates;
- reduce or discontinue their efforts to sell or support our product candidates;
- not devote the resources necessary to sell our product candidates in the volumes and within the time frames that we expect; or
- cease operations.

Any such events may result in decreased sales and lower revenue, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Coverage and reimbursement may not be available, or may be available at only limited levels, for our product candidates, which could make it difficult for us to sell our product candidates profitably, if approved.

Market acceptance and sales of our product candidates will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures. Successful commercialization of Trevyent, our AHPA product candidates or other product candidates will depend in part on the availability of governmental and third-party payor reimbursement for the cost of our product candidates. Government authorities, private health insurers and other organizations establish coverage and reimbursement policies for new products. In particular, in the United States, the Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and other medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, became law in the United States. ACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include: the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of 2% per fiscal year starting in 2013 and, due to subsequent legislative amendments to the statute, the reductions will stay in effect through 2025, unless additional congressional action is taken; and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and any new healthcare reform measures may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency with which any such drug candidate is prescribed or used.

Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the cost of prescription pharmaceuticals has been the subject of considerable discussion, and members of Congress and the Trump administration have stated that they will address such costs through new legislative and administrative measures. At the state level, legislatures are increasingly 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.

We expect that these health care reforms, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare, Medicaid and other health care 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, Medicaid or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements.

We expect to experience pricing pressures in connection with the sale of Trevyent and our other product candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, prospects, financial condition and results of operations.

We currently have no sales representatives or distribution personnel and limited marketing capabilities. If we are unable to develop directly or indirectly a sales and marketing and distribution capability, we will not be successful in commercializing Trevyent or other or future product candidates.

We have not yet built out an infrastructure to sell, market or distribute therapeutic products. If Trevyent is approved, we intend to commercialize Trevyent with contractual support from inVentiv Healthcare in the United States and through Cardiome in Europe, the Middle East and Canada. If any other or future product candidates are approved we may commercialize them directly and/or through commercial partners in the United States and with commercial partners outside of the United States. There are risks involved with both establishing our own sales and marketing and distribution capabilities and entering into third-party arrangements to perform these services. For example, we or our partners may not be successful in recruiting and training a sales force, which is expensive and time-consuming. In such case, the Trevyent product launch could be delayed.

We may be unable to identify appropriate commercial partners to distribute our products outside the United States or to negotiate terms with such commercial partners that are favorable or acceptable to us. Also, we may be unable to maintain those relationships. The inability to identify, successfully negotiate with, and maintain relationships with, commercial partners for distribution outside the United States could limit and/or delay our ability to commercialize our products outside the United States.

If we obtain approval to commercialize any of our product candidates outside the United States, we will be subject to additional risks.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in countries outside the United States;
- reduced protection for intellectual property rights;
- unexpected changes in 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;
- non-U.S. taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our chief executive officer and the other principal members of our executive team. Under the terms of their employment, our executives may terminate their employment with us at any time, and in fact, in November 2017, our Executive Vice President and Chief Operating Officer resigned his position with us. The loss of the services of any executive officer could impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified and experienced scientific, clinical, manufacturing and sales and marketing personnel 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. 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 employers or engaged by entities other than us and may have commitments under employment, consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our sales and marketing capabilities, and our company generally, in advance of commercialization of Trevyent, if approved, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of April 30, 2018, we had 24 full-time employees. Beginning in 2019, and in anticipation of commercialization of Trevyent, if approved, we expect to experience significant growth in the number of our employees and the scope of our operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;

- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing our company. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are an "emerging growth company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our 2015 initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means, among other things, that the market value of our ordinary shares that are held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these reduced requirements. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Guidelines and recommendations published by various organizations can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of therapies. Recommendations or guidelines suggesting the reduced use of our product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates.

Even if we receive regulatory approval for Trevyent and our other or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

Any regulatory approvals that we may receive for our product candidates will contain approved indicated uses, and we will be required to market any approved products in accordance with the indicated uses and our approved labeling. In addition, any regulatory approvals may contain conditions for approval or requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable regulatory authority outside the United States approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, Quality System Regulation, or QSR, requirements and current good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, the imposition of civil penalties or criminal prosecution.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. If we are not able to maintain regulatory compliance or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, regulatory sanctions may be applied or we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- foreign and state law equivalents of each of the above federal laws, such as the U.S. Foreign Corrupt Practices Act, or FCPA, anti-kickback and false claims laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws or regulations described above, comparable laws and regulations of non-U.S. jurisdictions or any other 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 ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any marketing approval.

It is impossible to predict when or if any of our product candidates will prove safe enough to receive regulatory approval. Undesirable side effects could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable regulatory authority outside the United States for the affected product candidate. Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend the marketing of such product;

- regulatory authorities may withdraw their approvals of such product;

- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;

- the FDA or other regulatory bodies may issue safety alerts, "Dear Healthcare Provider" letters, press releases or other communications containing warnings about such product;

- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies, or REMS, or a comparable regulatory authority outside the United States may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome and costly implementation requirements on us;

- we may be required to change the way the product is administered or conduct additional clinical trials;

- we could be sued and held liable for harm caused to subjects or patients;

- we may be subject to litigation or product liability claims; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion, or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we are able to commercialize any of our product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for specialty pharmaceutical products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some markets outside the United States, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue 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 regulatory approval.

Our ability to commercialize Trevyent or any other or future product candidates successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these 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 companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products 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 products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new 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. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our approved products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and establishing requirements for promotion.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products or otherwise to have improperly promoted our products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. It is also required to provide pertinent safety information about a product. If we are found to have promoted such off-label uses, or not to have provided adequate safety information, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and other forms of improper promotion. The United States government has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in 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 regulatory authorities outside the United States, provide accurate information to the FDA or comparable foreign 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 foreign regulatory authorities, comply with the FCPA and other anti-bribery laws, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We will adopt a code of conduct for our directors, officers and employees, or the Code of Business Conduct and Ethics, which will be effective as of consummation of this offering, but 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 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 harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures, co-promotion agreements or marketing collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership or marketing agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to any of our future product candidates. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;

- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

While we hold product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. 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.

We are subject to laws and regulations governing corruption, which will require us to develop and implement costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery and other unethical business practices, including the FCPA and anti-bribery and anti-corruption laws in other countries. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

Anti-bribery laws prohibit us, our employees and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence their performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice, or DOJ. The Securities and Exchange Commission, or the SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials; furthermore, in certain countries, hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials and have led to vigorous anti-bribery law enforcement actions imposing heavy fines in multiple jurisdictions.

It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers, distributors or their third party agents in connection with the prescription of certain pharmaceuticals. If our employees, affiliates, distributors or third party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations.

If we expand our operations, we may need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, encompass provisions relating to books and records that will apply to us as we become a public company and include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, the distraction of company personnel, legal defense costs and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us.

Our business involves the use of hazardous materials, and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

We and our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers are subject to United States federal, state and local as well as foreign laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state, federal or foreign authorities may curtail the use of hazardous materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected. In the future we may seek to establish longer term third-party manufacturing arrangements, pursuant to which we would seek to obtain contractual indemnification protection from such third-party manufacturers potentially limiting this liability exposure.

Business interruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, systems failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business interruptions could seriously harm our business and financial condition and increase our costs and expenses. Our management operates in our principal executive offices located in San Ramon, California. If our offices were affected by a natural or man-made disaster, particularly those that are characteristic of the region, such as wildfires and earthquakes, or other business interruption, our ability to manage our domestic and foreign operations could be impaired, which could materially and adversely affect our results of operations and financial condition. We currently rely, and intend to rely in the future, on our third-party manufacturers, to produce our supply of Trevyent or our AHPA product candidates. Our ability to obtain supplies could be disrupted, and our results of operations and financial condition could be materially and adversely affected if the operations of our third-party manufacturers were affected by a man-made or natural disaster or other business interruption. The ultimate impact of such events on us, our significant suppliers and our general infrastructure is unknown.

Under applicable employment laws, we may not be able to enforce covenants not to compete, and may, therefore, be unable to prevent competitors from benefiting from the expertise of some of our former employees involved in research and development activities.

We generally enter into non-competition agreements with our employees in Israel. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period following termination of employment. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees developed while working for us. For example, Israeli labor courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the protection of a company's trade secrets or other intellectual property. If we cannot demonstrate that harm would be caused to us, an Israeli court may refuse to enforce our non-compete restrictions or reduce the contemplated period of non-competition such that we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

Risks Related to Our Financial Condition and Need for Additional Capital

Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern and our auditors issued a "going concern" audit opinion in their report on our financial statements.

Our independent auditors have indicated in their report on our audited consolidated financial statements as of December 31, 2017, which are included in this report, that there is substantial doubt about our ability to continue as a going concern. A "going concern" opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. As of this Quarterly Report on Form 10-Q, the circumstances have not been changed and therefore the aforementioned going concern situation remains current. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

We need to raise additional capital in early 2019 to execute our current operating plan. If we fail to obtain additional financing, we would be forced to delay the development and, if approved, commercialization of our lead product candidate, Trevyent, or liquidate the company.

We are a development stage company with limited operating history. To date, we have focused primarily on developing our lead product candidate, Trevyent, our enabling PatchPump technology. While we believe that we have the financial resources to obtain FDA approval of Trevyent, we will need significant, additional capital to commercialize Trevyent, if approved, and to develop other product candidates, such as our AHPA programs. As of March 31, 2018, we had cash and cash equivalents (excluding restricted cash of $0.015 million) of $26.6 million and working capital of $23.9 million.

In April 2017, we raised approximately $28.1 million of net proceeds from the sale of our ordinary shares and warrants to purchase our ordinary shares in a private placement. Based on our current operating plan, we expect that the net proceeds from the April private placement, together with our existing cash and cash equivalents as of March 31, 2018, will enable us to fund our operating expenses through at least for the next 12 months since the filing date of this unaudited unterim financial statements on Form
10-Q. For a description of the terms of this private placement, see "Management's Discussion and Analysis—Liquidity and Capital Resources—Sources of Liquidity— *Recent Private Placement Financing*".

We will need to raise additional capital in early 2019 to execute our current operating plan. Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to operate our business, including our ability to develop and commercialize our product candidates.

We cannot guarantee that additional capital will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital, when required in 2019 or thereafter in the future, or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of Trevyent;
- seek corporate partners for Trevyent or our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- significantly curtail, or cease, operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to use, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse impact on our business operating results and prospects, including possible liquidation of the company.

In addition, we have secured, and may continue to secure, additional capital using credit facilities and other debt, and may substantially increase our reliance on such debt in the future. Such debt may be secured by a portion or substantially all of our assets. If we do not repay such indebtedness in a timely fashion, secured lenders could declare a default and foreclose upon our assets, which would result in harmful disruption to our business, the sale of assets for less than their fully realizable value, and possible bankruptcy. Such credit facilities also typically include several operational and financial covenants. If we fail to comply with the covenants and our other obligations under any credit facility, the secured lenders would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets, which would result in harmful disruption to our business, the sale of assets for less than their fully realizable value, and possible bankruptcy. In addition, future credit facilities may limit our ability to incur incremental debt without our lenders' permission.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares by us will result in additional dilution of the percentage ownership of our shareholders and may cause our share price to decline.

Until such time, if ever, as we can generate substantial product revenues, we expect that significant additional capital will be needed to continue our planned operations, including conducting clinical trials, commercialization efforts, expanding research and development activities and costs associated with operating as a public company. We may sell ordinary shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders and new investors. In addition, new shareholders could gain rights superior to our existing shareholders.

For example, in August 2016, we issued and sold in a private placement an aggregate of 6,554,016 ordinary shares, plus warrants to purchase up to an additional 6,554,016 ordinary shares, and in April 2017, we issued and sold in a private placement an aggregate of 5,031,550 ordinary shares, plus warrants to purchase up to an additional 2,515,775 ordinary shares. These share issuances resulted in dilution to our existing shareholders and any exercise of the warrants issued in these private placements will result in additional dilution of our existing shareholders. For a description of the terms of these private placements, see "Management's Discussion and Analysis—Liquidity and Capital Resources—Sources of Liquidity—*Recent Private Placement Financing* ".

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred significant net losses in each year since our inception, including net losses of $7.9 million, $19.0 million, $25.0 million, $25.9 million and $23.2 million for fiscal years 2013, 2014, 2015, 2016 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $122.7 million.

We have devoted most of our financial resources to product and technology development. To date, we have financed our operations primarily through the sale of equity securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success inside and outside the United States.

We expect to continue to incur substantial and increased expenses as we launch and commercialize Trevyent, if approved. We also expect a further increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

We have never generated any revenue from sales of our product candidates and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We do not anticipate generating revenue from sales of our product candidates for the foreseeable future, if ever.

Our ability to generate future revenue from product sales depends heavily on our success in:

- completing development of Trevyent;
- obtaining regulatory approval for Trevyent; and
- launching and commercializing Trevyent, either by building our own targeted sales force or by collaborating with third parties.

Even if Trevyent is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current service providers or our manufacturers may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

The termination or reduction of tax and other incentives that the Israeli government provides to us may increase the costs involved in operating a company in Israel.

We may be eligible for certain tax benefits provided to "Beneficiary Enterprises" under the Israeli Law for the Encouragement of Capital Investments, 5719-1959, referred to as the Investment Law. In order to be eligible for the tax benefits for "Beneficiary Enterprises," we must meet certain conditions stipulated in the Investment Law and its regulations, as amended. If we do not satisfy these conditions, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies was 26.5% for 2014 and 2015, and reduced to 25% for 2016 and for 24% for 2017 and 23% for 2018 and thereafter. Even if we were to become eligible for these tax benefits, they may be reduced, cancelled or discontinued. See "Israeli Tax Considerations and Government Programs—Tax Benefits under the Law for the Encouragement of Capital Investments, 5719-1959."

Adverse tax laws or regulations could be enacted or existing laws could be applied to us or our customers, which could increase the costs of our services and adversely impact our business.

The application of U.S. federal, state and local tax laws and of international tax laws to our industry is evolving. For example, on December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our ordinary shares is also uncertain and could be adverse. We urge our shareholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ordinary shares.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our market.

As of April 25, 2018, our intellectual property portfolio included six issued U.S. patents, as well as one allowed U.S. application, 15 issued foreign patents, as well as one allowed foreign application, 10 U.S. pending applications and 17 foreign pending applications relating to our PatchPump technology. The strength of patents in the life sciences field involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications, which can invalidate a patent or prevent a patent from issuing based on a pending patent application, has been found. Our patents and patent applications all relate to our PatchPump technology. The drug molecules that we will deliver using the PatchPump are generics. We cannot prevent our competitors from developing products that make use of the same drugs, so long as they do not infringe our PatchPump technology patents or the patents of our API suppliers. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated, which could adversely affect our ability to establish market share or successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our patent claims. If the patent applications we hold with respect to our PatchPump technology fail to issue or if the breadth or strength of protection of our patents or patent applications is threatened, competitors could directly compete against our products and we would have no recourse.

We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found valid and enforceable or will be unthreatened by third parties or will offer adequate coverage of our products. Further, if we encounter delays in regulatory approvals, the period of time during which we could market Trevyent, or our other product candidates under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent any patent application related to our PatchPump technology. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In the United States, the natural expiration of a maintained patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Once the patent life has expired for our PatchPump technology, we may be open to competition from competitors that will be able to freely use our technology described in our expired patent(s).

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or which we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, our competitors may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Changes in either the patent laws or interpretations of the patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or U.S. PTO, has developed new and generally untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the U.S. PTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. Further, the laws of some foreign countries do not tend to protect proprietary rights to the same extent or in the same manner as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement may not be as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. We may be unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, and therefore we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to pursue infringement litigation, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, 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. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the initiation of claims, or of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our PatchPump technology, our competitors might be able to enter the market using technology previously covered by such patents or patent applications, which would have a material adverse effect on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture Trevyent and intend to rely on third parties for the manufacture of our other or future product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

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

We employ individuals who were previously employed at other biotechnology, pharmaceutical and medical device companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our PatchPump technology. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We have invested and expect to continue to invest a significant amount of resources in the development of intellectual property by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions.

Recent decisions by the Committee have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. Further, the Committee has not yet determined the method for calculating this remuneration nor the criteria or circumstances under which an employee's waiver of his or her right to remuneration will be disregarded. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

We may be subject to other intellectual property litigation.

We may be subject to other intellectual property litigation. For example, a competitor or another intellectual property rights owner may assert that our products, or the operation of our business, infringe their intellectual property. Our involvement in intellectual property litigation could result in substantial costs and be a distraction to management and other employees and could adversely affect the sale of any products involved or the use or licensing of related intellectual property, even if we are successful in the litigation. In the event of an adverse result, we may, among other things, be subject to payment of substantial damage payments; cease the development, manufacture, use, sale or importation of products that infringe on another party's intellectual property rights; discontinue processes incorporating the infringing technology; expend significant resources to develop or acquire non-infringing intellectual property; or obtain licenses to the relevant intellectual property. We cannot offer any assurance that we will be successful in any intellectual property litigation or, if we were not successful in such litigation, that licenses to the intellectual property we are found to be infringing would be available on commercially reasonable terms, if at all. The cost of intellectual property litigation as well as the damages, licensing fees or royalties that we might be required to pay, could have a material adverse effect on our business.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, or other limitations of intellectual property rights result in inadequate protection for our business, they could significantly harm our business, results of operations and prospects.

Risks Related Our Ordinary Shares

Our share price is and may continue to be volatile, and purchasers of our ordinary shares can incur substantial losses.

Our share price is and is likely to remain volatile. The stock market in general and the market for specialty pharmaceutical companies in particular have experienced extreme 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 the following:

- our potential acquisition by United Therapeutics;
- trading volume of our ordinary shares;
- sales of our ordinary shares by us or our shareholders;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- the success of competitive products or technologies;
- the outcomes of any clinical or non-clinical studies regarding our current and future product candidates;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our ordinary shares, other comparable companies or our industry generally;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of The Nasdaq Stock Market, or Nasdaq, and provisions of the Companies Law that apply to public companies such as us. Compliance with the various reporting and other requirements applicable to public companies require considerable time and attention of management and significantly increase our legal, accounting and other expenses. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our shares could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act.

This, in turn, could have an adverse impact on trading prices for our ordinary shares and could adversely affect our ability to access the capital markets.

An active trading market for our ordinary shares may not develop.

Our ordinary shares are currently traded on Nasdaq Global Market, but we can provide no assurance that we will be able to maintain an active trading market for our shares on Nasdaq or any other exchange in the future. If an active market for our ordinary shares does not develop, it may be difficult for our shareholders to sell shares without depressing the market price for the shares or at all.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our share price and trading volume could decline.

The trading market for our ordinary shares will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

Because we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, capital appreciation, if any, will be our shareholders' sole source of gain.

We have never declared or paid cash dividends on our share capital. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our ordinary shares will be our shareholders' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends and may subject our dividends to Israeli withholding taxes.

Our principal shareholders and management own a significant percentage of our shares and will be able to exert significant control over matters subject to shareholder approval.

As of March 31, 2018, our executive officers, directors and 5% shareholders beneficially owned an aggregate of approximately 82.7% of our outstanding voting shares (including our outstanding warrants, vested stock options and those vesting within 60 days of March 31, 2018). These shareholders may have the ability to influence us through this ownership position. These shareholders may be able to determine all matters requiring shareholder approval. For example, they may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may feel are in your best interest as one of our shareholders.

Sales of a substantial number of our ordinary shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of our ordinary shares in the public market or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ordinary shares.

We may be a passive foreign investment company, which may result in adverse U.S. federal income tax consequences for U.S. Holders of our ordinary shares.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Our status as a PFIC may also depend on how quickly we use the cash proceeds from this offering in our business. Based on the nature of our current and expected income and the current and expected value and composition of our assets, we do not expect that we will be classified as a PFIC for the taxable year ending December 31, 2017. However, because PFIC status is determined on an annual basis and generally cannot be determined until the end of the taxable year, there can be no assurance that we will not be a PFIC for the current or future taxable years. If we are characterized as a PFIC, our shareholders who are U.S. Holders (as defined in "Material U.S. Federal Income Tax Considerations") may suffer adverse tax consequences, including the treatment of gains realized on the sale of our ordinary shares as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders, and the addition of interest charges to the tax on such gains and certain distributions. A U.S. shareholder of a PFIC generally may mitigate these adverse U.S. federal income tax consequences by making a "qualified electing fund" election, or, to a lesser extent, a "mark to market" election. However, we do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares by us pursuant to our equity incentive plans could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.

Pursuant to our Amended and Restated 2009 Stock Incentive Plan, our management is authorized to grant options to purchase our ordinary shares to our employees, directors and consultants. The number of shares available for future grant under our stock option plans will automatically increase on January 1st of each year, from January 1, 2017 through January 1, 2024, by an amount equal to four percent of all shares of our share capital outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our stock option plans each year, our shareholders may experience additional dilution, which could cause our share price to decline.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We may become obligated to pay liquidated damages if we fail to file, obtain effectiveness and maintain effectiveness of a registration statement pursuant to the requirements of the registration rights granted to the investor in our August 2016 and April 2017 private placements.

Under the subscription agreement we entered into in connection with our August 2016 private placement, we registered an additional 13,108,032 ordinary shares (including 6,554,016 ordinary shares underlying the warrants). If we are unable to maintain the effectiveness of the registration statement, we must pay liquidated damages in an amount equal to 1.0% of the aggregate purchase price of the securities for each 30-day period until we are able to comply with such obligations, subject to a maximum limit of 5% of the aggregate purchase price of the securities. Under certain circumstances, the registration statement can be suspended for up to two, 30-day periods without the payment of damages.

Under the subscription agreement we entered into in connection with our April 2017 private placement, we registered an additional 7,547,325 ordinary shares (including 2,515,775 ordinary shares underlying the warrants). If we are unable to maintain the effectiveness of the registration statement, we must pay liquidated damages in an amount equal to 1.0% of the aggregate purchase price of the securities for each 30-day period until we are able to comply with such obligations, subject to a maximum limit of 5% of the aggregate purchase price of the securities. Under certain circumstances, the registration statement can be suspended for up to two, 30-day periods without the payment of damages.

Risks Related to Our Operations in Israel

A significant portion of our R&D operations are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel.

Our business and operations may be directly influenced by the political, economic and military conditions affecting Israel at any given time. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. In recent years, these have included hostilities between Israel and Hezbollah in Lebanon and Hamas in the Gaza strip, both of which resulted in rockets being fired into Israel causing casualties and disruption of economic activities. Most recently, in July and August 2014, an armed conflict took place between Israel and Hamas, and since September 2015, there has been an increase in sporadic terror incidents conducted by individuals not necessarily associated with terror organizations. In addition, Israel faces threats from more distant neighbors, in particular, Iran and ISIS. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflict involving Israel could adversely affect our operations and results of operations.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to sell our products.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our revenues to decrease and adversely affect the share price of publicly traded companies having operations in Israel, such as us.

Our operations could be disrupted as a result of the obligation of our personnel to perform military service.

As of May 15, 2018, we had 13 full-time employees based in Israel, certain of whom may be called upon to perform up to 54 days in each three year period (and in the case of non-officer commanders or officers, up to 70 or 84 days, respectively, in each three year period) of military reserve duty until they reach the age of 40 (and in some cases, depending on their specific military profession up to 45 or even 49 years of age) and, in certain emergency circumstances, may be called to immediate and unlimited active duty. Our operations could be disrupted by the absence of one or more of these employees related to military service. Any such disruption could adversely affect our business, results of operations and financial condition.

We received Israeli government grants for certain research and development activities. The terms of the grants require us to satisfy specified conditions and to pay penalties in addition to repayment of the grants upon certain events.

Our research and development efforts were financed in part through grants from the IIA and RAD, in Israel. During 2005 and 2006, we received grants from the IIA and RAD with an aggregate total of approximately $786,000, including accrued LIBOR interest. As of March 31, 2018, there are no accrued royalties to the IIA.

Even following full repayment of any IIAgrants, we must nevertheless continue to comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 5744-1984, and related regulations, or collectively, the R&D Law. When a company develops know-how, technology or products using IIAgrants, the terms of these grants and the R&D Law restrict the transfer outside of Israel of such know-how, and the manufacturing or manufacturing rights of such products, technologies or know-how, without the prior approval of the IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIAfunding, the discretionary approval of an IIAcommittee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. We have applied for and received an approval from the IIAto transfer manufacturing of products developed under the programs financed by the IIAoutside of Israel to our subcontractors, subject to payment of an increased royalty rate and increased payment cap, in accordance with the royalties regulations described below. The actual rate of the increased royalty payments and cap were not determined by the IIA. The approval is also subject to maintaining all ownership rights regarding all of our intellectual property and know-how under SteadyMed Ltd. In Israel. Furthermore, the IIAmay impose certain conditions on any arrangement under which it permits us to transfer technology or development outside of Israel, which conditions may not be acceptable to us.

The transfer of IIA-supported technology or know-how or manufacturing or manufacturing rights related to aspects of such technologies outside of Israel may involve the payment of significant penalties and other amounts, depending upon the value of the transferred technology or know-how, the amount of IIAsupport, the time of completion of the IIA-supported research project and other factors. We may be required to pay an increased total amount of royalties, which may be up to 300% of the grant amounts (depending on the manufacturing percentage that is performed outside of Israel) plus interest, in case of manufacturing the developed products outside of Israel and up to 600% in case of transferring intellectual property rights in technologies developed using these grants. In the event that intellectual property rights are deemed to be transferred out of Israel, the grants amount from the IIAand the Incubator may become a loan to be repaid immediately up to 600% of the grants amounts. These restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIAfunding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

Exchange rate fluctuations between the U.S. dollar and other currencies may negatively affect our results of operations

We incur expenses in U.S. dollars, New Israeli Shekels, Euro and Pounds sterling, but our financial statements are denominated in U.S. dollars. As a result, we are exposed to the risks that the New Israeli Shekel or these other currencies may appreciate relative to the U.S. dollar. For example, should the New Israeli Shekel appreciate relative to the U.S. dollar, our U.S. dollar cost of operations in Israel would increase and our U.S. dollar-denominated results of operations would be adversely affected. We cannot predict any future trends or the rate of devaluation (if any) of the New Israeli Shekel or other currencies against the U.S. dollar.

It may be difficult to enforce a judgment of a U.S. court against us, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors.

We are incorporated in Israel. A judgment obtained against us in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It may also be difficult to effect service of process or to assert U.S. securities law claims in original actions instituted in Israel.

Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear such a claim, it may determine that Israeli, and not U.S., law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact by expert witness, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See “Enforceability of Civil Liabilities” in our prospectus dated March 19, 2015, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the “Prospectus”), for additional information on your ability to enforce a civil claim against us and our executive officers and directors.

Provisions of our restated articles of association and Israeli law and tax considerations may delay, prevent or make difficult a merger with, or an acquisition of, us, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, acquisition of our shares, in a way that the purchaser shall hold more than 90% of our issued and outstanding shares following that acquisition, is subject to a tender offer for all of our issued and outstanding shares. Such acquisition can only be completed if the acquirer receives positive responses from the holders of more than 95% of the issued share capital.

Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the company’s outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights. In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies; and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control, even if doing so would be beneficial to our shareholders, and therefore depress the price of our ordinary shares. See “Description of Share Capital—Acquisitions under Israeli Law” in the Prospectus for additional information.

Our restated articles of association provide that our directors (other than external directors) are elected on a staggered basis, such that a potential acquiror cannot readily replace our entire board of directors at a single annual general shareholder meeting. This could prevent a potential acquiror from receiving board approval for an acquisition proposal that our board of directors opposes.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our restated articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. companies. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting or class meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. A shareholder also has to refrain from deprivation of other shareholders. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company with regard to such vote or appointment. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. companies.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon our Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

The documents listed in the Exhibit Index of this Quarterly Report on Form 10-Q are incorporated by reference or are filed with this Quarterly Report on Form 10-Q, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	SEC File No.	Exhibit	Filing Date	
3.1	Eleventh Amended and Restated Articles of Association of SteadyMed Ltd.	8-K	001-36889	3.1	10/11/16	
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a)					X
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a)					X
32.1+	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

+ This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

STEADYMED LTD.
(Registrant)

Date: May 15, 2018

/s/ Jonathan M. N. Rigby
Jonathan M. N. Rigby
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2018

/s/ David W. Nassif
David W. Nassif
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jonathan M. N. Rigby, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SteadyMed Ltd.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2018

/s/ Jonathan M. N. Rigby
Jonathan M. N. Rigby
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David W. Nassif, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SteadyMed Ltd.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2018

/s/ David W. Nassif
David W. Nassif
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jonathan M. N. Rigby, Chief Executive Officer of SteadyMed Ltd. (the "Company"), and David W. Nassif, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 15, 2018

In Witness Whereof, the undersigned have set their hands hereto as of the 15th day of May 2018.

/s/ Jonathan M. N. Rigby
Jonathan M. N. Rigby
Chief Executive Officer

/s/ David W. Nassif
David W. Nassif
Chief Financial Officer

"This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of SteadyMed Ltd. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."